EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

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THE EFLM BI-MONTHLY NEWSLETTER

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In this issue:

EFLM Connects National Societies of Clinical Chemistry and Laboratory Medicine and Creates a Platform for all European "Specialists in Laboratory Medicine"

Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews

This autumn issue of the EuroLabNews commences with our regular Hot Topic column, this time around Professor Dilan Aslan, Pumakkale University, Turkey, presents the Importance of Process and Project Management Competencies in Laboratory Management, Quality Management and ISO 15189 Laboratory Accreditation. The EFLM Academy is announced by Professor Giuseppe Lippi, the EFLM Executive Board Secretary. To be launched on the 1st of January, 2020, it is a promising synthesis of all membership benefits on a common platform. Florent Vanstapel (Chair of the EFLM Quality and Regulations Committee) and Christa Cobbaert (Chair of the EFLM Working Group Test Evaluation) summarizes the main points of the new In vitro diagnostic medical devices regulation (IVDR), that replaces the former (98/79/EC) IVD directive (IVDD). One may want to note the transitions and various implications that will apply to laboratories in the EU. The EFLM Basic Biostatistics for Postgraduates / Specialists in Laboratory Medicine in collaboration with ACBI will be held on November 7th 2019, Athlone, Ireland. The author of this issue's Hot Topic Professor Dilan Aslan will be holding a Webinar "How should a medical laboratory specialist prepare for accreditation according to the ISO 15189" on the 8th of October. Daniel Rajdl, Chair of the Communication Committee gives an update of the EFLM publications. The Spanish Society of Laboratory Medicine present their latest activities, and the Croatian Society of Medical Biochemistry and Laboratory Medicine details their National recommendations for blood collection, processing, performance and reporting of results for coagulation screening assays. The IFCC corner summarizes the global happenings in Laboratory Medicine. Last but not least, the Calendar of Events lists all events in our field.

HOT TOPICS IN LABORATORY MEDICINE

Importance of Process and Project Management Competencies in Laboratory Management, Quality Management and ISO 15189 Laboratory Accreditation

by Diler Aslan, Emeritus Prof, Pamukkale University, Medical Faculty Dept. of Biochemistry. D-Tek Technology Development Ltd. Comp. Pamukkale Technology Development Area. Denizli-Turkey (daslan@pau.edu.tr, www.d-tek.com.tr)

Medical laboratory has a critical role in patient care and safety, and must provide the reliable test results in time, and cost-effectively. In order to fulfill these requisites, laboratory management should be organized by considering both the quality management system and accreditation requirements during the establishment. If a laboratory is organized according to the total testing process and its sub-processes in the context of the business process (BPM) and project management (PM), the requirements of quality management system and accreditation can be fulfilled more successfully, and continuous improvement can be implemented systematically. The process approach that incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking is employed in the new version of the "ISO 9001:2015 Quality management systems - Requirements" (1). The "ISO 17025:2017 General requirements for the competence of testing and calibration laboratories" also employs risk-based thinking, and is based on the ISO 9001:2015 (2).

To be continued on page 2

The "ISO 15189:2012 Medical Laboratories- Requirements for Quality and Competence" that is an internationally accepted accreditation standard is under review for the new version (3). Lucia Berte, a member of the ISO TC 212 Working Group 1, explained that the structure of this new version would be based on the structure of the ISO 17025:2017 and hence the ISO 9001:2015, because ISO 9001:2015 is a high-level quality standard therefore, the common structure is mandated by the ISO Secretariat. The table of contents for the new version will be changed similar to the ISO 17025:2017. Some clauses will be as follows: "4-General requirements (impartiality, confidentiality, ethics), 5-Management/Structural requirements (legal entity, laboratory director, laboratory services, and other sections), 6-Resource requirements (personnel, facilities, equipment, externally provided products and services), 7-Process requirements (pre-examination, examination, post- examination processes), 8-Management system requirements (Option A Management system documentation, document control, records control, risks and opportunities, improvement, corrective action, internal audit, management review). The process approach and risk-based thinking are common and basic approaches of these quality system and accreditation standards. In this context, process and project management knowledge, skills and competencies should be gained during the specialist education and training. However, the real life shows those subjects cannot be gained properly, although process management is in the Syllabus of European Federation of Clinical Chemistry and Laboratory Medicine (4). If a medical laboratory is organized with the knowledge of the business process lifecycle (5), then the quality system and accreditation standards and/or guidelines can be adapted easily. There are many tools in order to analyze the processes, and to determine and solve problems. The "Suppliers-Inputs-Process-Outputs-Customers (SIPOC) Diagram" and "Customers-Actors-Transformation-Worldview-Owner-Environment (CATWOE) Analysis" are some of useful tools (6,7).
Figure 1 shows the process analysis example by means of the SIPOC Diagram for the total testing process of a medical laboratory that the detailed information can be found in the article of "Which skills are needed and how they should be gained by laboratory medicine professionals for successful ISO 15189 accreditation" (8).

The SIPOC Diagram provides an overall picture of a process. The requirements for inputs, process, outputs and of customers should be set on the SIPOC Diagram of a process. These requirements provide the requirements in the clauses of the new version of the ISO 15189 as seen above.

