

EuroLabNews

THE EFLM BI-MONTHLY NEWSLETTER

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

Measurement Uncertainty in Medical Laboratories: Friend or Foe?



by Federica Braga, Research Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

In Laboratory Medicine a measurement is more accurate when it offers a smaller analytical error. An important assumption behind the uncertainty concept is that the bias (or systematic component of the measurement error) should be appropriately eliminated. To this aim, it is essential to define a reference measurement system describing a traceability chain, permitting a reliable transfer of the measurement trueness from the highest hierarchical levels of the chain to field methods. When measurement procedures operate under unbiased conditions, they produce results having an associated uncertainty that derives from the accumulated uncertainty of the corresponding traceability chain: uncertainty of the higher-order reference material used to transfer trueness, uncertainty of assay calibrator, and uncertainty due to the measurement random effects (i.e., imprecision of the measuring system and performance of individual laboratory using it) (Figure 1).

To be continued on page 2

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In this issue:

► Hot topics in Laboratory Medicine

Measurement Uncertainty in Medical Laboratories: Friend or Foe?

► News from EFLM Executive Board

Minutes from 9th EFLM General Meeting, Athens 2017

► News from EFLM Committees

EFLM webinars

► EFLM events

► Updates on EFLM Publications list

► The EFLM Office Informs

► News from EFLM National Societies

► Calendar of EFLM events and events under EFLM auspices

Foreword

by Harjit Pal Bhattoa, Editor EFLM EuroLabNews

In this current issue of the EFLM EuroLabNews Federica Braga presents Measurement Uncertainty in Medical Laboratories in the regular section of Laboratory Hot Topics. Ana-Maria Simundic, EFLM EB Secretary delivers the minutes of the Ninth EFLM General Meeting at Athens this year. Daniel Rajdl, Chair of the WG on Distance Education and e-learning, presents the forthcoming EFLM webinars. Ozkan Alatas, Chair of Congress Organizing Committee and President of Turkish Society of Clinical Biochemistry, invites all to participate in the 5th EFLM-UEMS European Joint Congress in Laboratory Medicine - "Laboratory Medicine at the Clinical Interface", in Antalya, Turkey in October, 2018. Snežana Jovičić, from the Society of Medical Biochemists of Serbia, covers the 13th EFLM Symposium for the Balkan Region. MariaStella Graziani, Chair of the EFLM Communications Committee, presents recent additions to the EFLM publications list. Heike Jahnke, CCLM Editor offers free access to all new CCLM articles for 3 days following publication. As a regular column of the EuroLabNews, news from National Societies of Italy, Spain and Kosovo give us an insight into their activities. Attendees may mark their calendars to attend stimulating meeting as mentioned in the Calendar of Events.





The measurement uncertainty obtained by combining those individual sources is called combined uncertainty. By multiplying the combined uncertainty by the so-called coverage factor (k), one obtains the expanded measurement uncertainty ($k = 2$ is recommended for a 95% confidence level).

The estimation of measurement uncertainty for clinical laboratories is needed to obtain the accreditation according to ISO 15189:2012 standard. Although laboratorians may easily understand the meaning, the determination of measurement uncertainty in actual practice may be difficult given that this standard does not clarify how it should be determined. In 2012, the Clinical and Laboratory Standards Institute (CLSI) published a guideline about measurement uncertainty, where the two available approaches to estimate the measurement uncertainty, the so-called "bottom-up" and "top-down" approaches, were described. The "bottom-up" approach is the

model originally proposed by the 'Guide to the Expression of Uncertainty of Measurement (GUM)', based on a comprehensive dissection of the measurement, in which each potential source of uncertainty is identified, quantified and combined to generate a combined uncertainty of the result using statistical propagation rules. This model has been endorsed by metrology institutes and suppliers of reference materials and must be used by reference measurement laboratories to obtain accreditation according to ISO 17025 and ISO 15195 standards for performing reference measurement procedures. The application of GUM in clinical laboratories is, however, not straightforward and has encountered many practical problems and objections. The "top-down" approach represents an alternative to the GUM model. It estimates the measurement uncertainty of laboratory results by using quality control data to derive the random components of uncertainty and certified reference materials for bias estimation. Some experimental studies have

demonstrated that the two approaches give equivalent estimates of uncertainty, so that clinical laboratories may use the simpler "top-down" approach to determine measurement uncertainty of their methods used in daily practice.

Once the combined uncertainty has been estimated, each user should compare it with the appropriate analytical performance specifications. The analytical goal that should be considered by laboratorians to evaluate the clinical acceptability of the measurement uncertainty for a given measuring system is that related to the reproducibility (read 'imprecision'), as the correct transfer of trueness along the selected metrological traceability chain should allow the obtainment of unbiased results. To allow clinical laboratory fulfilling the performance analytical specifications to provide clinically reliable patient results, it is necessary that the sources of uncertainties at the level of reference providers and *in vitro* medical diagnostics calibrators are sufficiently limited. Particularly, it is advisable to consume no more than 50% of the allowable total uncertainty budget at the level of the commercial calibrators to leave the remaining part of the budget for the measuring system imprecision (including the lot-to-lot variation of reagents) and individual laboratory performance.

In the traceability era, estimating measurement uncertainty and verifying that it fulfils the established budget at each level of the selected metrological traceability chain is essential to guarantee the reliability of the laboratory results and to avoid that the measurement error prevails on the associated clinical information. Ultimately, it is matter of patient safety. The next International Meeting (the 11th of the series) organized by CIRME, taking advantage from the presence of recognized experts in the field, is expected to further contribute spreading knowledge about this topic.

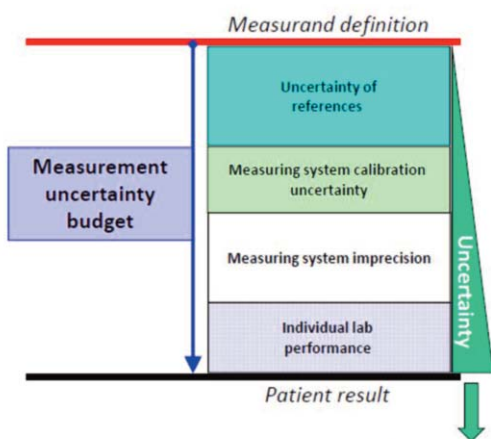


Figure 1. Sources of combined uncertainty in traceability implementation. U_{result} , combined uncertainty of patient result; U_{ref} , uncertainty of the higher-order reference material; U_{cal} , uncertainty of assay calibrator; U_{random} , uncertainty due to the measurement random effects.

$$U_{\text{result}} = (U_{\text{ref}}^2 + U_{\text{cal}}^2 + U_{\text{random}}^2)^{1/2}$$



Secure your space at the next CIRME meeting!

11th International Scientific Meeting

The conference at its 11th edition will deal with the widely discussed topic of the Measurement Uncertainty in Laboratory Medicine, including the definition of acceptable limits for the combined uncertainty budget in the implementation of metrological traceability, the role of total error in the uncertainty era, the information on measurement uncertainty to be communicated to clinicians and how, the definition of reference measurement procedures, the value-assignment protocol for the uncertainty of commercial calibrators, and the derivation of the uncertainty information from quality control data. Key note speakers: F. Braga (IT), F. Ceriotti (IT), A. Mosca (IT), M. Panteghini (IT), Mario Plebani (IT), W. Oosterhuis (NL), T. Orzechowski (US).

11th International Scientific Meeting

Measurement Uncertainty in Medical Laboratories: Friend or Foe?

