

# EuroLabNews THE EFLM BI-MONTHLY NEWSLETTER

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

### HOT TOPICS IN LABORATORY MEDICINE

New developments in clinical flow cytometry



by Frank Preijers, PhD, Dept. of Laboratory Medicine, Laboratory of Hematology, Radboud University Medical Center, Nijmegen, The Netherlands

Flow cytometry (FCM) is an indispensable technique for characterization of cell populations and deciphering complex cellular processes and interactions in a wide variety of normal and disease states. If a suspension can be made from a target population, it can be analyzed by flow cytometry. The recent developments in flow

cytometers equipped with 3-5 lasers and capable of detecting large number of fluorescent parameters has made FCM a fundamental tool for research and diagnostics purposes. However, due to the enormous number of parameters that influence the FCM techniques, from sample collection to data analysis, this overview will be far from complete.

To be continued on page 2



by Harjit Pal Bhattoa, Editor EFLM EuroLabNews In the current issue, Dr Frank Preijers illustrates the latest developments in Clinical Flow Cytometry with its wide-ranging diagnostic implications in the regular column of Laboratory Hot Topics. Giuseppe Lippi the EFLM Executive Board Secretary presents the EFLM Annual Report 2017, where all happenings in

Foreword

the past year are elegantly summarized. The EFLM Executive Board pays its respects to Prof Ad P Jansen, the founder of the EC4 who passed away on the 24th of January, 2018 at the blessed age of 94. An update on the EFLM publications list is provided by Maria Stella Graziani, Chair of the EFLM Communications Committee. National Societies of Spain, France and Serbia present their latest professional ventures, and the Austrian Society of Laboratory Medicine and Clinical Chemistry, German Society of Clinical Chemistry and Laboratory Medicine, Association of Clinical Biochemists in Ireland and Polish Society for Laboratory Diagnostics report changing of the guard. The Calendar of Events lists all happenings in our field; important dates may be marked in your diaries.

#### **Editorial information:**

Newsletter Editor: Dr. Harjit Bhattoa, Faculty of Medicine, Dept of Laboratory Medicine, University of Debrecen, Hungary

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To send your news or advertisement for publication on the newsletter write to: news@eflm.eu

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*EFLM Executive Board:* M. Neumaier, S. Sandberg, AM. Simundic, G. Lippi, H. Storm, T. Guimaraes, <u>T</u>. Zima

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As a spin off, FCM is increasingly used in clinical laboratories for diagnosis of various hematological malignancies, follow up of treatment, immunological screening, monitoring of functional impairment and enumeration of stem cells for stem cell transplantation. The rapid and sensitive multi-parameter detection, even at a single cell level, renders FCM a powerful tool to distinguish aberrant cells from normal. Due to technical aspects and the limitations of the previous versions of flow cytometers most analyses were performed with 3-to 4-colour analyses. As a consequence, the determination of a restricted number of markers on these cells, hampers an optimal immunophenotypical characterization of small leukemia and lymphoma populations and non-malignant lymphocyte subpopulations. In particular, determination of rare cell populations, such as minimal residual disease, or detailed characterization of small subsets of certain populations needs high-level polychromatic analyses. The identification of these populations demands instruments that offer multi-parameter analyses and possess a special configuration, such as stable and multiple powerful lasers, excellent optics and sufficient photo-multiplier-tubes (PMT's) to obtain an optimal separation of the different fluorescence spectra.

Recently, new flow cytometers have been developed that enable multi-color immunophenotyping for diagnostic use (up to 15 parameters) with high sensitivity, resolution, and dynamic range along with high-speed data collection combined with fast and easy-to-use software. Moreover, this improved performance is also supported by the development of highly specific antigen-binding monoclonal antibodies (MoAbs) and other reagents coupled to new fluorescent dyes expressing smaller wavelength bands, higher stability and higher intensities, special permeabilization reagents to determine adequately intracellular structures and new viability dyes to exclude dead and apoptotic cells. All these developments have enabled a strong improvement in characterization of cell populations.

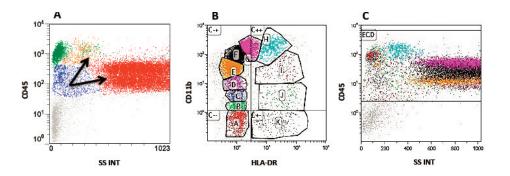
Another important aspect in modern FCM is improvement of the analysis software, such as Kaluza (Beckman Coulter, USA), Infinicyt (Cytognos, Spain), Flow-Jo (Becton Dickinson, USA) and FlowSOM (Bioconductor, Open Source software). Due to the tremendous increase in the number of FCM parameters and identification of targets, analysis of list-mode-data has become very complex. This requires the use of high content data modeling, and even more automation and exchange of fast and real time data analyses. Moreover, due to the multi-parameter FCM, the analysis of intensities of more than two MoAb-fluorochrome combinations in one plot (such as in radar plots in Kaluza, tree plots in FlowSOM and APS-view in Infinicyt) has become essential.