This diagram in the Figure 1 is for the business process of a medical laboratory. The standard operation procedure can be written according to this overall view to the TTS, and the specific procedures for each test can be prepared according to their requirements. The management and support processes that can be extracted from the SIPOC Diagram are designed according to the legal regulations, standards, guidelines, scientific papers, and analysis/measurement methods, and the documents are prepared for providing reliable test results in time and cost-effectively (9). The problem solving skills is one of the main tools for continuous process improvement. The CATWOE and root-cause analysis with the project management knowledge is valuable for improvement activities.

Main challenge is to combine the interrelations of all components and elements in the context of requirements that are changing rapidly. The use of the business process and project management tools are recommended, because evidence shows that standardized and continually optimized processes are enormously influence diagnostic performance, patient safety and patient life quality, and provides systematic review for continuous improvement (10).

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5*	4*	1*	2*	3*
S **Suppliers**	**I** **Inputs**	**P** **Process**	**O** **Outputs**	**Customers**
Who supplies materials/inputs to the process?	What triggers you to act? What resources are needed or provided by the suppliers?	What are the major steps in the process? What are the key steps/"core processes" that help you transform inputs into useable services or products?	What products or services are created by the process?	Who receives the outputs? Who uses the outputs? Who gets benefits from the outputs?

• Clinicians
• Patients
• Health Care Organization
• Laboratory Management
• Legal Authority
• Kit Manufacturers
	Those triggers the process:
	Clinician's test Order
	Specimen (Patient body material, Primary Sample)
	Resources:
	• Personnel
	• Method
	• Equipment
	• Materials
	• Facilities
	• Measurement
	• Guidelines
	• Regulations
	• Standards
		• Patient admits to clinician
		• Clinician establish a clinical question
		  ○ Decides the test
		  ○ Orders the test
		• Specimen is collected
		• Specimen is transported to the laboratory
		• Specimen is processed
		• Analytical sample is produced
		• Analysis or examination is executed
		  ○ Material is analyzed or examined, and
		  ○ Quality control materials analyzed
		• Test results are evaluated technically
		  ○ Quality materials result are accepted
		  ○ Patient test results are accepted
		• Patient test results are evaluated clinically
		• Patient Laboratory Test report is accepted
		• Patient Laboratory Test Report is released
		• Clinician interprets the patient test results
		• Clinician decides the treatments or interventions
		• Patient has higher life quality
			Outputs:
			Patient test results (Patient Laboratory Report)
				Clinicians
				Patients
				Government

The sub-processes of a total testing process

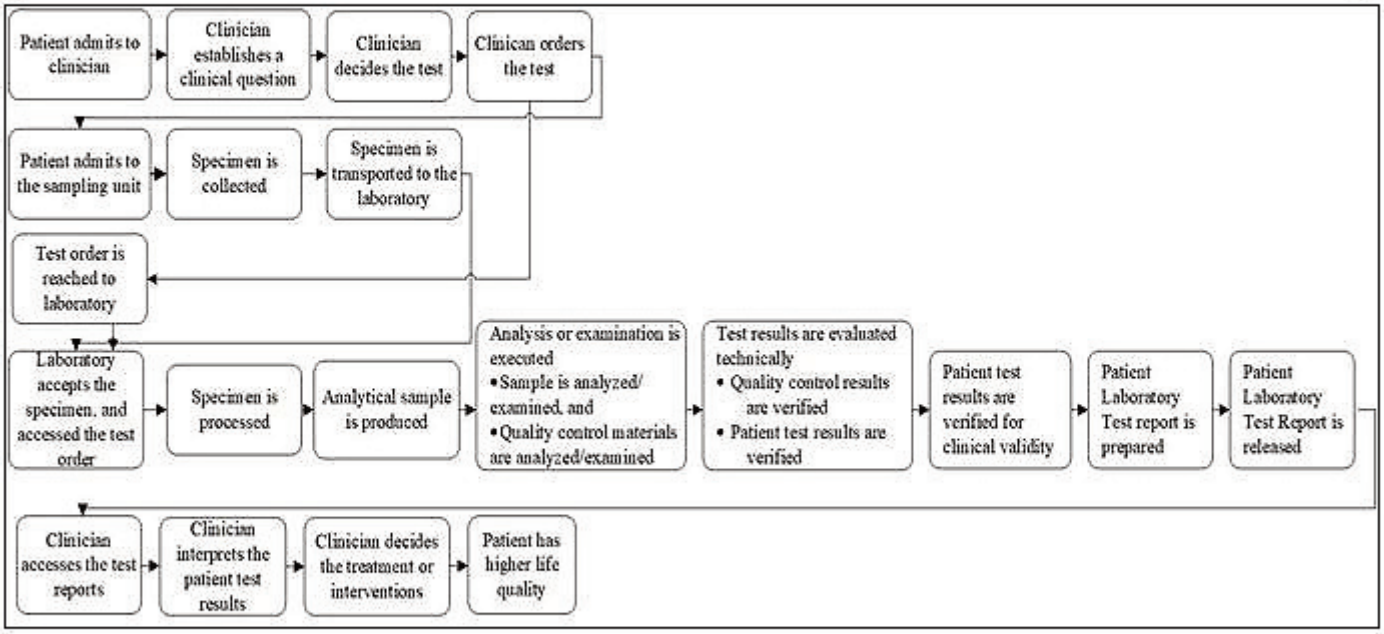

*Figure 1. SIPOC Diagram for total testing process (TTS) of a medical laboratory. *The numbers in the first row show the step sequences in the analysis of a process.*

EFLM EXECUTIVE BOARD INFORMS

New EFLM initiative: the EFLM Academy

by Giuseppe Lippi, EFLM Executive Board Secretary

The EFLM Executive Board is pleased to announce a new EFLM initiative: the EFLM Academy.
This is a package of professional benefits for individual members. The aims of EFLM Academy are:

1. To provide a web domain comprising an information and communication platform;
2. To support education, training and continuous professional development of laboratory medicine practitioners;
3. To raise the profile of EFLM.