Milano, Italy

November 30th, 2017

[Click here to access the full programme](#)

Ninth EFLM General Meeting

Minutes

Minutes taken by Ana-Maria Simundic, EFLM EB Secretary

Presentations and documents referred to in these minutes can be viewed and downloaded from EFLM's website: <https://www.eflm.eu/site/page/a/1058/>

1. Opening and welcome

The EFLM President, Sverre Sandberg (SS), greeted the audience and welcomed delegates to the General Meeting (GM) in Athens. SS pointed out that IFCC proposal 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 announced a small break before the elections, to allow all delegates who were out at other meetings, to come for voting. 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.

2. Approval of the minutes of the previous GM

No matters arising from the minutes of the last GM in Paris, June 2015.

Minutes were approved.

3. President's report

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. SS encouraged all NSs to engage more in the work of EFLM and invited all countries who 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 all participants to let us know if there are some things which we need to do better.

The inclusion of EC4 into the EFLM structure was successfully managed and SS explained how it was done and why is it important. 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.

4. Treasurer's report

Huib Storm (HS), EFLM Treasurer, gave a report on the following:

1. Audit
2. Balance sheet 2016
3. 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 obtain 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 with 25/25 votes in favour.

5. Election Executive Board 2018-2019

Mauro Panteghini, the Past President (MP) has briefly explained the procedure of elections for the EB members. According to current EFLM membership, the quorum is 21 members. During the voting procedure there were 25 NSs present. Majority represents 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-years term as EFLM Treasurer (third term)

Candidates for 2 Member-at-large positions were:

- Prof. Tiago GUIMARAES (Portugal)
- Prof. Grazyna SYPNIEWSKA (Poland)
- Prof. Michel LANGLOIS (Belgium)
- Prof. Tomas ZIMA (Czech Rep)

Thus, for Member-at-large there were 4 candidates and a candidate needs more than 50% of votes. If nobody has the majority, the candidate who has the lowest number of votes is left out and there is another round of voting, until some candidate gets a majority of votes.

As there were 4 candidates for 2 Member-at-large positions, MP invited GM members to first vote for a first position.

1. Member-at-large position

Candidate	number of votes (1 round)	number of votes (2 round)
Grazyna SYPNIEWSKA	5	left out
Tiago GUIMARAES	9	14
Tomas ZIMA	6	11
Michel LANGLOIS	5	left out

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 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.

2. Member-at-large position

Candidate	number of votes
Grazyna SYPNIEWSKA	3
Tomas ZIMA	13
Michel LANGLOIS	9



As Tomas Zima had received the majority of votes, he was elected for the second Member-at-large position (third term).

6. Membership - National Societies

- Application of the Kosovan Association for Clinical Chemistry as Full IFCC Member

Kosovo has been accepted as IFCC Full Member. Therefore their membership is, in accordance with the EFLM bylaws, automatically upgraded from Affiliated to Full membership. AMS has briefly informed the NSs about that.

- Slovak Society for Laboratory Medicine (SSLM) has requested to become a Provisional Member

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.

7. Reports from Committee chairs

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). Power point presentations with reports can be viewed and downloaded from EFLM's website: <https://www.eflm.eu/site/page/a/1058/>.

There were several questions asked from the audience.

Q: Hans Janssen (NL): asked how C-S chair is seeing the necessity to have internationally acceptable standards and documents. How do we plan to work with the rest of the world?

C-S chair replied that producing standards and recommendations is viewed as an important activity within EFLM. He stated he was due to meet Philippe Gillery, Chair of the IFCC Scientific Division, later during the Athens meeting to ensure a co-ordinated approach to these activities and where there was any overlap that this be approached jointly. The EFLM will hopefully also be able to 'adapt or adopt' some existing excellent guidelines from its constituent national societies.

Q: Ian Young (UK): asked about the position of C-P and EFLM regarding the Brexit?

GW: replied that we should stop talking about EU and start talking about Europe.

Q: Ferruccio Cerriotti (IT): asked whether EFLM Syllabus is published. C-P chair replied that version 5 is almost complete and shall soon (within not more than 4 months) be made available to all NSs. It will be submitted for publication by the end of 2017.

Q: Ferruccio Cerriotti (IT): reiterated the request to NSs to respond to

surveys. SS added that EFLM needs feedback from its members. EFLM NSs members are kindly requested to respond to various EFLM requests and share with EFLM their views and needs.

No further questions were raised.

8. Report from IFCC

Maurizio Ferrari (MF) has given a report about the past and ongoing activities within the IFCC. Power point presentation with this report can be viewed and downloaded from EFLM's website: <https://www.eflm.eu/site/page/a/1058/>.

He emphasised the intense activity of various IFCC units and difficulties in managing and supervising their work. The number of Task forces has increased and they are not under strict control. It was therefore decided to maintain very few task forces and move all other under the divisions. To achieve that, some new divisions shall be created. One new division shall be Emerging technology division. The chair will be Sergio Bernardini. IFCC shall communicate all these changes with its members in a timely manner.

No questions were raised.

9. Date and place of the next EFLM GM

The next GM shall take place in October 2018 in Antalya.

The exact time and date shall be communicated soon.

GA was closed at 18:00.

Save the new GM date in your agenda: at the last EB meeting, it was decided to schedule the next GM in Mannheim, Germany on **19 June 2018** from h. 16.00 to 19.00 (instead of Antalya) on occasion of the 2nd EFLM Strategic Conference which will be held on 18 and 19 June (further information will follow in due course).

NEWS FROM EFLM COMMITTEES

EFLM WEBINARS



by Daniel Rajdl, Chair of the EFLM WG Distance Education and e-Learning

The EFLM WG "Distance Education and e-Learning" in collaboration with the EFLM WG "Congress and Post-Graduate Education" are pleased to inform about next EFLM webinars. The attendance to EFLM webinars is free of charge. For those not able to attend, the recording of all EFLM webinars is available on at the new EFLM e-learning platform <https://elearning.eflm.eu>

October 18, 2017 at h. 18.00 CET

(new final scheduled date compared to the first one announced)

HEPATIC FIBROSIS ASSESSMENT USING MULTIPARAMETRIC BIOMARKER TESTS

Speaker: Ralf Lichtinghagen (DE)

Moderator: Merve Sibel Gungoren (TR)

Abstract: The stage of fibrosis is the most important single predictor of significant morbidity and mortality in chronic liver disease. The mechanisms leading to fibrosis and eventually cirrhosis are thought to be similar, irrespective of

the underlying etiology. At cellular level, hepatic stellate cells (HSC) undergo a phenotypic switch usually addressed as transactivation. Activated HSC are regarded as the main source of extracellular matrix (ECM) in the fibrotic liver. Additional cell types namely fibroblasts and myofibroblasts may also contribute to ECM deposition. Despite the similarities in pathophysiology at cellular level, morphogenesis and histologic appearance of the fibrotic liver may differ according to the etiology. Liver biopsy remains the gold standard to evaluate liver fibrosis. Not least, one has to keep in mind that liver biopsy provides additional information like histological grading and etiology that may be overlooked when surrogate markers are used. Ideally, those tests should answer two questions. 1) What is the stage of fibrotic organ damage (i.e. the amount of deposited ECM and the disturbed balance of hepatic microarchitecture)? 2) What is the net balance between ECM deposition and degradation (i.e. the dynamics of ECM turnover)? The former serves to evaluate the prognosis and indicate therapy, while the latter might be used to control the efficacy of treatment with regard to disease progression. Many different parameters including standard clinical chemistry and parameters of matrix metabolism have been evaluated. In the last decade, markers were assembled to multiparametric scores. Here, we can distinguish scores assembled of standard clinical chemistry markers (e.g. aspartate aminotransferase-to-platelet ratio index, FibroTest, Forns' index) from scores using circulating markers of hepatic matrix metabolism like hyaluronic acid (HA), tissue inhibitor of metalloproteinases-1 (TIMP-1), matrix metalloproteinase-2, propeptide of type III procollagen (PIIINP). In the webinar we will learn further details about the relevant complex scores, the clinical evaluation and current practical guidelines.