As a consequence of all these developments the FCM diagnostics of malignancies is strongly improved due to a better discrimination of

malignant cells from normal cells by improvement of fluorescence pattern recognition. Each cell stage in the differentiation pathway from stem cell to blood cell can be identified by a unique combination of MoAbs directed against differentiation antigens that vary in degree of expression during the maturation process of the cell. The intensity of fluorescence from the binding of MoAbs on the cell, depends on the variation in antigen density resulting in an appropriate fluorescence expression pattern during this maturation. Integration of the expression levels of the different antigens is essential as a reference to decide whether a cell is normal or aberrant. Abnormal maturation can be the result of expansion of neoplastic cells, but may also be the result of an arrest of differentiation, immunesuppressive treatment or an infection or primary immunedeficiency. Most of these abnormalities may result in a relative change of the distribution of subpopulations in one or more cell lineages. However, neoplastic malignancies frequently have an aberrant immunophenotype that is not found in neither normal bone marrow nor other abnormalities . More or less antigens and antigen expression on different levels can be found in these leukemic cells; this implies that knowledge of the normal cell maturation pattern facilitates recognition of malignant cells. A high amount of antigens must be studied extensively on their expression in the various hematopoietic differentiation stages (Figure 1). This information is crucial to determine whether a cell population is aberrant or not.

Although multi-color FCM offers many advantages, this technique requires extensive experience of sample MoAbs-fluorochrome conjugates, handling, flow cytometer settings and sample analysis. The balancing of the combinations of MoAbs and fluorochromes is crucial. Due to complexity of multi-color analyses, less optimal PMT settings and compensation are difficult to detect, even resulting in a wrong interpretation. Besides, combination of conjugates on the single cell level can influence each other tremendously, thus resulting in quenching or FRET (Försters resonance energy transfer) effects. As a consequence, the question raises "how to guarantee the quality of immunophenotyping?". Standardization of all facets of clinical FCM might be essential but is expensive and hampers innovation. Harmonization appears to be more applicable and affordable while giving same results and can be assisted by new developments in techniques, such as specifically dried MoAbs reagents (such as DuracloneTM, Beckman Coulter, USA) that result in higher stability and less batch variation whereas intensities are equal as with liquid reagents (Figure 2), improved viability staining and instruments that offer a complete pre-analytical treatment and analysis of samples (such as the AquiosTM, Beckman Coulter, USA).

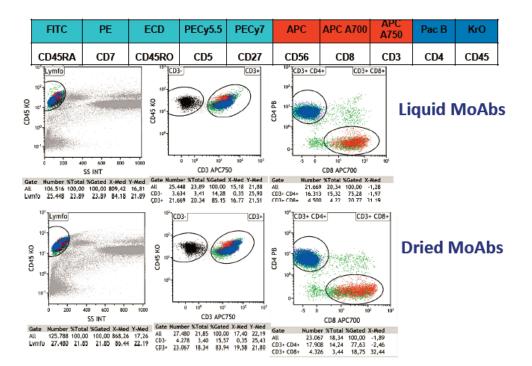
Acquiring knowledge of the technical aspects continuously appears to be necessary to guarantee the quality of diagnostics. Therefore, continuous education, as offered by the society for clinical FCM, the European Society of Clinical Cell Analysis (ESCCA), is essential.



#### Figure 1.

The maturation pathway of progenitor cells to neutrophils and monocytes in normal bone marrow by using CD45/SS, CD11b, HLA-DR.

- A. CD45/SS: Mono-myeloid progenitors (blue) differentiate into the mature myeloid populations (red) or monocyte (orange).
  B. HLA-DR/CD11b: Mono-myeloid progenitors (gate K) differentiate from gate B to gate G into the neutrophils and from gate J to gate
- H into monocytes.
- C. The colours of the gate in figure B can be found back in the plot of CD45/SS enabling to follow the flow cytometrical maturation pathway within the bone marrow sample.



#### Figure 2.

Comparison of intensities and pattern of a liquid and dried MoAb panel. A 10-colour panel directed T-cell subpopulaties in liquid and dry composition was tested in 20 samples and analyzed on 3 Navios FCM instruments (Beckman Coulter, USA). Plots of same representative MoAbs are shown. Intensities were all comparable.

**EFLM Annual Report 2017** 

#### by Giuseppe Lippi, EFLM Executive Board Secretary

#### **GENERAL MEETING**

EFLM held its tenth General Meeting in conjunction with the EFLM EuroMedLab on 11 June 2017 in Athens, Greece, where 25 out of 40 EFLM Member Societies (NS), were represented. The EFLM President, Sverre Sandberg (SS), greeted the audience and welcomed delegates to the General Meeting (GM) in Athens. SS pointed out that the IFCC proposal concerning membership of IFCC shall not be discussed, because it will first be elaborated in more details within IFCC. Once EFLM receives a well elaborated proposal, it will be discussed among EFLM members.

SS reminded all attendees that EFLM is 10 years old and that one of the founders of EFLM was Vic Blaton, who sadly passed away earlier this year and who had the idea that there should be one organization within Europe and that therefore EC4 and FESC should be merged. SS called for one minute of silence to memorize the legacy of Vic Blaton.

SS provided an overview of the recent EFLM activities, since the last GM in Paris. SS said that EFLM is representing laboratory medicine in Europe and that EFLM is doing what NSs wants it to do. SS called all participants to send their proposals for future actions and activities to EFLM. Furthermore, SS pointed out that the goal of EFLM is to include representatives from all EFLM NSs in different functional units of





EFLM. SS encouraged all NSs to engage more in the work of EFLM and invited all countries which are not represented yet within the EFLM, to send their nominations to various WGs. SS again reminded NSs why there was a change in bylaws. He continued by emphasizing that EFLM is trying to make a new image. SS called on all participants and national representatives (NRs) to support the Executive Board (EB) in all EFLM matters, where they may see improvements. The inclusion of EC4 into the EFLM structure was successfully managed and SS explained why this was important and how it was done. Furthermore, he gave a brief overview of the ongoing and future projects within EFLM. At the end of his presentation, SS thanked all EFLM officers who voluntarily contribute to EFLM for their hard work. There were no comments. The report was endorsed.