The EFLM Academy will be officially launched on **January 1st 2020.** With this date, all benefits of the EFLM Academy shall become active for all its members.

What are the benefits of EFLM Academy members?

The benefits of membership in the EFLM Academy are listed below:

- Free on-line subscription to CCLM, the official EFLM journal;
- Unlimited access to all documents (laboratory standards) of the CLSI (Clinical and Laboratory Standards Institute) database;
- Regular e-mail notifications of all EFLM activities, programmes and opportunities;
- Eligibility to apply for EFLM travel grants *(subordinated to application's criteria of each specific EFLM initiative)*
- Reduced registration fee to all EFLM conferences and courses
- Free access to EFLM webinar

Who can be a member of EFLM Academy?

All members of the EFLM National Societies are eligible for membership in the EFLM Academy. Members who also meet the requirements for "European Specialists in Laboratory Medicine" will, by joining the EFLM Academy, automatically be enrolled into the EFLM Register (without any additional cost). From **January 1st 2020**, joining the EFLM Register will only be possible through applying to the EFLM Academy.

How can I become a member of the EFLM Academy?

EFLM encourages its National Societies to establish automatic block enrollment of all its members into the EFLM Academy. If the National Society does not support block enrollment, individual members of the EFLM National Societies can apply directly at the EFLM Academy through the dedicated on-line subscription service in the EFLM website. The annual fee is **15 Euros.**

We hope that you will consider the EFLM Academy an opportunity interesting for your members and we ask you to announce this benefit package to your members in a timely manner to allow sufficient time to already join the EFLM Academy at the start in 2020.

NEWS FROM EFLM FUNCTIONAL UNITS

News from the EU IVDR front

by Florent Vanstapel[1] and Christa Cobbaert[2], EC observers in IVD WG#8 under the MDCG for the IVDR

[1]Chair of the EFLM Quality and Regulations Committee,
[2]Chair of the EFLM Working Group Test Evaluation

The new In vitro diagnostic medical devices regulation (IVDR)

The new IVDR was published 5 May 2017 and can be consulted at (Click here for more information). It replaces the former (98/79/EC) IVD directive (IVDD).

The IVDR introduces scope enlargement and a risk-based classification of medical tests. This brings along expanded involvement of notified bodies that have to assess the majority (ca. 85%) of IVDs with respect to IVDR compliance (namely for class B, C and D tests), requires evaluation and documentation of clinical evidence (i.e. scientific validity, analytical and clinical performance of tests), introduces universal device identification codes (UDI), and necessitates the set-up of an EudaMed database (Click here for more information) for the deposition by IVD-industry of information about devices, lot-specific data, and post-market surveillance data. Although exempted from CE-IVD regulations, the requirements that labs have to fulfill to run in-house developed tests are also addressed.

Transition Period

From 25 May 2022 the IVDR fully applies. For devices placed on the market under the IVDD a transition period is provided. Certificates issued under the IVD directive before that date remain valid for an additional 2 years, and devices already on the market may continue to be made available until 27 May 2025. From 26 May 2024 all devices placed on the market must conform to the IVDR.

Implementing Regulations

The EU Commission has installed a Medical Device Coordination Group (MDCG) – in vitro Diagnostic Working Group to develop the essential implementing acts and actions (Click here for more information). To follow progress a portal has been opened at Click here for more information, and the rolling plan can be consulted at Click here for more information.

Databases for the registration of manufacturers and deposition of data have been opened, or are under development. Currently the focus is on the definition of classification codes, the definition of independent diagnostic software devices, adoption of common technical specifications for class D devices, the format of summary statements about the devices (read inserts).

The EFLM has stakeholder observer status in this process.

Conformity Assessment

Existing national conformity assessment bodies are encouraged to apply for notified body status. They can assess both medical and in vitro diagnostic medical devices. By now some 10 IVDR applications are under review.

Class A devices are subject to review by EU reference laboratories and expert panels. Other devices (class B-C) will be reviewed by representative device per generic device group. Up to 80% of devices fall in classes A through C.

The EFLM initiated a Task Force to look into the consequences for the laboratory, especially for in house developed tests.

What's new in EFLM Publications

by Daniel Rajdl, Chair of the EFLM Communication Committee

Practice in financial support of third party organised conferences and courses at a national level for health care professionals in Europe

Daria Pašalić, Evgenija Homšak, Antonio Buño, Katarzyna Bergmann, Ciriaco Carru

Clin Chem Lab Med 2019, Full-Text available here

Two different surveys related to the practice and knowledge of the new Ethical MedTech Code were conducted with European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) National Societies' (NSs) representatives, and their (NSs) individual members. 25 out of 40 EFLM NS representatives replied; more than half declared that all different types of financial resources were available for supporting the continuing professional education of health care professionals (HCPs). In addition, 322 individual responses collected from 31 NSs, answered that the institutional director (50.3%) or laboratory chief (70.1%) made generally made a decision, without specific criteria. The MedTech Europe Code is already adopted or is about to be adopted in numerous EFLM NSs, but most of them have not implemented it as yet. The use of the Code and better communication between IVD companies and HCPs are necessary to guarantee an improved and fair use of financial support, as well as better choices for the organisation and attendance at scientific events.