About the speaker: Prof. Dr. Ralf Lichtinghagen obtained his doctorate at Ruhr University Bochum in the field of Neurobiochemistry in 1989. At the beginning of the 1990s he undertook further training at Hannover Medical University (Institute of Clinical Chemistry) to qualify as a European Specialist in Laboratory Medicine. He carried out different research projects on the pathophysiology of the extracellular matrix in chronic liver disease and acquired his authorization to teach Clinical Chemistry at the university in 2001. Today his main areas of research are molecular diagnostics and new biomarkers. In addition to his responsibilities in patient care and research he gives lectures in Clinical Chemistry / Laboratory Diagnostics and is the academic head of the Medical Laboratory Assistants School. Prof. Lichtinghagen is a chair of EFLM Education and Training Committee since 2016.

November 7, 2017 at h. 18.00 CET

THE DEVELOPMENT OF GUIDELINES AND RECOMMENDATIONS FOR PERIPHERAL BLOOD FILM REVIEW INTERNATIONALLY

Speaker: Anna Merino (ES)
Moderator: to be defined

Abstract: not yet available.

About the speaker: Anna Merino González MD, PhD is a Senior consultant of cytology unit of Hemotherapy-Hemostasis Department in Hospital Clinic of Barcelona. Her main research interests are: morphology and identification of hematopoietic progenitor cells using flow cytometry, external quality programs in peripheral blood smear and automatic classification of abnormal peripheral blood cells. She has written 2 monographies and more than 80 articles in scientific journals with H-index 17. She is also a corresponding member of EFLM Working Group Distant Education and e-Learning.

November 14, 2017 at h. 18.00 CET

HARMONIZATION OF PREANALYTICAL PHASE IN EUROPE

Speaker: Ana-Maria Simundic (HR)
Moderator: João Tiago Guimarães (PT)

Abstract: European National Societies, members of EFLM, have agreed in Porto, during the 3rd EFLM-BD European Preanalytical Phase Conference that harmonization of preanalytical practices and policies is necessary and possible in each and every country in Europe as well as internationally, at the European level. The Working group for Preanalytical phase (WG-PRE) of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM), has taken the leading role in this process. The aim of this e-seminar is to present past, ongoing and future WG-PRE activities and various projects which aim is to improve the quality of preanalytical phase in Europe as well as to promote wide harmonization of preanalytical practices, patient safety improvement and reduction of unnecessary waste and healthcare expenses.

About the speaker: Since 2011, Prof. Simundic is the Chair of the EFLM working group for Preanalytical phase (WG-PRE), since 2011 and also serves as EFLM (European Federation of Clinical Chemistry and Laboratory Medicine) Executive Board Secretary. Moreover, Prof. Simundic is the President of the Croatian Society of Medical Biochemistry and Laboratory Medicine and the Editor-in-chief of the Scientific Journal Biochemia Medica, which is the official Journal of Croatian society. During her career, she has published over 100 scientific papers and several book chapters and has been invited as a guest speaker at numerous international meetings and conferences. She was awarded with the: Best Young Scientist award in 2000, Best Research award for 2011 by the Croatian Society of Medical Biochemistry and Laboratory Medicine, "Per Hyltoft Petersen Award" in 2012, by the Slovak Society of Laboratory Medicine, Honorary membership of the Hungarian Society for Laboratory Medicine in 2012. Currently, Prof. Simundic serves as the Head of the Department for Medical Laboratory Diagnostics of the Clinical Hospital Sveti Duh and teaches Clinical Chemistry at the University of Pharmacy and Medical Biochemistry in Zagreb.

December 19, 2017 at h. 18.00 CET

LABORATORY HEMOSTASIS

Speaker: Giuseppe Lippi (IT)
Moderator: to be defined

Abstract: Hemostasis is a complicated mechanism finalized to preventing unjustified bleeding during vascular injury, or unwarranted thrombosis when the vessels are substantially intact. Hemostasis is typically classified in two essential steps. The first event is an endothelial injury, which activates primary hemostasis and is then followed by activation of secondary hemostasis. Specifically, primary hemostasis develops with recruitment of a many platelets being at site of vascular injury. Platelets are subjected to a sequential process of activation, adhesion and aggregation. This initial hemostatic plug is however unstable, since it is vulnerable to fast dissolution within in the local blood, especially in arteries. To prevent dissolution, additional fundamental mechanisms of secondary hemostasis (also known as blood coagulation) are activated, with the aim to stabilize the initial plug by large fibrin deposition.

The diagnostics of bleeding disorders of primary and secondary hemostasis remains a challenge for laboratory professionals, especially those lacking experience background, experience and skill on this topic. Bleeding is essentially due to many acquired or congenital conditions, impairing either primary or secondary hemostasis. A universal consensus on the diagnostics of bleeding diseases remains an unmet target, so that the aim of



this Webinar is providing practical guidance for laboratory professionals who are less familiar with this important area of in vitro diagnostic testing. A practical strategy for diagnosing bleeding disorders of primary and secondary hemostasis is necessarily based on a multifaceted and multistep strategy, entailing accurate personal and family history collection, interpretation results of the so-called first-line hemostasis tests, then followed by interpretation (when necessary) of second- and third-line test to identify the both nature and severity of bleeding disease. The observation of profound hemorrhages rather than muco-cutaneous bleeding suggests a disorder of secondary hemostasis. Although positive family history can be frequently seen in patients with congenital disorders, the absence of clinically significant symptoms in relatives cannot be considered always suggestive of acquired disorders. The next phase is based on performance of the so-called first-line coagulation tests, mainly represented by activated partial thromboplastin time (APTT), prothrombin time (PT) and fibrinogen, especially when the family history is not indicative of specific factor deficiencies. The observation of abnormal results of these tests and the combination of results can help driving performance of the so-called second-line tests, which especially entail clotting factor assays. The so-called third-line tests (especially entailing immunologic tests of coagulation factors and molecular biology) are then useful to make a final diagnosis and/or for detecting the specific nature of the protein deficiency.

About the speaker: Giuseppe Lippi was born in Padova (Italy) on October 4th, 1967. He has taken the degree in Medicine in 1986 and the specialization in Clinical Biochemistry and Laboratory Medicine in 1992. He currently serves as Full Professor of Clinical Biochemistry and Molecular Biology at the University of Verona (Italy) and Director of the Clinical Chemistry and Haematology laboratories of the University Hospital of Verona (Italy). He has published more than 1400 articles in peer-reviewed journals, his total Impact Factor is over 5300 and the Hirsch Index (H-index) is 72. He has participated to more than 500 national and international congresses and has given more than 250 lectures to national and international meetings. In 2017 he has been appointed as Secretary of European Federation of Clinical Chemistry and Laboratory Medicine (EFLM). He has been awarded with the 2014 Management Sciences and Patient Safety Division Award of the American Association for Clinical Chemistry (AACC) for outstanding contributions in the field of patient safety in the clinical laboratory/healthcare industry, and with the 2015 Outstanding Speaker Award by the AACC. He has also received research grants from the European Community and from the Regional Health Care Service. Giuseppe Lippi is Editor in Chief of "Annals of Translational Medicine" and "Journal of Laboratory and Precision Medicine" and also serves as Associate Editor of the journals "Clinical Chemistry and Laboratory Medicine", "Seminars in Thrombosis and Hemostasis" and "Diagnosis", is the National Representative of the Italian Society of Clinical Biochemistry and Laboratory Medicine (SIBioC) and member of the European Federation of Laboratory Medicine (EFLM) Working Group on Preanalytical Variability (WG-PA). The main fields of research include pre-analytical variability, analytical and clinical validation of biomarkers,

diagnostics of the acute coronary syndrome, metabolism of lipoproteins and relevant assay methods, frailty, diagnosis and management of disorders of hemostasis..