Huib Storm (HS), EFLM Treasurer, gave a report on audit, balance sheet 2016, internal budget 2016. Audit of the EFLM financial matters for 2016 had been done in accordance with GAAP (General Accountant Audit principles) by the certified auditor. The audit was successful and EFLM has obtained a certificate proving that EFLM accounts are maintained fully in accordance with the Belgian law and GAAP. HS presented the Balance sheet for 2016 according to Belgian GAAP and invited EFLM NSs for its approval. GM has approved the accounts by General Meeting (which constitutes the discharge for EB members). HS has also presented the Internal Budget 2017 and asked for its formal approval. EFLM GM approved the Internal budget unanimously.

During the GM elections were held for the positions of EFLM Vice President, Secretary, Treasurer and the two Full Members. Mauro Panteghini, the Past President (MP) acted as election supervisor and communicated the formalities: with 25 NSs present at the GM floor, the quorum of 21 votes was reached and simple majority defined at 13 votes. All decisions are made by a simple voting (majority of votes present). Ana-Maria Simundic was the only candidate and was elected by acclamation as EFLM President-elect. Giuseppe Lippi was the only candidate and was elected by acclamation as EFLM Secretary. Huib Storm was the only candidate and was elected by acclamation for a second two-year term as EFLM Treasurer. Candidates for 2 Member-at-large positions were: Tiago GUIMARAES (Portugal), Grazyna SYPNIEWSKA (Poland), Michel LANGLOIS (Belgium) and Tomas ZIMA (Czech Rep). As there were 4 candidates for 2 Member-at-large positions, MP invited GM members to first vote for a first position. Two candidates had the same lowest number (5) of votes (SYPNIEWSKA and LANGLOIS). MP said that according to the procedure there should be another voting round, but he said that NSs could also decide to exclude two last candidates with the least number of votes. NSs voted for the preferred choice and 20/25 NSs were in favour of dropping the last two candidates. As Tiago Guimaraes had received the majority of votes, out of the two remaining candidates, he was elected for the first Member-at-large position. As Tomas Zima had received the majority of votes, he was elected for the second Member-at-large position (third term).

EFLM EB had already discussed rules for the election of the Regional Federation Representatives to the IFCC Executive Board on several occasions. EFLM EB strongly supports that an individual representing a Region is selected by a Region according to the Region agreed electoral process and that this person participates in the policies and actions of a Region. If a separate election is organized by IFCC to elect a "regional representative" in their EB, EFLM EB thinks that there will not be any structural connection between the Regional Federation (e.g., EFLM) and IFCC. To overcome this situation, MP presented a proposal for the Election Procedure for European Region in which 1) the EFLM EB recommends the EFLM President or his/her representative (i.e., a person seated in the EFLM EB) to its Members for being elected at the IFCC EB; 2) the constituent NS officially nominates this person to IFCC for organizing a ballot to have the NRs approval. The GM has fully supported this proposal and gave the mandate to the EFLM EB to propose an official procedure, which manages all necessary steps in accordance with this decision (including a change in the EFLM statutes if needed). The proposal was voted electronically and approved by more than <sup>3</sup>/<sub>4</sub> of the NSs.

In the remaining part of the GM, Kosovo was automatically endorsed as EFLM Full Member having received the status of IFCC Full Member, whilst Slovak Society for Laboratory Medicine has applied for Provisional membership and has submitted all necessary documents. This is a subject to voting by the EFLM NSs. This decision has been voted for by 25/25 votes.

Reports about the past and ongoing activities within the EFLM functional units were given by the Science Committee (E. Kilpatrick, C-S Chair), Profession Committee (G. Wieringa, C-P Chair), Quality & Regulations Committee (W. Huisman, C-Q-R Chair), Education & Training Committee (R. Lichtinghagen, C-ET Chair) and Communication Committee (M. Graziani, C-ET Chair).

#### **EXECUTIVE BOARD**

Some of the leading activities planned and developed during 2017 are listed below.

- New image of EFLM (new logo, new website, new Newsletter).
- Definition of the policy for the nomination of the Regional representation at the IFCC Board.
- Improve the quality, number and spread of EFLM Publications.
- Develop of an EFLM CPD Scheme.
- Establish and increase collaboration with clinical societies.
- Develop the visibility and collaboration with IFCC and IFCC Regional Federations.
- Liaise with EC and accrediting institutions.
- Promote the profession increasing awareness of the importance of clinical laboratories in health care and at society level.
- Optimise the activities of EFLM functional units (Committees, Working Groups and Task and Finish Groups).
- Develop visibility and collaboration with EFLM National Societies. During 2017, EB members. participated in 5 EFLM National Society meetings hosted by Belgium (Simundic), Bulgaria (Zima), Czech Republic (Sandberg), France and Latvia (Neumaier).
- Strengthen and formalize relationships with industrial partners.
- Fostering the development of active WG Young Members.
- Strategic planning. The EB feels that it would be good to have a strategic planning for a longer period (5-10 years). Each EB could produce its Action plan for its term of office, but strategy is related to much longer period.

#### COMMITTEES

#### Committee – Communication (C-C)

In 2017 the C-C had two main focus: the restyling of the EFLM image and the consolidation of the collaboration with the its National Societies. The restyling of the EFLM image has been successfully completed with creation of a new logo and organization of a new website. The site incorporates now the activities of the European Register of Specialists in Laboratory Medicine and has a page dedicated to the General Public, that can be of help in bringing EFLM and the profession closer to the non-professionals. A big effort was devoted in 2017 to conception and production of the EFLM NewsLetter; EuroLabNews is now issued every two months and delivered to more than 4000 subscribers to the EFLM mailing list. The bulletin contains a number of regular columns aimed to inform the readers about the main activities of the Federation and of its National Societies. The presence of EFLM in the social media continued to receive great consideration. In 2017, an intensive campaign has been carried out to increase the visibility of the activities promoted by the EFLM among laboratory professionals. The number of followers and the number of interactions with the news published on the social media by EFLM are both increasing. The needs and the expectations of National Societies have both been explored with the help of a Satisfaction Survey. The results of the Survey will be used to improve the relationships with the National Societies and to better focus the efforts and the resources of the Federation. The comprehensive history of EFLM received also attention and a document has been created to illustrate the milestones of EFLM. The document is now on the EFLM website.