Investigations on the clinical utility of apolipoprotein B measurement: a research priority

Michel Langlois

Eur J Prev Cardiol. 2019, Full-Text available here

In the recent publication by Khan et al. (Association of lowering apolipoprotein B with mortality and cardiovascular outcomes across various lipid lowering therapies: A systematic
review and meta-analysis) including a systematic review and a meta-analysis including more than 330,000 patients from 29 clinical trials on the association of decrease in apoB concentration with all-cause mortality and cardiovascular outcomes across different lipid-lowering drug classes, it was found that statins and other therapies which clear apoB by upregulating low-density lipoprotein (LDL)-receptor expression reduce cardiovascular risk proportional to the decrease in apoB concentration, whereas interventions which lower apoB independent of LDL-receptor did not demonstrate this association. Reduction in all-cause mortality per decrease in apoB was found only with statins.
This invited editorial discusses the clinical utility of apolipoprotein B measurement by evaluating the key characteristics for a diagnostic biomarker defined by EFLM Working Group on Test Evaluation - analytical performance, clinical performance, clinical effectiveness and cost-effectiveness - to become a medically useful test.
In conclusion, apoB is promising but not yet ready for therapeutic decision making and follow-up in clinical practice. Given the potential of apoB assays to provide accurate and comparable test results across laboratories worldwide, a prerequisite which cannot
be met with standard LDL-cholesterol measurements or calculations, the research priority now is to investigate the clinical effectiveness and cost-effectiveness of apoB measurements.

Systematic review and meta-analysis of within-subject and between-subject biological variation estimates of 20 haematological parameters

Abdurrahman Coskun, Federica Braga, Anna Carobene, Xavier Tejedor Ganduxe, Aasne K. Aarsand, Pilar Fernández-Calle, Jorge Díaz-Garzón Marco, William Bartlett,Niels Jonker, Berna Aslan, Joana Minchinela, Beatriz Boned, Elisabet Gonzalez-Lao,Fernando Marques-Garcia, Carmen Perich, Carmen Ricos, Margarita Simón and Sverre Sandberg, on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Biological Variation and Task Group for the Biological Variation Database

Clin Chem Lab Med 2019, Full-Text available here

The publication from Working Group on Biological Variation and Task Group for the Biological Variation Database includes appraisal of the quality of publications reporting BV data for CBC parameters by systematic literature search compliance evaluation with the 14 BV Data Critical Appraisal Checklist (BIVAC) criteria (scored as A, B, C or D, indicating decreasing compliance). In total, 32 studies were identified; four received a BIVAC grade A, 2 B, 20 C and 6 D. Meta-analysis derived CVI and CVG estimates were generally lower or in line with those published in a historical BV database available online. Except for reticulocytes, CVI estimates of erythrocyte related parameters were below 3%, whereas platelet (except MPV and PDW) and leukocyte related parameters ranged from 5% to 15%.
A systematic review of CBC parameters has provided updated, global estimates of CVI and CVG that will be included in the newly published European Federation of Clinical Chemistry and Laboratory Medicine BV Database (https://biologicalvariation.eu/)

UPCOMING EFLM EVENTS

EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with ACBI

by AnnMarie O'Grady, ACBI Conference Coordinator

The EFLM Basic Biostatistics for Postgraduates / Specialists in Laboratory Medicine in collaboration with ACBI will be held on November 7th 2019, Athlone, Ireland.

EFLM are delighted to join forces with the Association of Clinical Biochemists in Ireland (ACBI) to deliver this invaluable event at the Radisson Blu Hotel in Athlone, in the heart of Ireland. The workshop is hosted by President-Elect of EFLM Ana-Maria Simundic (Prof, PhD) and her colleague, Vanja Radisic (PhD) who are bringing their knowledge, experience and skills of Biostatistics to the EFLM's national society members in Ireland (ACBI).
Subject matter includes presentations on data distribution, data summary measures and presentations on how to examine differences between numerical and qualitative data and to more fully comprehend correlation and regression.
The course has the added value of finishing with 2 hours of practical examples where Ana-Maria and Vanja both share real life examples they have learnt from their work at their Clinical Hospital Sveti Duh in Zagreb (Croatia).
The course finishes with a tour of Athlone Castle to provide that perfect mix of science and culture! ACBI have a small charge of €35 (inclusive of lunch, tea & coffee and tour) for those applying for this packed full day workshop.

For all further information please click here for more information.

UPCOMING EFLM EVENTS

EFLM Webinar: How should a medical laboratory specialist prepare for accreditation according to the ISO 15189

by Darko Cerne, Chair of the EFLM WG Distance Education and eLearning

EFLM is happy to remind you that the attendance to the webinars is free of charge and that the recording of the lectures will be available afterwards on at the EFLM elearning platform for those unable to attend.