January 23, 2018 at h. 18.00 CET *(preliminary date)*

FAECAL HAEMOGLOBIN: NEWER APPROACHES TO SCREENING AND DIAGNOSIS OF COLORECTAL DISEASE

Speaker: Callum G. Fraser (UK)

Moderator: Sally C Benton (UK)

Abstract: not yet available.

About the speaker: Prof. Fraser graduated BSc and PhD from the University of Aberdeen. After a year of postdoctoral work in the National Research Council of Canada in Ottawa, he returned to the University of Aberdeen as Lecturer in Chemical Pathology. From 1975, he was Chief Clinical Biochemist at the then new Flinders Medical Centre in South Australia and Honorary Senior Lecturer in Clinical Biochemistry in the Flinders University of South Australia, later Associate Professor. He returned to Scotland in 1983 and was Director of Biochemical Medicine, NHS Tayside, and Honorary Senior Lecturer in the Universities of Dundee and St Andrews. He is currently Consultant to the Scottish Colorectal Cancer Screening Research Unit; Honorary Professor, Centre for Research into Cancer Prevention and Screening, University of Dundee, and Honorary Consultant Clinical Biochemist, NHS Tayside. He has published over 300 papers, 11 book chapters and two monographs, *Interpretation of Clinical Chemistry Laboratory Data* and the best-selling "Biological Variation: From Principles to Practice": both books have been translated into Spanish and the second into Japanese, Russian and Italian also. He has served on many regional, national and international professional bodies. Over the last 15 years, he has been heavily involved in the setting up of the UK Colorectal Cancer Screening Pilot, the development and roll-out of the Scottish Bowel Screening Programme and the assessment of newer faecal tests. He is a founding Member of the Expert Working Group on Faecal Immunochemical Tests for Screening of the Colorectal Cancer Screening Committee, World Endoscopy Organization. He has been honoured by the Foundation Award and Honorary Membership of the Association for Clinical Biochemistry and Laboratory Medicine. In 2017, he was awarded with the EFLM-Roche Scientific Award for Laboratory Medicine.

March 6, 2018 at h. 18.00 CET

(new final scheduled date compared to the first one announced)

RELIABLE ESTIMATES OF BIOLOGICAL VARIATION – THE WAY FORWARD

Speaker: Aasne Karine Aarsand (NO)

Moderator: Bill Bartlett (UK)

Abstract: Biological variation (BV) data has many appliances in the daily laboratory life, being used both when evaluating the diagnosis and monitoring of disease and for setting analytical performance specifications. Thus, the quality of our work directly depends on the reliability of the BV estimates used as basis for these processes. Widely varying BV estimates are available for different measurands, and it is likely that this may be caused by differences in study design and statistical handling. Addressing this issue, the EFLM established in 2014 an EFLM Task and Finish Group (TFG) for

the Biological Variation Database. The TFG is made up by members from the EFLM Working Group on Biological Variation, the Analytical Quality Commission of the Spanish Society of Clinical Chemistry and experts in the area. The TFG has developed a critical appraisal list for evaluation of studies on BV and this will be used as basis for the setup of a database with measures of BV, the derived performance specifications and the evidence behind it.

About the speaker: Aasne K. Aarsand, M.D. Ph.D., is a consultant in medical biochemistry at the Norwegian Porphyria Centre (NAPOS) and the Laboratory of Clinical Biochemistry, Haukeland University Hospital and at the Norwegian Quality Improvement of Laboratory Examinations (NOKLUS), Haraldsplass Deaconess Hospital, Bergen, Norway. She received her Ph.D. in porphyria diagnostics from the University of Bergen in 2012. Her research interests include the evidence-based use of diagnostic markers, in particular in the porphyrias, biological variation and harmonisation of the total testing process. She is Chair of the Biological Variation Working Group and a member of the Task and Finish Group for the Biological Variation Database in the European Federation of Clinical Chemistry and Laboratory Medicine. She is also manager of the European Porphyria Registry and part of the Steering Committee of the European Porphyria Network (EPNET).

March 27, 2018 at h. 14.00 CET (*preliminary date*)

M-PROTEIN DIAGNOSTICS OF MULTIPLE MYELOMA PATIENTS TREATED WITH BIOLOGICS

Speaker: Hans Jacobs (NL)
Moderator: Jillian Tate (AU)

Abstract: Treatment of multiple myeloma (MM) has substantially changed with the recent introduction of therapeutic monoclonal antibodies (mAb) which have further improved the rates and depth of clinical response. mAb therapy in MM patients has

introduced new challenges in how therapy responses can be defined. On the one hand, recently approved mAb interfere with routine M-protein diagnostics. On the other hand, given the high rates of complete responses, new response categories need to be defined to measure minimal residual disease. As a reaction to these challenges research has focused on adaptations of conventional M-protein diagnostics to mitigate interference and on the introduction of novel methods that enable the identification of minimal residual disease. The aim of this e-seminar is to discuss how mAb therapy has changed both the therapeutic as well as the diagnostic landscape of MM.

About the speaker: Dr. J.F.M. (Hans) Jacobs. M.D., Ph.D. works as Laboratory Specialist Medical Immunology at the Radboud University Medical Centre, Nijmegen, The Netherlands. He is specialized in onco-immunology, monitoring cancer-immunotherapy trials, and biomarker development for IVD applications. As head of the national reference centre for M-protein diagnostics at the Radboudumc, dr. Jacobs coordinates the Dutch External Quality Assessment program for M-protein diagnostics since 2012. He is national board member the SKML section Humoral Immunology and National board member Kalibration-2000. Within the IFCC framework, dr. Jacobs is involved in the harmonization and standardization of M-protein diagnostics. Dr. Jacobs is co-author of more than 60 international articles and book-chapters. Since 2016 he is member of the editorial board of 'Clinical Chemistry and Laboratory Medicine'. Dr. Jacobs teaches immunology courses at the Radboudumc and the University of Twente.

Dr. Jacobs is awarded with: (2017) KWF Young Investigator Grant (Dutch Cancer Society); (2016) Young Investigator Award Dutch Society of Clinical Chemistry; (2016) Research Grant Radboudumc Oncology Foundation; (2013) Kalibration-2000 Grant, (2012) Noyons Grant; (2012) ZonMW Veni Grant (The Netherlands Organisation for Scientific Research)

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EFLM EVENTS

Upcoming event: 5th EFLM-UEMS European Joint Congress in Laboratory Medicine "Laboratory Medicine at the Clinical Interface", October 10-13, 2018



by Ozkan Alatas, Chair of Congress Organizing Committee and President of Turkish Society of Clinical Biochemistry

The Joint EFLM and UEMS-LM/MB European Joint Congress in Laboratory Medicine was initiated in October 2010 in Lisbon. Since then, this biannual event gained great attention. 5th EFLM-UEMS European Joint Congress in Laboratory Medicine will be held in Antalya, Turkey, on October 10-13, 2018 at Titanic Beach Lara Hotel by Turkish Society of Clinical Biochemistry.

Owing to the theme of "Laboratory Medicine at the Clinical Interface", invited speakers are experts from laboratory medicine and clinical medicine as well. Building on the success of previous congresses, 5th EFLM-UEMS European Joint Congress in Laboratory Medicine will include plenary sessions, symposiums, oral and poster presentations.

The Joint Congress will provide an ideal forum to stimulate intense discussions in laboratory medicine as well as to establish collaborations which is very important for young professionals in the field.

Antalya, the beautiful city on the Mediterranean coast of Turkey, is well known not only with its natural and cultural beauties but also historical places especially ruins of antic cities. The congress venue promises the participants take a break from the intensive scientific program and enjoy Turkish cuisine and social program

in the autumn days. Pre and post-congress tours will make your visit unforgettable.

Only through your kind participation, we may enjoy a fruitful congress feast. We are expecting your valuable contributions to the 5th EFLM-UEMS European Joint Congress in Laboratory Medicine.