#### **Committee – Education and Training (C-ET)**

C-ET has been involved in the organization of the 13<sup>th</sup> Symposium of the Balkan region and is involved in the Congress Organizing Committee for the 23<sup>rd</sup> EuroMedLab in Barcelona and the 14<sup>th</sup> Symposium of the Balkan region. A new version of the EFLM European Syllabus has been finalized in cooperation with C-P. After endorsement by the national societies it will be published soon. In order to maintain the EFLM European Syllabus and to deliver new revision courses (EFLM European Syllabus Courses) for emerging Specialists in Laboratory Medicine (EuSpLM), the foundation of a new TG EFLM European Syllabus (TG-EES) was initiated. TFG CPD Crediting System produced documents on accreditation of CPD events for medical and non-medical Specialists in Laboratory Medicine and successfully completed the project. A newly initiated WG Laboratory Medicine Credit Points (WG-LMCP) will establish and run the EFLM system to allocate credit points for educational events. The website for a program for exchanging practice and practical training within EFLM countries (EFLMLabX) was finished by WG-CPE, so that a successful start of the program is ensured. A MedTech European Code survey initiated by WG-CPE is currently running in all EFLM member societies. In 2017 WG-DE launched the new e-learning platform and started issuing of certificates of attendance for webinars. WG-DE realized four webinars and one internal webinar for EFLM officers, four webinars have been recorded from EuroMedLab in Athens and from CELME Congress in Prague.

#### Committee – Profession (C-P) and EC4 Foundation

At the beginning of 2017, the C-P welcomed a new working group charged with growing the Register of Specialists in Laboratory Medicine (EUSpLM), and adjudicating applications from potential registrants. By the end of 2017 the working group chair had re-established automatic registration from the Netherlands and, for the first time, auto-registration has been established from Croatia. In March the working group were delighted to welcome 12 corresponding members to its fold (including a representative from outside the European Union), drawn from national societies with longstanding interest and support for achieving recognition of specialist practice under EU Directive 2013/55/EC (The recognition of professional qualifications). The new infrastructure represents a seamless transition to the new ways of working. Towards the end of 2017, encouraging news was received that the EU Commission had invited Laboratory Medicine to propose a Common Training Framework for specialist practice, a welcomed invitation coinciding with completion of version 5 of the syllabus for specialist education and training. 2017 closed with the successful transfer of the EUSpLM database to the Milan office and finalization of new software on the EFLM web site that will allow ready access for individual and auto-registration in 2018.

#### Committee – Quality and Regulations (C-QR)

WG A/ISO (Accreditation and ISO) is working on several papers concerning retention time, point of care testing (POCT), measurement uncertainty and validation/verification. All members are active in making these documents generally applicable. The chair of the Committee was active in ISO TC212 WG1 especially in relation with risk management and POCT outside the hospital environment. The chair of the WG was active in CEN TC140 and the Health Care Committee of EA (European cooperation on Accreditation. Having influence on standards, guidelines and the way these are used in accreditation, and the implementation of the IVD Directive, is an important aspect of the Committee.

#### **Committee – Science (C-S)**

The eight WGs under this Committee (Biological Variation, Guidelines, Harmonization of the Total Testing Process, Patient Focused Laboratory Medicine, Personalized Laboratory Medicine, Postanalytical Phase, Preanalytical Phase and Test Evaluation), two Task Groups (Biological variation Database and Performance Specifications Based on Outcome Studies) and one Task and Finish Group (Standardization of the Colour Coding for Blood Collection Closures) remain highly active in focusing on topics which are of direct relevance in improving the effectiveness of laboratory medicine to patients. 2017 was a particularly productive year when a number of initiatives started to come to fruition. Particular highlights include: the publication of a checklist for assessing the quality of biological variation (BV) studies and the ongoing development of a BV database. The European Biological Variation Study (EuBIVAS), has published BV estimates for many routinely measured enzymes and for creatinine, with plans for reporting on many other tests including those of lipids, electrolytes and coagulation. There have been initiatives between the EFLM and the European Athersclerosis Society with a joint consensus paper on quantifying atherogenic lipoproteins being submitted. Other papers either published or submitted include recommendations on very clinically relevant topics such as those on venous blood sampling, order of blood draw, managing hemolyzed samples and on serum indices. The Science Committee of the EFLM has traditionally been in close contact with the Scientific Division of the IFCC and now also plans collaborate closely with the new Emerging Technology Division.

#### MEETINGS

EFLM has organized four meetings during 2017:

- 1. 4<sup>th</sup> EFLM-BD European Conference on Preanalytical Phase. Amsterdam (NL), 24-25 March 2017.
- 2. EuroMedLab 2017. Athens (GR), 11 15 June 2017
- 3. 13<sup>th</sup> EFLM Symposium for Balkan Region. Belgrade (SRB), 21 22 September 2017
- 4. EFLM Symposium: Cutting Edge at Laboratory Medicine (CELME 2017). Prague (CZ), 5-6 October 2017

#### **WEBINARS**

- EFLM has organized three Webinars during 2017:
- 1. The development of guidelines and recommendations for peripheral blood film review internationally. on-line, 7 November 2017.
- 2. Harmonization of preanalytical phase in Europe. on-line, 21 November 2017.
- 3. Laboratory hemostasis. on-line, 19 December 2017

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laboratory medicine: 3 years on from the Milan Strategic Conference. Clin Chem Lab Med. 2017 Oct 26;55(12):1849-1856.