Speaker: Diler Aslan (TR)
Moderator: Sedef Yenice (TR)
Date: 8th October 2019 at 18:00 CET

The "ISO 15189:2012 Medical laboratories – Requirements for quality and competence" Standard is globally accepted accreditation standard for medical laboratories. It is based upon the "ISO 9001 Quality management systems – Requirements" and "ISO 17025 General requirements for the competence of testing and calibration" Standards. The last versions of these standards, ISO 9001:2015 and ISO 17025:2017, focus on process approach and risk-based thinking, and they can be adapted more easily to the "Plan-Do-Check-Act" Cycle that is the fundamental continuous quality improvement tool. It is expected that the next ISO 15189 version has the similar approach since the ISO 9001:2015 is a high-level structure standard in quality management. In this context, if the "Total Testing Process" of a medical laboratory and sub-processes (pre-pre-, pre-examination/analytical, examination/analytical, post-, post-post-examination/analytical processes) are established according to the "Business Process Management" principles, the requirements of ISO 15189 can be fulfilled. Laboratory accreditation impacts positively on patient care and health system if it is executed at the laboratory, health institution, and national levels in a coordinative manner. This positive effect depends upon the knowledge, skills and competencies of the laboratory specialists and/or laboratory professionals. In this webinar, we will try to explain:

- how to establish the total testing process and its sub-processes of a medical laboratory (also for a specific analyte that has inherent characteristics) according to the process approach and risk-based quality control;
- how to correlate the process components to the requirements for the ISO 15189; and
- which knowledge and competencies are necessary according to the requirements of the ISO 15189.

HOW TO REGISTER
Registration at elearning platform.
Did you miss any EFLM webinar?
Do not worry: The recorded version of all EFLM webinars is available at https://elearning.eflm.eu/

Newly posted recorded webinar: Harmonisation of autoimmune tests (Speaker: Joanna Sheldon, UK)

NEWS FROM EFLM NATIONAL SOCIETIES

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

by Josefina Mora, Executive Secretary of SEQCML Board

The Spanish Society of Laboratory Medicine (SEQC^{ML}), founded in 1976, 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 establish guidelines and recommendations for training in the field of Laboratory Medicine. For more information: click here.
Spanish Society of Laboratory Medicine (SEQC^{ML}) headquarters in Barcelona hosts the International Editors Meeting of Lab Tests Online, in which improvements were agreed to exchange and standardize its contents

- Spanish-language website of LTO, promoted by SEQC^{ML}, is considered a success, as it is one of those that attracts the most traffic worldwide
- Representatives of the US delegation reported on changes in their Editorial Committee and made their contents available to other delegations

Barcelona, August 21, 2019. In May, the International Editors Meeting of Lab Tests Online (LTO) was held at the headquarters of the Spanish Society of Laboratory Medicine (SEQC^{ML}) in Barcelona. This website, whose Spanish-language edition is run by SEQC^{ML}, provides the general public with rigorous information about more than 1,200 analytical tests, as well as news and other resources.
The International Editors Meeting held in Barcelona was attended by representatives from the United States, Poland, Czech Republic, Brazil, Greece, Hungary, and Spain. The Spanish team was made up of Marina Canyelles, Mariano Cortés, Patrocinio Chueca, Ramón Deulofeu, Chelo Fernández, Maite Panadero, Carlos Sisternas, and Laura Valls. During the meeting, described as "very productive", attendees discussed the new contents to be developed during 2020 in the different international LTO portals. Likewise, new editorial guidelines were created to standardize the content of these international sites, and an update was provided on the status of the different countries' websites.
More detailed reports on the specific cases of Poland and Spain were presented at the meeting. The website of our country is considered a success, as it is one of the ones that attracts the most traffic globally - about 350,000 unique users per month during the year 2019 to date, with an increase of 25% in relation to the previous year.
In this regard, the activities carried out by the Spanish Editorial Committee to invigorate the website were reviewed, such as the eight new articles and 24 resources for patients that were published on the Spanish site throughout 2018 to complement the information provided on clinical analysis. Also mentioned were social media posts, with an increase in Facebook and Twitter users of 83% and

360%, respectively, over the past year. The launch of the photographic contest 'Photography of emotion', aimed at LTO users, was also highlighted.

International Contents

Among other operational and legal aspects, the International Editors Meeting of LTO approved recommendations such as each site submitting to the others a monthly summary of the updates and revisions made. It was also agreed to centralize in Ellen O'Connell, North American representative, all the suggestions for new articles and other contents for the year 2020 that are developed by the North American delegation, and that the US will share their editorial indications with the other countries.

Also in relation to the USA, their representatives reported on the election of Dr. Christine Snozek as Scientific Editorial Director of LTO USA, replacing Robert Dufour, who has been carrying out this task since the beginning of the website.

Documents were also distributed during the meeting with the updated principal editorial recommendations and some examples of standard answers for the most common user questions. Likewise, some criteria were established regarding brand image, such as updating logos and withdrawing references to currently inactive sites.

Figure 1. Laura Valls, member of the Editorial Board of LTO Spain during the presentation of the results.

Figure 2. Group photo of the members from different countries attending the meeting.