Check out the congress website for more information: <http://eflm-uems-antalya2018.org/>





EFLM EVENTS

13th EFLM Symposium for Balkan Region Laboratory Medicine Management: Leadership Skills for Effective Laboratory

by Dr Snežana Jovičić, Society of Medical Biochemists of Serbia

Thirteen years ago, European Federation for Clinical Chemistry (EFLM) appointed Belgrade and the Society of Medical Biochemists of Serbia as the organizer of educational symposia for clinical chemists and laboratory medicine professionals of the Balkan region. These annual symposia have been organized with great success in the twelve previous years, always covering the topics of the greatest current interest in the field of clinical chemistry and laboratory medicine. In this manner, this year's EFLM Symposium for Balkan Region entitled "Laboratory Medicine Management: Leadership Skills for Effective Laboratory" successfully fulfilled high expectations set thirteen years ago. The 13th EFLM Symposium for Balkan Region was held on 21 and 22 September, and organized under the auspices of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC), Balkan Clinical Laboratory Federation (BCLF), Ministry of Education, Science and Technological Development of Serbia and Ministry of Health of Serbia.

During the two-day Symposium, eminent foreign and local experts introduced participants to the latest developments in the management in laboratory medicine, leadership skills of laboratory medicine professionals, laboratory medicine planning, organization and strategy, medical laboratory accreditation and competence, and laboratory medicine environmental health and safety. Also, the optimization of the post-analytical phase, economy of

consolidation and decentralization of medical laboratories, how to use laboratory information system and manage laboratory data, and also how to implement economic evaluation of laboratory testing were elaborated. Experiences regarding accreditation process and total quality management were discussed, with the accent on the balance between the accreditation process and patient safety, possible errors and risks in sample collection, and how to register frequent pre-analytical incidents, and efficiently manage unexpected events and accidents. Special attention was given to laboratory reports form, its categorization and actions, as well as to the use of statistics in laboratory practice.

The 13th EFLM Symposium for Balkan Region opened prof. Sverre Sandberg, the EFLM President, with the reminder of the role and current developments in the EFLM. The welcoming word of the Symposium President prof. Nada Majkić-Singh followed, when the participants were introduced with



SVERRE SANDBERG, EFLM PRESIDENT
ADDRESSES TO THE SYMPOSIUM PARTICIPANTS

the Society of Medical Biochemists of Serbia's activities and the contents of the previous symposia. The first session of the Symposium was dealing with types of medical laboratories and strategy. In the first part, the word was about the role of laboratory medicine in the evolution of medical practice. Prof. Paul Collinson (St George's Medical School, London, UK) was the first speaker, and his inspiring talk was dedicated to laboratory medicine faced with the evolution of medical practice. Since laboratory medicine is an integral part of medical practice, medical practice usually lead laboratory medicine, but equally laboratory medicine can be the standard setter and innovate and develop to support or extend clinical medical practice. Prof. Collinson presented examples for the initiative of laboratory medicine in treatment monitoring, in the introduction of new tests, in responsiveness to new treatment strategies which utilize testing in novel ways, and in its response to the appearance of new diseases. Prof. Ivan Brandslund (Health Science Faculty, University of Southern Denmark, Hospital Lillebaelt, and Vejle County Hospital, Denmark) followed with his lecture that elaborated principles of leadership in clinical laboratories, based on the European Foundation for Quality Management Excellence model mixed with a personal experience of what is necessary and helpful.



SYMPOSIUM LECTURERS: SVERRE SANDBERG, NADA MAJKIĆ-SINGH, BERNARD GOUGET, SNEŽNA JOVIČIĆ, VERA LUKIĆ, NATAŠA BOGAVAC-STANOJEVIĆ, PAUL COLINSON, IVAN BRANDSLUND

In the second part of the first session, the issues in leadership and management in clinical biochemistry were discussed. Dr Per Jorgensen (Copenhagen University Hospital – Rigshospitalet, Denmark) analyzed the influence of the rapid scientific and technological advancements that increase the diagnostic possibilities and change the interfaces among the various specialties of laboratory medicine, the increase of the demands for laboratory tests with demographic changes with a growing elderly population, the increased complexity of the health care systems and the more well-informed patients that call for improved clinical pathways, the change of the modern European countries from "production societies" towards knowledge and innovation societies" that increases the need for integration of research into daily clinical work, as well as the need for a quicker integration of new knowledge into clinical practice. The lecture about the optimization of the post-analytical phase of prof. Sverre Sandberg (University of Bergen, Norway) followed. Prof. Sandberg elaborated this topic from the main features of post analytical phase - verification of results, reflex/reflective testing, report forms, reference limits, reference change values, how to comment test results and report critical results, to the post-post analytical phase, which is usually outside the direct influence of laboratory health

persons. The focus was on how laboratory professionals should work with the post-analytical phases to secure a sensible use of laboratory and clinical resources.

The second session was dedicated to laboratory medicine planning and organisation. The evolution of the medical laboratories in France in the light of economics, managerial and architectural challenges were analyzed by prof. Bernard Gouget (Counsellor for Public Health at the Fédération Hospitalière de France). The role of laboratory information system (LIS) in laboratory medicine through an experience and practical examples was presented by dr Vera Lukić (Laboratory Department at the Railway Healthcare Institute, Belgrade, Serbia), who evaluated advantages of using LIS, and discussed further possibilities in its use. Laboratory data management and the wide range of possibilities of using the large amount of information produced by laboratory information systems, the use of queries performed into the laboratory and clinical databases, and the appropriate analytical approach were presented by dr Snežana Jovičić (Center for Medical Biochemistry, Clinical Center of Serbia, Faculty of Pharmacy, University of Belgrade, Serbia). Prof. Nataša Bogavac-Stanojević (Faculty of Pharmacy, University of Belgrade, Serbia) discussed the implementation of economic evaluation of laboratory testing. The most appropriate tool for quantitative assessment of the economic value of laboratory testing are cost-effectiveness (CEA) and cost-utility (CUA) analysis. However, recently emerged the multicriteria decision analysis which allows comparison of diagnostic strategies in terms of benefits, opportunities, costs and risks. All analysis are constructed to identify laboratory test that produce the greatest healthcare benefit with the resources available.

The third session was dedicated to the medical laboratory accreditation and competence. In this session, total quality management and accreditation were discussed. First, prof. Matthias Nauck (University of Greifswald, Germany) presented the benefits and experiences with the EFQM (European Foundation for Quality Management) Excellence Model for Medical Laboratory. Prof. Mario Plebani (School of Medicine, University of Padova, Italy) followed with his talk about the ISO 15189 accreditation in the sense of navigation between quality management and patient safety, and its last version oriented on process approach with detailed division with clearly defined requirements. Prof. Plebani elaborated the benefits of accreditation are standardization of all processes, responsibility of each member of team, personal policy, demonstrability of results, systematic evaluation of suppliers, better communication with partners. The accreditation of laboratories improves facilitation of accurate and rapid diagnostics, efficiency of treatment and reduction of errors in the laboratory process. This system of standard procedures has the aim to improve the quality and patient safety, through the verification of examination procedures for imprecision, trueness and diagnostic accuracy, and for estimating measurement uncertainty. Also, the role of quality indicators (QIs) as a fundamental requirements of the ISO 15189 was discussed. Prof. Tomáš Zima (First Faculty of Medicine, Charles University and General University Hospital Prague, Czech Republic) continued with the lecture about accreditation system, process and benefits for laboratories. He stressed that the benefits of accreditation are standardization of all processes, responsibility of each member of team, personal policy, demonstrability of results, systematic evaluation of suppliers, and better communication with partners. The accreditation of labs improves facilitation of accurate and rapid diagnostics, efficiency of treatment and reduction of errors in the laboratory process.