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Sverre Sandberg, EFLM Past-President

Michael Neumaier, EFLM President

## In memory of Prof Dr. Ad P Jansen: founder of EC4

by the EFLM Executive Board



On 24th of January 2018 Prof Dr Ad Jansen passed away at the blessed age of 94.

Prof Jansen was one of the icons of clinical chemistry in its very early days. His work is invaluable for our profession in the Netherlands and also in Europe. Ad Jansen was closely linked to the founding of NVKC, one of the oldest societies for clinical chemistry in the world. He also founded SKML in 1974, one of the first NEQAS organizations. He realized that international cooperation is paramount to harmonize across borders and in particular in the six countries of the European Communities at that time. He started co-operation in quality control with colleagues in UK, France, West-Germany, Belgium, UK and Ireland.

Prof Jansen was also founder of EC4. The founding meeting took place in The Netherlands on May 6<sup>th</sup> 1977. The aim was to reach a sectorial directive for clinical chemists for mutual recognition of diploma's, certificates and other evidence of formal qualifications in clinical chemistry in order to overcome possible discrimination of clinical chemists of non-medical origin. It still forms the basis of the work of EFLM Profession Committee.

Prof Jansen was admired for his vision. Much of his work still has great impact on the practice of laboratory medicine and it's organization at national and European scale but we are remembered for who we are as much as for what we do, and in addition to his many achievements, Ad Jansen was one of the nicest people you could ever wish to meet. His friendliness, amiability and open mind next to his boundless energy made him a very beloved person. The memory of him is kept with respect and love.

## Updates of the EFLM Publication list

by Maria Stella Graziani, Chair of the Communication Committee

#### The use of error and uncertainty methods in the medical laboratory

Oosterhuis WP, Bayat H, Armbruster D, Coskun A, Freeman KP, Kallner A, Koch D, Mackenzie F, Migliarino G, Orth M, Sandberg S, Sylte MS, Westgard S, Theodorsson E.

All authors are members of the Task and Finish Group on Total Error of the EFLM. Clin Chem Lab Med 2018; 56: 209–9

This paper presents the consensus reached within the EFLM task group established after the 1<sup>st</sup> Strategic EFLM Conference (Milan, 2014). The task of the group was to elaborate a proposal on how to use the Total Error concept and how to possibly combine measures of bias and imprecision in performance specifications. The conclusion of the paper is that error methods are at the moment the most used methods for quality assurance and analytical performance specifications in laboratory medicine and that error and uncertainty methods are complementary when evaluating measurement results in medical laboratories.

The EFLM Working Group on pre-analytical phase (WG-PRE) issued two more papers related to the management of samples with hemolyis, icterus and lipaemia continuing their effort towards the harmonization of the pre-analytical phase.

#### Practical recommendations for managing hemolyzed samples in clinical chemistry testing

Lippi G, Cadamuro J, von Meyer A, Simundic AM, on behalf of the EFLM Working Group for Preanalytical Phase (WG-PRE) Clin Chem Lab Med 2018 doi 10.1515/cclm-2017-1104

The aim of this paper is to suggest a pragmatic approach for managing results of clinical chemistry testing in hemolyzed samples, attempting to balance the need to produce quality laboratory data with clinical need to release the test results. You can find here below a short summary of the main recommendations; however, a careful reading of the paper is highly advisable. 1. Always check the sample quality before testing; 2. Use preferably the automatic assessment of the H-index; 3. If H-index was unavailable, the visual assessment will be allowed; 4. The H-index results should be transferred to the lab information system; 5. Define a standardized procedure to manage test results in hemolyzed samples; 6. Always use control materials to check the analytical performance of the H-index.

#### Local quality assurance of serum or plasma (HIL) indices

Lippi G, Cadamuro J, von Meyer A, Simundic AM, on behalf of the EFLM Working Group for Preanalytical Phase (WG-PRE) Clin biochem 2018 doi 10.1016/j.clinbiochem-2018-02-018

This article is aimed to provide an expert opinion about management of internal quality control (IQC) assessment for HIL indices. The Authors support the use of in-house prepared IQC materials with at least two different levels for each interfering substance (haemoglobin, bilirubin, lipaemia). IQC testing should be performed at least 2 times per day, and systematically recorded. When results do not meet their set performance goals, the ensuing procedure should mirror that of conventional laboratory IQC management. These recommendations should help clinical laboratories improving the quality of the total testing process.



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Via Carlo Farini, 81 20159 Milano - ITALY Ms Ester Licandri Ph. +390266802323 ext. 920 ester.licandri@mzcongressi.com



#### **NEWS FROM EFLM NATIONAL SOCIETIES**

News from the Spanish Society of Laboratory Medicine (SEQC<sup>ML</sup>)



Within the framework of the XI National Clinical Laboratory Congress (Labclin 2017) organized by the Spanish Society of Laboratory Medicine (SEQC<sup>ML</sup>), the Spanish Association of Medical Biopatho-

logy-Laboratory Medicine (AEBM) and the Spanish Clinical Laboratory Association (AEFA)

## The patient as the center of actions and technology, protagonists of Labclin 2017

- Greater participation with physicians is necessary for the development of adequate protocols and clinical pathways, and in the approach to complex cases
- Working with information generated by laboratories using artificial intelligence tools is considered a great future opportunity for the sector
- In this year's edition, special attention was paid to communications

**Madrid, November 14, 2017** - The clinical laboratory evolves at the speed of technological development, which implies that it is in continuous advancement. This leads to many challenges - such as advances in technology, the study of circulating tumor DNA, the automation of processes such as microbiology, and the management of analytical systems at Point of Care - and, therefore, a process of constant updating is needed.