News from the Spanish Society of Laboratory Medicine (SEQCML): Glucose and HbA1c in laboratory medicine and POCT in different clinical settings

by Josefina Mora, Executive Secretary of SEQCML Board

The SEQCML promotes a consensus document about the laboratory tests for the screening, diagnosis and glycaemic control of diabetes mellitus

• The document offers guidelines regarding glucose and HbA1c, both measured in the laboratory medicine and in the bedside testing, as POCT

• It includes the participation of various scientific societies and shows an overview of carrying out these tests in different care areas

• The guideline addresses the latest developments in the use of HbA1c, considering its advantages instead of glucose measurement **Madrid, September 2, 2019.** The term diabetes mellitus (DM) includes a group of diseases characterized by chronic hyperglycaemia. To help patients with these pathologies reducing the risk of developing chronic complications, it is important to diagnose early and regularly identify the intensity of the metabolic disorder. The most common analyses for this are the measurement of glucose and glycated haemoglobin (HbA1c), which can be carried out both in the clinical laboratory and in different environments, within what is known as laboratory tests at the patient care site, or Point-of-Care Testing (POCT). At the present time, there is a lot of heterogeneity regarding how these analytical measurements are done, and the Spanish Society of Laboratory Medicine (SEQCML) considers it necessary to promote an overview in relation to the measurement of glucose and HbA1c for patients with DM. That is why this scientific society has promoted the development of a consensus document, with the participation of various scientific societies representing the different professionals involved in the care of these patients. The result of this effort is the document 'Glucose and HbA1c in laboratory medicine and Point-of-Care Testing in different clinical settings', recently published, and in whose preparation have participated, in addition to the SEQCML, members of the Spanish Society of Diabetes (SED), the Spanish Society of Urgent and Emergency Medicine (SEMES), the Spanish Society of Family and Community Medicine (semFYC), the Spanish Society of Family and Community Pharmacy (SEFAC), the Spanish Society of Internal Medicine (SEMI), the Spanish Society of Endocrinology and Nutrition (SEEN), the Spanish Society of Primary Care Physicians (SEMERGEN), and the Spanish Society of Intensive and Critical Medicine and Coronary Units (SEMICYUC). This document seeks to answer questions such as when a glucose or HbA1c determination should be requested to the laboratory medicine and when it can be performed as POCT, how often the measurements should be taken, and how the results should be interpreted in each case, among other issues. New developments in this area are also included, since HbA1c has been included as a diagnostic criterion for diabetes mellitus by the American Diabetes Association (ADA), the International Diabetes Federation (IDF), and the World Health Organization (WHO). This recommendation is based on certain advantages of its measurement instead of glucose, such as the convenience of not requiring the patient to fast and less intra-individual variability.

Overview of the care process

"Health professionals who participate in the care of these patients can come from very different areas. The same patient can be managed in a community pharmacy, then go to a primary care consultation, a hospital emergency department, be admitted to a critical care unit,

etc. To be able to offer proper health care, there should be fluid communication among all the areas involved, with an overview of the care process," explains Dr. Paloma Oliver, of the Commission on Laboratory Testing at the Point of Care (POCT) of the SEQCML and coordinator of the document. Dr. Oliver points out that it is important for there to be a clear definition as to when the glucose or HbA1c measurement should be requested to the laboratory and when it should be carried out as POCT in the clinical setting.

The document focuses especially on the POCT, since, in relation to these tests and in accordance with national and international guidelines, it is essential that there is a multidisciplinary group led by the laboratory to carry out the different functions that are needed to perform this type of measurement. "With this document, the various professionals have tried to advance a little more in this direction with a multidisciplinary perspective, considering the distinctive features of the measurements in the laboratory and POCT, and also regarding each clinical environment, always with the focus squarely on what it unites us all, which is the health care of our patients", says Dr. Oliver.

News from Croatian Society of Medical Biochemistry and Laboratory Medicine: National recommendations for blood collection, processing, performance and reporting of results for coagulation screening assays prothrombin time, activated partial thromboplastin time, thrombin time, fibrinogen and D-dimer

by Ana Bronić, Desiree Coen Herak, Sandra Margetić and Marija Milić, members of the CSMBLM WG for Laboratory Coagulation

In 2015, Croatian Society of Medical Biochemistry and Laboratory Medicine (CSMBLM) formed the Working Group for Laboratory Coagulation (WGLC). First aim of the WGLC was to assess current practices and policies among laboratories performing coagulation testing in Croatia. A thorough survey was performed and substantial variability in practice and policies in particular areas of coagulation testing was recorded. This prompted the need for creation of document that should help in standardization of all phases of most common performed coagulation assays: prothrombin time (PT), activated partial prothrombin time (APTT), thrombin time (TT), fibrinogen and D-dimer (1). Thus, recent publications and guidelines related to coagulation testing were reviewed and the first version of the recommendations was evaluated by international experts. Following the evaluation and the review, the document was forwarded to public discussion through CSMBLM website for a month. The final version of recommendations was published in 2019 in Biochemia Medica, the official journal of CSMBLM in English language and as the booklet with recommendations in Croatian language (2, 3).

Recommendations are primarily intended to laboratory personnel involved in coagulation testing. The purpose of the document was to provide the basic recommendations for all phases of testing for most commonly performed coagulation assays PT, APTT, TT, fibrinogen and D-dimer. The document was divided into three major sections: preanalytical, analytical and postanalytical phase of testing. Procedures of each phase were commented and clear recommendations were listed at the end of each section (2).