The last, fourth session in its first part was dealing with the laboratory medicine environmental health and safety. Prof. Svetlana Ignjatović (Faculty of Pharmacy, University of Belgrade; Centre for Medical Biochemistry, Clinical Centre of Serbia) focused on the form of laboratory reports, its categorization and actions. Dr Herbert Stekel (General Hospital Linz, Austria) made a review

of possible errors and risks in sample collection, like the correct identification of the patient, the time of sampling, the sample volume, the use of additives, and – last but not least – the time of transportation and the information given to the laboratory. Dr Zorica Šumarac (Centre for Medical Biochemistry, Clinical Centre of Serbia) presented experience with forming the register of frequent pre-analytical incidents, and efficient management of unexpected events and accidents. This part of the fourth session ended with the review of efficient management of unexpected events and accidents within laboratory medicine by prof. Duško Mirković (Faculty of Pharmacy, University of Belgrade; Centre for Medical Biochemistry, Clinical Centre of Serbia). In the second part, dr Ciprian-Valentin Mihali (“Vasile Goldis” Western University of Arad, Romania) presented his work on nanoparticles and other pollutants emitted by apartment heating appliances fuelled, as an important public health issue. The Symposium was closed with the talk of prof. dr Jelena Kotur-Stevuljević (Faculty of Pharmacy, University of Belgrade, Serbia) on the use of statistics in laboratory practice and its connection to university teaching.



ANA ĐORĐEVIĆ AND TAMARA STAMENIĆ, PHARMACEUTICAL FACULTY STUDENTS PRESENTING LECTURE “NEXT GENERATION LEADERS”

The special lecture was prepared by the students of medical biochemistry of the Faculty of Pharmacy, University of Belgrade, organized in the Team of Medical Biochemistry Students, Belgrade Pharmacy Students’ Association. Their representatives, Ana Đorđević and Tamara Stamenić, presented their view on laboratory medicine management and leadership for effective laboratory, in an original and refreshing way.

The central event of the 13th EFLM Symposium for Balkan Region was the presentation of the Honorary Diploma of the Society of Medical Biochemists of Serbia, as the highest recognition presented to foreign colleagues, for promoting Clinical Chemistry and Laboratory Medicine in Europe and globally, and for significant contribution to the work and development of the Society of Medical Biochemists of Serbia. It was awarded, so far, to Prof. Victor Blaton, Prof. Stojan Danev, and Prof. Simone Zerah. On this occasion, the Honorary Diploma was awarded to the distinguished professor Mario Plebani for his huge activity and great contribution to the development and improvement of Clinical Chemistry and Laboratory Medicine at the national and international level, as well as for his contribution to the work and development of the Society of Medical Biochemists of Serbia.



ZORICA ŠUMARAC AND MARIO PLEBANI. RECEIVING SMBS HONORARY DIPLOMA

The 13th EFLM Symposium for Balkan region, with over 200 participants from Balkan and European countries, fulfilled the high expectations defined during the previous ones. The presence of distinguished lecturers gave very high recognition and prestige to this Meeting, which influences the development of clinical chemistry and laboratory medicine in the Balkan region and strives to focus on the new data in the field of laboratory medicine. This is the opportunity to thank them and all the participants for another successful symposium.



Update of the EFLM Publication List

by Maria Stella Graziani, Chair of the EFLM Communication Committee

Three more impressive articles by EFLM Working Groups have been made available, attesting once more to the engagement of EFLM functional units in valuable scientific activity.

DEFINING A ROADMAP FOR HARMONIZING QUALITY INDICATORS IN LABORATORY MEDICINE: A CONSENSUS STATEMENT ON BEHALF OF THE IFCC WORKING GROUP "LABORATORY ERROR AND PATIENT SAFETY" AND EFLM TASK AND FINISH GROUP "PERFORMANCE SPECIFICATIONS FOR THE EXTRA-ANALYTICAL PHASES"

Sciacovelli L, Panteghini M, Lippi G, Sumarac Z, Cadamuro J, De Olivera Galoro CA, Del Pino Castro IG, Shcolnik W, Plebani M.

Clin Chem Lab Med 2017;55:1478-88

This joint paper by the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases" reports on the outcomes of the 2016 Consensus Conference held in Padova (Italy). The aim of the Conference was to achieve a consensus for effective harmonization of quality indicators (QIs) that are needed to evaluate the performances of Clinical Laboratories and to recognize the critical aspects where improvement actions are necessary. A general agreement was obtained; the main outcomes are: i. the release of a new version of model of quality indicators (MQI), ii. the approval of a criterion for establishing performance specifications and iii. the definition of the type of information that should be provided within the report to the clinical laboratories participating to the QIs

project.

This Consensus is particularly important because, despite the large number of papers published and the many presentations during international scientific meetings, a large and steady participation of clinical laboratories to the MQI project has been difficult to achieve. The two main strategies identified by the experts at the Conference are the involvement of national scientific societies, accreditation bodies and EQA/PT providers of different countries, as a means for disseminating the MQI project and promoting the participation of laboratories and the selection and appointment of a National Leader, who should coordinate and manage the MQI project in each country.

A SURVEY OF PATIENTS' VIEWS FROM EIGHT EUROPEAN COUNTRIES OF INTERPRETIVE SUPPORT FROM SPECIALISTS IN LABORATORY MEDICINE

Watson ID, Oosterhuis WP, Jorgensen PE, Z. Dikmen ZG, Siodmiak J, Jovicic S, et al. on behalf of the European Federation of Clinical Chemistry and Laboratory Medicine Working Group on Patient Focused Laboratory Medicine

Clin Chem Lab Med 2017;55:1496-500

The study was established to determine whether patients are interested in receiving their laboratory medicine results possibly with explanatory notes. For the scope, a survey was carried out in eight European countries (Czech Republic, Denmark, Estonia, Netherlands, Norway, Poland, Serbia, Turkey) interviewing 1084 individuals. A significant proportion of subjects (65%) are interested in receiving the laboratory results and

a very large percentage of these (72%) are willing to obtain individualized comment and interpretation on the reports as well. Furthermore, a specialist in Laboratory Medicine is an acceptable professional for such a purpose for a mean percentage of 62% of those responding positively. Considering that a previous work by the same group (Clin Chem Lab Med 2015;53:1961-6) demonstrated a willingness by Laboratory Medicine professionals to engage in such practice, there is an opportunity to progress such an initiative. This is a very interesting chance to make Laboratory Medicine directly connect with patients offering a new paradigm for the provision of laboratory medicine activities. This challenge needs to be addressed with active engagement by the profession.

Interested professionals wishing to proceed are invited to visit the Working Group on Patient Focused Laboratory Medicine webpage at the EFLM website; they could find there a productive advice. (<https://www.eflm.eu/upload/docs/Basic%20Guidance%20for%20PFLM%202017.pdf>).

THE EU BIVAS PROJECT: WITHIN AND BETWEEN-SUBJECT BIOLOGICAL VARIATION DATA FOR SERUM CREATININE USING ENZYMATIC AND ALKALINE PICRATE METHODS AND IMPLICATIONS FOR MONITORING.

Carobene A, Marino I, Coşkun A, Serteser M, Unsal I, Guerra E, et al. on behalf of the European Biological Variation Study of the EFLM Working Group on Biological Variation

Clin Chem 2017 (doi 10.1373/clinchem.2017.275115)

This is another important paper carried out by the EFLM Working Group on Biological Variation reporting on the biological variation (BV) indices for serum creatinine using both enzymatic and alkaline picrate measurement methods in the frame of the EuBIVAS (European Biological Variation Study) that was established to deliver rigorously determined BV indices.

The study involved 91 healthy subjects from six different European Centers while the tests have been performed centrally at the S. Raffaele Hospital in Milan (Italy). The within-subject BV estimates were similar for enzymatic (4.4%) and alkaline picrate (4.7%) methods, and lower than the estimate presently available online (CVI=5.9%). The analytical variation for alkaline picrate methods indicates that this method fails to fulfil analytical performance specifications for imprecision.