With the aim of exchanging experiences and promoting professional and human relationships, and updating this knowledge, the Spanish Society of Laboratory Medicine (SEQC<sup>ML</sup>) in collaboration with the Spanish Association of Medical Biopathology Laboratory Medicine (AEBM) and the Spanish Clinical Laboratories Association (AEFA), held the 11<sup>th</sup> National Congress of the Clinical Laboratory (Labclin 2017) in Malaga from November 15 to 17, one of the most important congresses in the national health scene based on number of attendees.

"In scientific matters we have a leading-edge program - we will discuss the new advances in cardiovascular biomarkers, updates in diabetes, and the use of circulating tumor DNA, among many other issues of interest. It should be noted that very important figures in the scientific field will be involved, so our expectations for learning are very high," explained Dr. Maria Luisa Hortas, member of the SEQC<sup>ML</sup> and the Scientific Committee of the Congress, in an announcement prior to the event. According to the expert, "our scientific program gathers together the latest news, trends, and leading research, and as a result the Congress has become a national benchmark for the sector".

She continued: "In addition, within the training program, we look for activities that contribute to practical excellence on a day-to-day basis. For example, we address training related to ISO 15189 accreditation, or the seminar "What is a clinical case: guidelines for its development", which will be given by Dr. María Dolores Martín Escalante, director of the Internal Medicine Unit of Costa del Sol Hospital and vice president of the Andalusian Society of Internal Medicine (SEMI), who is also editor of the international journal "Revista Española de Cases Clinicos de Medicina Interna (Reccmi) [Spanish Journal of Clinical Cases in Internal Medicine]".

For her part, Dr. Pastora Rodríguez Vázquez, member of the SEQC<sup>ML</sup> and the Organizing Committee of the Congress, declared prior to the event that this year program would emphasize key topics of laboratory medicine such as the evolution of day-to-day practices, accreditation, perspectives in organic pathologies, new technologies or applications, new medical strategies, and translational research, always taking into account that the patient is at the center of these activities, efforts, and discussions.

"So," she added, "we will discuss the most current issues in the field of laboratory medicine, which is always in expansion, and we will have extraordinary speakers, both national and international, towards that end." It should be highlighted that the scientific program was carried out with the participation of more than seventy moderators and speakers, who presented new aspects of basic science and clinical practice, and explored new challenges for laboratory diagnosis.

#### News of the 11<sup>th</sup> Edition of Labclin

"As an important new item, in this edition we have tried to give greater visibility to communications. Therefore, the Scientific Committee will select - according to the strict established criteria of quality, theme and form - up to eighteen of the projects received for oral presentation during the symposiums ", noted Dr. Rodríguez prior to the Congress.

"In fact, one of the main conclusions we obtained in the satisfaction survey from the last edition was the need to strengthen the presence of oral presentations. That is why we have worked on this with special attention for this edition of the Congress. This year, 2017, we have selected 30 oral communications, of the 1059 papers submitted, to be presented during the corresponding sessions, either within the symposia or within the award space", explained Dr. Hortas prior to the event.

"We know the important contribution that these papers represent for the positioning of our collective - explained the expert - for the strengthening of the pillars of our congress and for the enrichment of the scientific community. For this reason, we will continue working to increase the visibility of all those projects that, under the strict quality standards that correspond to our discipline, result in the enrichment of our scientific resources."

"In addition to the projects and oral presentations, this year we are looking forward with special interest to some topics such as the challenges of personalized medicine, new developments in cardiovascular disease, Point of Care management, and new diagnostic opportunities originating in the laboratories, such as circulating tumor DNA", noted Dr. Rodríguez.

#### **NEWS FROM EFLM NATIONAL SOCIETIES**

# News from the French Society of Clinical Biology Accreditation of medical laboratories: Success for the 50% cap.

by Bernard Gouget, Councelor for Public Health FHF, President Human Healthcare Section Committee-COFRAC, SFBC International committee; Alain Suiro, Vice President, Human Healthcare Section Committee-COFRAC; Hélène Mehay, Head of the Human Healthcare section COFRAC

December 31, 2017 was an important step for laboratory medicine in France: that of the first deadline set for Medical Laboratories (LBM) as part of the legislative obligation to accredit their activity, 864 of 869 medical laboratories, including 305 hospitals are currently accredited ( i.e., 99.3% of these). A winning bet that illustrates mobilization, and which rewards the collective effort of



the entire profession of laboratory medicine, institutions and COFRAC for the implementation of a reform essential to the quality of care.

Making accreditation compulsory for the practice of laboratory medicine activities is an ambitious choice on the part of the public authorities. Medical laboratories had to meet two criteria as of December 31, 2017: to be accredited on each of the three test families (biochemistry-genetics, immunology-hematologyreproductive biology, microbiology) and in at least 50% of their activity.

Introduced by Order No. 2010-49 of January 13, 2010 on laboratory medicine, the accreditation obligation concerns all public and private medical laboratories in France. It seeks to guarantee their competence and the quality of services provided.

This accreditation provides an additional guarantee to patients on the value of the examinations practiced, and fits directly into the main thrusts of the national health strategy. The change in the schedule allowing until December 31, 2017 for medical laboratories to be accredited has proven to be a well-calibrated measure. It made it possible to plan evaluations in an optimized manner, given the resources available to evaluators and to have sufficient time to comply before the deadline.