Section on preanalytical phase in coagulation testing include recommendations related to test request, patient preparation, venipuncture and sample collection. Most of these procedures should be in compliance to already published National recommendations for venous blood sampling (3). Additionally, procedures for correction of citrate volume in samples with high haematocrit values, handling of interferences as well as transport and appropriate timeframes for analysis of coagulation samples were discussed and recommended. Considering analytical phase the most important analytical features of PT, APTT, TT, fibrinogen and D-dimer were highlighted. In addition, main recommendations related to quality control were given. The section on postanalytical phase includes comments and recommendations on reference intervals, cut-off values and harmonization of result reporting wherever it is possible. In addition, suggestions on reporting of critical values and adding of appropriate interpretative comments related to the both preanalytical, analytical and postanalytical phases of testing were proposed.

At the end of the document, summary list of recommendations for all phases of testing for most commonly performed coagulation assays PT, APTT, TT, fibrinogen and D-dimer was provided in a form of table as an Appendix (2).

Thus, we hope that the document would be helpful in everyday practice. Such recommendations should be considered as an important step towards standardization of procedures and generating harmonized data among Croatian laboratories performing routine haemostasis assays. However, WGLC continues its work on standardization and recommendations would be updated according to new findings.

1. Bronić A. Coen Herak D. Milić M. Margetić S. Policies and practices in haemostasis testing among laboratories in Croatia: a survey on behalf of a Working Group for Laboratory Coagulation of the Croatian Society of Medical Biochemistry and Laboratory Medicine. Biochem Med (Zagreb) 2017; 27(1):199–216
2. Bronić A. Coen Herak D. Milić M. Margetić S. Croatian Society of Medical Biochemistry and Laboratory Medicine: National recommendations for blood collection, processing, performance and reporting of results for coagulation screening assays: Prothrombin time, Activated partial thromboplastin time, Thrombin time, Fibrinogen and D-dimer. Biochem Med (Zagreb) 2019;29(2):020503. Available at: https://www.biochemia-medica.com/en/journal/29/2/10.11613/BM.2019.020503
3. Bronić A. Coen Herak D. Milić M. Margetić S. Hrvatsko društvo za medicinsku biokemiju i laboratorijsku medicinu: Nacionalne preporuke za postupke uzorkovanja, pripreme i analize uzoraka te izvještavanje rezultata probirnih koagulacijskih pretraga protrombinskog vremena, aktiviranog parcijalnog tromboplastinskog vremena, trombinskog vremena, fibrinogena i D-dimera. (In Croatian) Available at: https://www.hdmblm.hr/images/vijesti/-2019/11-06/Nacionalne_preporuke_koagulacija_HRV.pdf

Dr Psarra, IFCC eNews editor welcomes us back to the fascinating lab world! We are all looking forward to new developments at work trying to keep pace with them. Developments in our lab work make our life much more interesting and full of surprises. In the IFCC eNews issue, you will find out about many developments: people in IFCC committees and workgroups are studying them and are trying to make them easy and accessible to colleagues all over the world. Should we adopt them? Under which circumstances? Go through the articles and discover what is new, what is worth trying and what we should all know. Discover the people and the societies in order to connect with them. An article on Labtestsonline will explain the present and the future of this important website, and don't forget the congresses and meetings lying ahead. Stay tuned with IFCC, read the eNews!

SEVEN EUROPEAN TEAMS RECOGNIZED IN 2019 FOR UNIVANTS OF HEALTHCARE EXCELLENCE

Last year, the IFCC joined 7 leading organizations in healthcare to promote excellence through collaboration and data insights generated from the clinical laboratory. The UNIVANTS of Healthcare Excellence (HCE) Award offers local and international recognition to integrated care teams who have demonstrated measurable benefits to patients, payors, clinicians and entire health systems. The call to action for best practice sharing in association with the UNIVANTS of HCE Award Program was heard across the globe with approximately 100 countries actively engaged within the program's inaugural year. Winners were selected based on the merit of their outcomes, through a multidisciplinary panel of judges with direct associations within IFCC, AACC, EHMA, Modern Healthcare, HIMSS, NAHQ and/or IHE. Abbott, the creator and sponsor of the award, had no role in the scoring process. This August, three teams were announced as winners for the program's highest honor including the title of including the prestigious title of UNIVANTS of HCE WINNERS. All three of winning these teams were from Europe, as well as 4 additional European teams were recognized with DISTINCTION as program finalists. These outcomes speak highly to the valued contributions of laboratory medicine throughout Europe, demonstrating both positive innovation and proactive, cross-discipline collaboration to achieve measurable healthcare outcomes. To learn more about the winning care teams or submit a best practice for the 2020 UNIVANTS of HCE Awards, please visit the program website at www.UnivantsHCE.com. In the meantime, huge congratulations to the European Teams being recognized in 2019:

UNIVANTS OF HCE WINNERS

Intelligent Liver Function Testing (iLFT): A Cost-Effective Way to Increase Early Diagnosis of Liver Disease
University of Dundee - UK

Improved Diagnostic Pathway and Treatment for Hospitalized Patients with Acute Kidney Injury
Ernst von Bergmann Hospital - Dialysis Center Potsdam - Diaverum Kidney Care Center MVZ Potsdam affiliated with Otto-von-Guericke University Magdeburg -DE

Improving the Safety of Mothers and Babies Using Angiogenic Biomarkers for Pre-Eclampsia
Clinical Biochemistry, Oxford University NHS Foundation Trust- UK