The BV estimates obtained in this study are widely applicable and they may be used to determine the analytical performance specifications for imprecision at international levels in the absence of suitable clinical outcome studies. The alkaline picrate method failed to meet these specifications, raising questions regarding its future use. This interesting and rigorous study apart from offering robust BV indices, adds another tile in the worldwide debate on the methods to be used to measure serum creatinine to obtain accurate estimates of glomerular filtration rate.

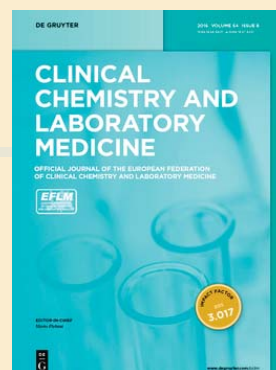
The list of the EFLM publications is available on www.eflm.eu under EFLM Publications, where you can download the full papers.

THE EFLM OFFICE INFORMS

Free access to all new issues of CCLM for 3 days upon publication

by Heike Jahnke, CCLM Journal Editor

We are pleased to inform you that De Gruyter publisher offers limited free access for all new issues of *Clinical Chemistry and Laboratory Medicine* (CCLM) published until the end of 2017. All articles of the issues published until December 2017 are freely available online for 3 days upon publication. Please subscribe to the eTOC alert of CCLM here: **Get Your eTOC Alert**. Upon receipt of the eTOC alert you have Licensed Access to the entire contents of CCLM for 3 days!



NEWS FROM EFLM NATIONAL SOCIETIES

News from SIBioC, Italian Society of Clinical Chemistry and Laboratory Medicine SIBioC commitment on the appropriateness of the requests

by Giuseppe Lippi, Section of Clinical Biochemistry, University of Verona, Verona, Italy and SIBioC National Representative for EFLM and Maria Stella Graziani, Referee for the SIBioC distance education activity

Appropriateness of test request is a leading priority for Clinical Laboratories, in order to regulate laboratory data generation and contextually assuring the most favourable clinical outcomes. The recent worldwide transition from secondary to primary care for many patients with modest or chronic clinical conditions emphasizes a sector of human medicine where a large number of tests involve a relatively narrow testing repertoire.

In this scenario and in the firm believe that educational activities based on scientific evidence should be the basis of dialogue between clinical laboratory and stakeholders, SIBioC has developed a project to create distance learning courses, freely available to primary care clinicians in Italy, with collaboration of Medical Scientific Societies and Federations. SIBioC succeeded to include the activity in mandatory continuous professional education for healthcare professionals in Italy.

The event, after introduction, includes a number of short presentations (around 15 minutes each), addressing 17 different but commonplace clinical conditions in primary care, embracing the domains of screening, diagnosis, prognostication and therapeutic monitoring. The full list of topics and names of speakers are shown in the table below.

Each presentation, given by skilled Laboratory professionals, contains indications about appropriateness of test request along with suggestions on the interpretation of laboratory data.

The course is also available to laboratory professionals; from this educational activity they should gain competence for the important activity of counselling with requesting physicians.

The indications of each presentation are evidence-based and obtained from National and International Guidelines available to participants as supplementary educational material.

The course has been available on line from SIBioC website for 9 months so far; the current number (September 2017) of subscribers is **527** laboratory professionals and **193** primary care physicians.

Appropriateness in the primary care practice.

Editors: MS Graziani, M Ciaccio, B Lo Sasso

Introduction	S Campo
The value of Laboratory Medicine	M Plebani
1. Allergy	AT Scacchetti
2. Amenorrhoea	A Fortunato
3. Anaemia	S Buoro / A Dolci
4. Anticoagulant therapy	G Lippi / B Morelli
5. Autoimmunity	T Trenti
6. Chronic Kidney Disease	MS Graziani
7. Diabetes	A Mosca
8. Dyslipidaemia	MS Graziani
9. Estro/progestinic treatment	B Morelli
10. Heart failure	M Zaninotto
11. Hepatic genetic diseases	G Castaldo
12. Hypertension	D Giavarina
13. Imaging techniques and contrast media	M Mussap
14. Low risk monoclonal gammopathy	A Terreni
15. Osteoporosis	F Pagani
16. Tumor markers	M Gion
17. Thyroid	M Ciaccio



NEWS FROM EFLM NATIONAL SOCIETIES

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

SEQC^{ML}

Sociedad Española de Medicina de Laboratorio

Leading national and international professionals participated in the **VI International Clinical Laboratory and Quality Symposium in Barcelona on May 30th and 31st**. The event was a

reference event in the field both for its scientific program and for the prestige of its speakers.

The field of clinical analysis is continually evolving, but it is nevertheless necessary to continue moving forward in the standardization of the entire clinical laboratory process. It is important that laboratory results be transferable between centers and countries so as to avoid confusion in their interpretation.

Similarly, despite continuing improvement in measurement procedures and the constant reduction of imprecision in analytic methods, there are still systematic deviations in measurement methods among the different manufacturers of in vitro diagnostic methods.

Therefore, the coordination and standardization of the entire analytic process will be the key for the future in the clinical laboratory field.

This was one of the central themes of the VI International Clinical Laboratory and Quality Symposium that was held in Barcelona on May 30-31. **The event was organized by the Spanish Society of Laboratory Medicine (SEQC^{ML}) and the Foundation for Quality Control in Clinical Laboratories (FPCQLC).**

Leading national and international professionals presented their experiences and gave updates on the latest news on topics such as quality in the sample extraction process, stability of biological tests, analytical and extra-analytical quality specifications, standardization, consensus on critical values, programs for external quality guarantees, and risk management.

Among the projects presented during the symposium - all relevant for guaranteeing quality in clinical laboratories, some that stood out were the project to create a database for the stability of biological tests, and the project to establish critical values via the technological tool Health Consensus (a platform to facilitate consensus among health professionals by allowing them to consult online while at the same time receiving immediate replies with



the opinion of all parties consulted. Thus, through an interactive process, a consensus on protocols or concrete initiatives can be reached).

Equally important is the project to improve the Database on Biological Variation that is being carried out by a recently created workgroup made up of professionals from Spain (the Commission on Analytical Quality of the SEQC^{ML}) and various representatives from the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) from Norway, the United Kingdom, Italy, Holland, Canada, Turkey, and Australia.

"We are making great progress to assure the launch and ongoing updating of the database, which will have a great impact on the quality of clinical analysis", stressed Professor Sverre Sandberg, President of the EFLM and coordinator of the group.

For Professor Sandberg, "Spanish laboratories contribute greatly to the European Scientific Society in many areas, such as monitoring methods, improvement of test requests, and work on biological variation, in which Spain is strongly represented".

The importance of control procedures and programs for external quality assurance

"The end result of laboratory services depends not only on the analytical phase, which of course is important, but also on all of the different parts of the "chain", from the request for the correct tests to the report of the results and their interpretation by doctors", explains the president of the EFLM.

For her part, Dr. M^a Antonia Llopis, President of the Committee on External Quality Programs for the SEQC^{ML}, referred to the importance of quality in the pre- and post-analytic phases, as this is where the greatest percentage of laboratory errors occur.



"Much of the pre-analytic phase takes place outside of the laboratory, with participation from the patients themselves to professionals from various areas, both in healthcare and out, which makes control more difficult. The processes of extraction, collection of samples, and identification have a great impact on patient safety. That's why it is so important to make laboratories aware of the importance of establishing proper control procedures as well as programs for external quality assurance", she noted.

Currently there are few organizations that provide programs for external guarantee of pre-analytic quality, and the SEQC^{ML} was a pioneer in Europe in the organization of these programs. With close to 20 years of experience, in 2014 it provided a new focus on this program by basing it on quality indicators.