The Regional Health Agencies have been informed that the accreditation process has not been completed for 5 medical laboratories that have been the subject of a first negative decision and for which the control of the discrepancies identified during their initial assessment must be verified. A single private practice laboratory gave notification of refusal of accreditation. Out of 305 hospital medical laboratories, 3 medical laboratories are still awaiting a decision for restructuring reasons or exceptional situations.

The next step, by November 1, 2020, is to obtain accreditation for all medical laboratory activities. Also, the Human Health Section of COFRAC has already implemented a concentration strategy to improve the performance of its actions by optimizing processes and wished to strengthen the support of professionals in this essential new phase to guarantee the success of the reform (www.cofrac.fr)

## NEWS FROM EFLM NATIONAL SOCIETIES News from the Society of Medical Biochemists of Serbia The twentieth annual Professor Ivan Berkeš scientific conference

by Snežana Jovičić, Society of Medical Biochemists of Serbia

Honoring the life and work of Professor Ivan Berkeš, one of the founders of the medical biochemistry profession in former Yugoslavia, the Society of Medical Biochemists of Serbia organized for the twentieth time in December 2017, the traditional annual Scientific Conference. Professor Ivan Berkeš taught at Universities of Zagreb, Skopje and Belgrade. His work at the Faculty of Pharmacy, University of Belgrade, was crowned in designing the postgraduate specialization studies program, and in the foundation of clinical enzymology as an independent discipline. Professor Berkeš was mentor to over 150 medical biochemistry specialists, and several dozen of PhD students. He authored over 200 papers in international and national journals, as well as several books. Upon his death, in 1997, his former students gathered in the Society of Medical Biochemists of Serbia, established the Scientific Foundation "Professor Ivan Berkeš". The Foundation traditionally awards the best students graduated at the Faculty of Pharmacy University of Belgrade and organizes the Annual Scientific Conference where the doctoral dissertations defended in the field of medical biochemistry during the past year are presented.

The twentieth annual Scientific Conference was organized traditionally by Professor Nada Majkić-Singh, Pofessor Berkeš'

student and associate, who contributed the most to the remembrance of his legacy. The Conference was held 7 December 2017 under the patronage of the Society of Medical Biochemists of Serbia, Scientific Foundation "Professor Ivan Berkeš" and the Faculty of Pharmacy University of Belgrade. It gathered over 200 participants –students, older colleagues who were the students of Professor Berkeš, young graduated medical biochemists, and teachers of the Faculty of Pharmacy. Traditional guests were the family members of Professor Berkeš – his son and grandson, with their families.

Professor Nada Majkić-Singh opened the Conference, with the opening welcome and word on its history and significance. On behalf of the Faculty of Pharmacy, the participants were welcomed by the Vice Dean, professor Nataša Bogavac-Stanojević. After the opening words, the choir of students "Raskovnik" performed, adding the festivity to the event. The opening ceremony was closed by awarding the valedictorians of the two graduate programs of the Faculty of Pharmacy University of Belgrade – Tamara Antonić, Master of Pharmacy-Medical Biochemist, and Sandra Tešić, Master of Pharmacy. Prof. Nada Majkić-Singh and Professor Marina Milenković, the Vice Dean for Education, handed the awards to this year's laureates.

Professor Svetlana Ignjatović and Professor Vesna Spasojević-



Figure 1.

Choir of students of Faculty of Pharmacy "Raskovnik"; the conductor Djordje Perović, on the piano Vladimir Vujović.



#### Figure 2.

Laureate of the "Professor Ivan Berkeš" Scientific Foundation, Tamara Antonić (in the middle) with professor Marina Milenković (left) and professor Nada Majkić-Singh (right).



#### Figure 3.

Laureate of the "Professor Ivan Berkeš" Scientific Foundation, Sandra Tešić (in the middle) with professor Marina Milenković (left) and professor Nada Majkić-Singh (right).

Kalimanovska chaired the scientific part of the Conference. The program encompassed all of the three fields of the medical biochemistry curriculum - medical biochemistry, toxicological chemistry and sanitary chemistry. In the first part, the results of the ongoing scientific projects of the Faculty of Pharmacy and Ministry of Science, Education and Technological Development were presented. The speakers were Professor Aleksandra Zeljković ("Assessment of LCAT and CETP activities as a tool for estimation of structural and functional properties of HDL particles") and Professor Mirjana Bećarević ("Diagnostic and therapy of antiphospholipid syndrome"). The second part was dedicated to the doctoral thesis presentations. Dr Marina Pjanović presented her work on bone formation markers and vitamin D in pregnancy. Metabolic and immunological effects of administration of two Lactobacillus strains in mice fed a high fat diet were presented by Dr Ana Djurić. The Conference was closed with the presentation on the study on rats of cadmium and polychlorinated biphenyls mixture toxicity by Dr Aleksandra Buha-Đorđević.



Figure 4. Family of professor Berkeš and audience at the Conference.



#### Figure 5.

Participants in the scientific part of the Conference with laureates (from left to right): assistant Milica Miljković, professor Aleksandra Zeljković, professor Vesna Matović, professor Vesna Spasojević-Kalimanovska, professor Nataša Bogavac-Stanojević, Tamara Antonić, professor Marina Milenković, professor Nada Majkić-Singh, Sandra Tešić, professor Mirjana Bećarević, professor Svetlana Ignjatović.

#### Austrian Society of Laboratory Medicine and Clinical Chemistry (ÖGLMKC)

Dr. Georg Mustafa (Salzburg) is the new President of the Austrian Society of Laboratory Medicine and Clinical Chemistry replacing Prof. Alexander Haushofer. A warm welcome to Dr. Mustafa and a thank you to the outgoing President Prof. Haushofer.