UNIVANTS OF HCE RECOGNITION OF DISTINCTION

Identifying Untreated Hepatitis B and Hepatitis C via Opt-out Screening Program in Urban ED Settings
Guy's and St Thomas' NHS Foundation Trust -UK

Avoiding Insufficient Therapies and Overdosing with Co-Reporting eGFRs for Personalized Drug Therapy and Improved Outcomes – *Marienhospital -DE*

Optimization of Heart Failure Management using Biomarkers in Patients with Low Risk for Rehospitalization
University Medical Center Groningen -NL

FH ALERT: Identification of Patients with Familial Hypercholesterolemia (FH) by using the Expertise and Resources of the Clinical Laboratory *SYNLAB Holding Deutschland GmbH -DE*

eJIFCC Vol 30 n°2 - In this issue: **Non-coding RNAs as potential laboratory biomarkers.** Since the discovery of non-coding RNAs, enormous information has been accumulated about the function of these molecules acting as fine-tuners of cellular processes in development, maintenance of homeostasis up to the generation of malignancies. Altered expression of non-coding RNAs have been implicated in the pathogenesis of diverse human diseases suggesting their potential to become diagnostic or prognostic molecular biomarkers in the near future. This special issue of the eJIFCC incorporates a series of manuscripts that discuss the possibilities and challenges in the use of non-coding RNAs as non-invasive biomarkers in various clinical conditions, especially focusing on cell-free miRNAs in different human diseases. Click here to download your own copy.

Calendar of EFLM events and events under EFLM auspices

Do not miss the opportunity to have your event listed here. **Apply for EFLM auspices!** For more information visit: *https://www.eflm.eu/site/page/a/1048/* or email *eflm@eflm.eu*

41st National Conference LABAC
Paris (FR) 1 October 2019 Click here for information

4th ACTC (Advances in Circulating Tumor Cells) - Liquid Biopsy: Latest Advances and Future Challenges
Corfu (GR) 2-5 October 2019 Click here for information

CELME 2019: Emerging Challenges in Laboratory Medicine EFLM Symposium in collaboration with the Czech Society of Clinical Biochemistry
Prague (CZ) 3-4 October 2019 Click here for information

EFLM webinar: How should a medical laboratory specialist prepare for accreditation according to the ISO 15189
On-line 8 October 2019 Click here for information

LABKVALITA 2019 - Biennial Conference with international participation on Quality in Laboratory Testing
Nový Smokovec (SK) 10-11 October 2019 Click here for information

8th International Conference on Quality of Medical Laboratories in Slovenia
Ljubljana (SL) 15 October 2019 Click here for information

5th ESPT Congress Precision Medicine and Personalised Health
Seville (SP) 16-18 October 2019 Click here for information

EQALM Symposium 2019
Ljubljana (SL) 17-18 October 2019 Click here for information

International Conference on Laboratory Medicine "From Bench to Diagnostic-Therapeutic Pathways"
Padova (IT) 23 October 2019 Click here for information

EFLM Postgraduate Course on "How to write a good scientific and professional article" in collaboration with the Turkish Biochemical Society
Antalya (TR) 26-27 October 2019 Click here for information

Joint Congress of 27th Balkan Clinical Laboratory Federation (BCLF) Congress and 30th National Biochemistry Congress (NBC) of TBS
Antalya (TR) 27-31 October 2019 Click here for information

3èmes Journées Francophones de Biologie Médicale
Monaco (MC) 6-8 November 2019 Click here for information

EFLM Postgraduate Course on Biostatistics in Laboratory Medicine in collaboration with the Association of Association of Clinical Biochemists in Ireland
Athlon (IR) 7 November 2019 Click here for information

The Value of Laboratory Medicine into Clinical Medicine
Erice (IT) 7-9 November 2019 Click here for information

42nd Annual ACBI Conference
Athlone (IR) 8-9 November 2019 Click here for information

51st National Congress of SIBioC – Laboratory Medicine in Frailty and Frailty of Laboratory Medicine
Padua (IT) 20-22 November 2019 Click here for information

17th EEKX-KB National Congress of Clinical Chemistry
Athens (GR) 21-23 November 2019 Click here for information

JIB 2019: Journées de l'innovation en biologie
Paris (FR) 21-22 November 2019 Click here for information

13th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "The Internal Quality Control in the Traceability Era"
Milan (IT) 28 November 2019 Click here for information

Journees de biologie praticienne
Paris (FR) 7-8 December 2019 Click here for information

EFLM webinar: Essential Leadership Management for Laboratory Professionals
On-line 17 December 2019 Click here for information

International Congress on Quality in Laboratory Medicine
Helsinki (FI) 6-7 February 2020 Click here for information

42nd LABAC Conference
Paris (FR) 9 April 2020 Click here for information

XXXVII Nordic Congress in Medical Biochemistry
Trondheim (NO) 9-12 June 2020 Click here for information

The 10th Santorini Conference "Systems medicine and personalised health & therapy" - The odyssey from hope to practice: Patient first - Keeps Ithaca always in your mind
Santorini (GR), 28 September-1 October 2020 Click here for information

3rd EFLM Strategic Conference "Demand Management"
Zagreb (HR) 27-28 November 2020 Click here for information

EuroMedLab 2021 - 24th IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine
Munich (DE) 16-20 May 2021 Click here for information