Diagnostic clinical tests for hereditary diseases

Every year there is an increase in the number of hereditary diseases (generally mono-genic) for which the genetic

cause is known. This is why the number of requests for these studies increases daily, as does their variety. In addition, as methodologies are becoming simpler, they can be done more rapidly. These advances also have their negative aspect, as they can bring about requests for genetic studies without the use of appropriate diagnostic criteria. Therefore, the Symposium addressed the External Quality Assurance Programs for hereditary diseases.

"It's not always clear when to request a genetic study. To know if one should be done or not, available diagnostic guidelines for

the suspected disease should be consulted, as well as recent literature. The clinical history, a physical exam, and family history are particularly relevant in this context. In general, the most important points are the age at diagnosis, multi-focal or bilateral affection, and alterations that are components of a syndrome".

"To maintain a quality standard in genetic studies, these must be done in reference centers that participate in the External Quality Assurance Programs that exist specifically for each disease", concluded the president of the SEQC^{ML} Committee on External Quality Assurance Programs.



NEWS ABOUT EFLM NATIONAL SOCIETIES

The Kosovo Association of Clinical Chemistry



The Kosovo Association of Clinical Chemistry (KACC) was established in 2000, as a voluntary and non-profit professional association that represents specialists of Clinical Chemistry in Kosovo. Today, we have more than 85 members, specialists, doctors of science, assistant professors and professors involved in the healthcare system, research and education.

Our activities are: the promotion of clinical chemistry as a professional scientific discipline; the exchange of scientific knowledge; supporting the development and promotion of scientific research in relevant fields; raising the quality of communication between scientists in Kosovo and abroad; raising awareness of clinical chemistry, laboratory medicine and the advancement of young researchers; cooperation with similar foreign associations and cooperation with international organizations.

The board is executive component of KACC and head of the board act the role of President of KACC as well.

During year 2015, Dr. Shemsi Veseli was appointed as a President of the KACC. Since that period Dr. Veseli and his team worked hard to improve and develop the function of the association on the international cooperation level and as a result of this commitment KACC was accepted as a full member of IFCC and EFLM.

Members of the Kosovo Association of Clinical Chemistry are participating continuously on all EFLM, IFCC and other relevant Congresses and Conferences in the field of clinical chemistry and laboratory medicine.

It is important to mention that on May 2017 KACC organized the 4th Conference of Kosova Association of Clinical Chemistry which was attended by more than 400 participants from Kosovo and abroad. There were nearly 25 presentations by Kosovar and International authors dedicated to professionals from clinical chemistry, laboratory medicine and various fields that share the same interest. During this conference KACC honoured 4 senior and founding members who have contributed in different fields related the development process of KACC.

Kosovo Association of Clinical Chemistry during 2017 organized the cycle of 12 lectures for laboratory staff, providing a good opportunity for supporting practical perspectives and recent scientific and technological advances in clinical chemistry and laboratory medicine.

Since every event begins with the vision, KACC next vision is organizing symposium under the auspices of EFLM in Prishtina which will improve our professional work and especially the quality service to our patients.



DR. GRAMOS BEGOLLI, DR. NORMA BUDIMA AND DR. VALDETE HAXHIBEQIRI WITH THE EFLM PRESIDENT AT THE EFLM GENERAL MEETING IN ATHENS.



Calendar of EFLM events and events under EFLM auspices

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11-14 October 2017

14th Annual Congress of the German Society of Clinical Chemistry and Laboratory Medicine (DGKL)

Oldenburg (DE)

<http://en.dgkl2017.de>

7 November 2017

EFLM webinar: The development of guidelines and recommendations for peripheral blood film review internationally

on-line

<https://elearning.eflm.eu>



16-18 October 2017

49th National Congress of S.I.Bio.C. - Laboratory Medicine

Laboratory Medicine and Clinical Practice: from present to the future

Florence (IT)

<http://congresso.sibioc.it/2017/home>

14 November 2017

EFLM webinar: Harmonization of preanalytical phase in Europe

on-line

<https://elearning.eflm.eu>



16-17 October 2017

Journées Nationales 2017 de la Société Française de Biologie Clinique

Paris (FR)

<http://www.sfbc.asso.fr/>

15-17 November 2017

XI National Congress of Clinical Laboratory

Malaga (SP)

<http://labclin2017.es>

18 October 2017

EFLM webinar: Hepatic fibrosis assessment using multiparametric biomarker tests

on-line

<https://elearning.eflm.eu>



30 November 2017

11th International Scientific Meeting of the Centre of Metrological Traceability in Laboratory Medicine (CIRME) "Measurement Uncertainty in Medical Laboratories: Friend or Foe?"

Milan (IT) <http://users.unimi.it/cirme/home/index.php?selCategoria=210>

19-20 October 2017

EQALM Symposium 2017

Dublin (IR)

www.eqalm.org

1 December 2017

JBP 2017 - Journées de Biologie Praticienne

Paris (FR)

For info: mail to mf.gaudeau.toussaint@gmail.com

20 -22 October 2017

XIVth International Congress of Pediatric Laboratory Medicine

Durban (ZA)

<http://www.icplm2017.org/>

4-5 December 2017

JCTLM Members & Stakeholders Meeting

Paris (FR)

<http://www.bipm.org/en/committees/jc/jctlm/workshop-2017.html>

26 October 2017

International Conference on Laboratory Medicine "Uncertainty, Quality, Safety And Accreditation in Laboratory Medicine

Padova (IT)

http://www.lcongressi.it/home_eng.htm

12 December 2017

7th International Conference on Quality of Medical Laboratories

Brdo pri Kranju (SI)

<http://www.szkkml.si>

<p>19 December 2017 EFLM webinar: Laboratory hemostasis on-line https://elearning.eflm.eu</p>	<p>18-19 June 2018 2nd EFLM Strategic Conference The end of laboratory medicine as we know it? Mannheim (DE) www.eflm.eu</p>
<p>19-21 December 2017 The First International Congress on Biomedicine Tehran (IR) www.icb2017.com</p>	<p>21-22 June 2018 7th International Symposium on Critical Care Testing and Blood Gases Antibes (FR) www.criticalcaretesting-antibes2018.eu/</p>
<p>23 January 2018 EFLM webinar: Faecal haemoglobin: newer approaches to screening and diagnosis of colorectal disease on-line https://elearning.eflm.eu</p>	<p>30 September - 3 October 2018 9th Santorini Conference "Systems Medicine and Personalised Health & Therapy - The Odyssey from Hope to Practice" Santorini (GR) www.santoriniconference.org</p>
<p>8-9 February 2018 International Congress on Quality in Laboratory Medicine Helsinki (FI) https://www.labquality.fi/en/eqas/labquality-days-congress/</p>	<p>10-13 October 2018 5th EFLM-UEMS Joint Congress Laboratory Medicine at the clinical interface Antalya (TR) http://eflm-uems-antalya2018.org</p>
<p>6 March 2018 EFLM webinar: Reliable estimates of biological variation – the way forward On-line https://elearning.eflm.eu</p>	<p>22-23 March 2019 5th EFLM-BD European Conference on Preanalytical Phase Biannual Conference organized by the EFLM WG "Preanalytical Phase" in collaboration with BD Munich (DE) http://www.preanalytical-phase.org</p>
<p>12-15 June 2018 XXXVI Nordic Congress in Clinical Chemistry Helsinki (FI) http://www.nfkk2018.fi/</p>	<p>27 March 2018 EFLM webinar: M-protein diagnostics of multiple myeloma patients treated with biologics On-line https://elearning.eflm.eu</p>
<p>19-23 May 2019 EuroMedLab 2019 23rd IFCC-EFLM European Congress of Clinical Chemistry and Laboratory Medicine Barcelona (SP)</p>	

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