#### German Society of Clinical Chemistry and Laboratory Medicine (DGKL)

Prof. Matthias Nauck (Inst for Clinical Chemistry and Laboratory Medicine, University of Greifswald) is the new President of the German Society of Clinical Chemistry and Laboratory Medicine replacing Prof. Berend Isermann. A warm welcome to Prof. Nauck and a thank you to the outgoing President Prof. Isermann.

#### Association of Clinical Biochemists in Ireland (ACBI)

Ms Caroline Joyce (Clinical Biochemistry Department, Cork University Hospital) is the new EFLM National Representative for the Association of Clinical Biochemists in Ireland replacing Dr Graham Lee acting now as new ACBI President replacing Ms Paula O'Shea. A warm welcome to Ms. Joyce, congratulations to Dr. Lee for the new appointment and a thank you to the outgoing President Ms O'Shea.

#### **Polish Society for Laboratory Diagnostics (PTDL)**

Dr. Anna Mertas (Medical Univ. of Silesia in Katowice, Dept of Microbiology and Immunology in Zabrze) is the new President of the Polish Society for Laboratory Diagnostics replacing Prof. Bogdan Solnica. A warm welcome to Dr. Mertas and a thank you to the outgoing President Prof. Solnica.

# Calendar of EFLM events and events under EFLM auspices

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3 April 2018 How to perform tube validation? EFLM webinar on-line https://elearning.eflm.eu	3-5 May 2018 11 <sup>th</sup> International Symposium on Minimal Residual Cancer - ISMRC 2018 Montpellier (FR) http://www.ismrc2018.com/en/
15-19 April 2018 <b>11<sup>th</sup> International Symposium on Pneumococci and</b> <b>Pneumococcal Diseases (ISPPD-11)</b> Melbourne, Australia http://isppd.kenes.com/2018	9-12 may 2018 <b>2<sup>nd</sup> Congress of the Romanian Association of Laboratory</b> <b>Medicine (RALM)</b> Bucharest, Romania http://www.raml-conference.ro/
17 April 2018      The role of EQA in the verification of in vitro medical diagnostics EFLM webinar      on-line    https://elearning.eflm.eu/course/info.php?id=32	9-12 may 2018 9 <sup>th</sup> Congress of Croatian Society of Medical Biochemistry and Laboratory Medicine Zagreb (HR) http://kongreszagreb2018.hdmblm.hr/index.php/en/
20-23 April 2018 <b>11<sup>th</sup> International &amp; 16th National Congress on Quality</b> <b>Improvement in Clinical Laboratories</b> Tehran, Iran http://www.iqctehran.ir	10-12 May 2018 <b>14<sup>th</sup> Baltic Congress of Laboratory Medicine (BALM)</b> Vilnius, Lithuania https://www.balm2018.lt/
24-25 April 2018 <b>Theory and Practice of Laboratory Medicine</b> Kiev, Ukraine http://acclmu.org.ua/en/	15 May 2018 The order of draw EFLM webinar on-line https://elearning.eflm.eu
28-29 April 2018 <b>TBS-BD Pranalytical Phase Symposium</b> Kayseri (TR) https://tbd-bdpreanalitikevregunleri.org/	22-23 May 201851th Annual Meeting of the Israeli Society for ClinicalLaboratory SciencesBarcelona (SP)http://www.ilmar.org.il/index_doc.asp

23-25 May 2018 XVI Meeting of the SEQC-ML Scientific Committee Madrid, Spain www.seqc.es	3-5 October 2018 <b>26<sup>th</sup> Meeting of Balkan Clinical Laboratory Federation and the 6th</b> <b>National Congress of the Macedonian Society for Medical</b> <b>Biochemistry and Laboratory Medicine</b> Skopje, Macedonia http://www.bclf.info/index.htm
24-25 May 2018	4-6 October 2018
XXI Serbian Congress of Medical Biochemistry and	9th Russian Conference on Clinical Hemostasiology
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Laboratory Medicine with international participation	and Hemorheology
Belgrade, Serbia www.dmbj.org.rs	St Petersburg, Russia http://coith2018.com/en/main
30-31 May 2018	10-13 October 2018
International Course "The new era of Laboratory	5th EFLM-UEMS Joint Congress
Medicine: from Diagnosis to Clinical Management"	Laboratory Medicine at the clinical interface
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Erice (IT) For more information: chiara.bellia@unipa.it	Antalya, Turkey
6-8 June 2018 Focus 2018 – Annual Meeting of the ACB Manchester, UK www.acb.org.uk/focus	16-17 October 2018 <b>2èmes Journées Francophones de Biologie Médicale</b> Paris (FR) www.jfbm.fr
	30 October 2018
10-13 June 2018	International Conference on Laboratory Medicine "Laboratory
41 <sup>st</sup> European Congress of Cytology (ECC 2018)	Medicine: 25 years on "
Madrid, Spain http://www.cytology2018.com/	Padova (IT) http://www.lccongressi.it/laboratorymedicine2018/
12-15 June 2018	27 November 2018
	Preanalytical mysteries
XXXVI Nordic Congress in Clinical Chemistry	EFLM webinar
Helsinki, Finland http://www.nfkk2018.fi/	on-line https://elearning.eflm.eu
18-19 June 2018	
	29 November 2018
7 <sup>th</sup> International Symposium on Critical Care Testing and	12 <sup>th</sup> International Scientific CIRME Meeting "Standardization
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Blood Gases	in Laboratory Medicine and Patient Safety"
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