In order to support residents' and post-residents' training in the different areas of clinical laboratory, SEQC –through Fundación José Luis Castaño– has launched this year **seven post-residency grants,** twice as many as in previous editions (financed equally by Fundación and SEQC).

Por ello, para apoyar la formación de los residentes y post-residentes en las distintas áreas del Laboratorio Clínico, la SEQC -a través de la Fundación José Luis Castaño- convoca este año **siete becas post-residencia,** el doble que en ediciones anteriores (financiadas la mitad por la Fundación y la mitad por la SEQC).

First EAS - EFLM consensus guideline on non-fasting lipid testing and reporting

by Michel R. Langlois

Chair, EFLM Task & Finish Group on Laboratory Testing for Dyslipidemia (TFG-LTD)

EAS-EFLM Consensus Panel

EFLM TFG-LTD members:

Michel Langlois – Belgium (co-chair),

Hannsjörg Baum – Germany, Pulkki Kari – Finland, Christa Cobbaert – The Netherlands, Grazyna Sypniewska – Poland.

EAS members:

Børge Nordestgaard – Denmark (co-chair),

Jan Borén – Sweden, Olivier Descamps – Belgium, Arnold von Eckardstein – Switzerland, Olov Wiklund – Sweden.

Invited experts: Eric Bruckert – France, John Chapman – France, Pia Kamstrup – Denmark, Genovefa Kolovou – Greece, Florian Kronenberg – Austria, Anne Langsted – Denmark, Samia Mora – USA, Alan Remaley – USA, Nader Rifai – USA, Emilio Ros – Spain, Gerald Watts – Australia.

New recommendation of the *European Atherosclerosis Society* (EAS) and the *European Federation of Clinical Chemistry and Laboratory Medicine* (EFLM) Joint Consensus Panel suggests that fasting blood sampling is no longer necessary for lipid testing. Indeed, studies of the Consensus Panel suggest that postprandial effects do not weaken, and even may strengthen, the risk associations of lipids with cardiovascular disease.

New research from Denmark, Canada and the US involving more than 300,000 individuals showed that most lipid measurements differ minimally when performed non-fasting or fasting, with negligible changes for HDL cholesterol, slight changes (up to 8 mg/dL) for total cholesterol, LDL cholesterol, and non-HDL cholesterol, and modest increases (up to 25 mg/dL) for triglycerides. These changes are clinically insignificant: large prospective studies over the past several decades have consistently found that non-fasting lipids show either similar – or sometimes even stronger – cardiovascular risk associations compared with fasting lipids.

Non-fasting cholesterol measurements include 'remnant cholesterol', a strong causal risk factor for developing atherosclerosis independent of LDL cholesterol. 'Remnant cholesterol' is the cholesterol in all triglyceride-rich lipoproteins: in the fasting state this is the cholesterol in VLDL particles and their remnants, in the non-fasting state this includes the cholesterol in chylomicron remnants. Postprandial accumulation of remnants contributes to the development of atherosclerosis because, like LDL particles, small remnant particles are easily trapped inside the arterial vascular wall. The atherosclerotic potential of remnants is underestimated in the traditional fasting lipid profile. Non-fasting lipid tests are therefore more relevant for the assessment of cardiovascular risk than fasting tests.

Remnant cholesterol is included in 'non-HDL cholesterol', calculated as total cholesterol – HDL cholesterol. Non-HDL-cholesterol (or apolipoprotein B, the molecule carried by non-HDL particles) is a comprehensive marker of all atherogenic lipoproteins – LDL, remnants, and Lp(a). Non-fasting lipid tests allow to

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Table Flagging of lipid concentration risk cutpoints on laboratory reports

Test	Desirable value
Triglycerides	Fasting <1.7 mmol/L (150 mg/dL) Nonfasting <2 mmol/L (175 mg/dL)
Total cholesterol	<5 mmol/L (190 mg/dL)
LDL cholesterol	<3 mmol/L (115 mg/dL)
Non-HDL cholesterol	Fasting <3.8 mmol/L (145 mg/dL) Nonfasting <3.9 mmol/L (150 mg/dL)
HDL cholesterol	>1 mmol/L (40 mg/dL)
Apolipoprotein A1	>1.25 g/L (125 mg/dL)
Apolipoprotein B	<1.0 g/L (100 mg/dL)
Lipoprotein(a)	<50 mg/dL

assess the total spectrum of cholesterol: "the good (HDL), the bad (LDL), and the ugly (remnant) cholesterol"!

The 2016 EAS-EFLM Consensus Panel provided specific cutpoints for desirable fasting and non-fasting lipid concentrations to be reported by the laboratories (Table). The Panel defined elevated non-fasting triglycerides as ≥175 mg/dL (≥2 mmol/L) and recommended repeat fasting measurement is necessary when non-fasting triglycerides are >400 mg/dL. They recommend flagging of alert values for life-threatening conditions on the laboratory reports, such as triglycerides >880 mg/dL (chylomicronemia syndrome with risk of acute pancreatitis) and LDL cholesterol >190 mg/dL (Familial Hypercholesterolemia).

This is the first international recommendation for non-fasting lipid testing in routine clinical practice. In Denmark a non-fasting lipid profile has been the standard since 2009. It is well-known that fasting is not practical for patients, especially for patients with diabetes or other medical conditions that make it difficult to fast, and for children. Most patients are not fasting when they are initially evaluated by their doctors, meaning that patients often have to return on an alternate day for fasting blood sampling and a repeat visit to the doctor is necessary. For the laboratories, requiring routine fasting samples reduces workflow efficiency due to the early morning congestion of blood samples. All these factors contribute to lack of efficiency in the healthcare system and to increased healthcare costs. These problems disappear by using non-fasting lipid tests.

This recommendation is the result of fruitful collaboration between the EAS and the EFLM *Task and Finish Group – Laboratory Testing for Dyslipidemia* (TFG-LTD), involving 21 World medical experts from Europe, Australia, and the US.

Reference

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EFLM campaign for the harmonization of the units of measurement

by Ferruccio Ceriotti
EFLM WG-H Chair
on behalf of the EFLM WG-Harmonisation in Total Testing Process

Following last year's survey on Harmonisation activities, the EFLM WG-H intends to start a campaign for the harmonization of units of measurement.

The campaign is articulated in various steps and, to be effective without generating confusion among the patients and the clinicians, it should be coordinated within each country and, possibly, amongst countries. For this reason we are proposing a series of dates for the implementation of these changes and of suggestions on how to implement them effectively.

In the following document, you can find the first two steps proposed. A third one will be the promotion of the use of mmol/L for reporting electrolytes (Sodium, Potassium, Chloride, Calcium, Magnesium and Inorganic Phosphate), a specific document will be prepared and distributed afterwards.

The WG is closely working with EFLM National Societies to explore the feasibility of the project.

HARMONISATION OF THE UNITS OF MEASUREMENT

Step 1: Change from mL to L as unit of volume

As indicated by Dybkaer and Jorgensen 50 years ago (1), the litre (or liter), symbolized "**L**", is the recommended unit of volume. Despite this clear recommendation, very frequently the millilitre "mL" is still used as unit of volume. Changing from mL to "**L**" is very easy, the numbers will not change. A single time warning to the clinicians and general practitioners "**Please note the new units**" will be sufficient.

Here below a non-exhaustive scheme of the requested changes.

From	To
mg/mL	g/L
µg/mL	mg/L
ng/mL	µg/L
pg/mL	ng/L
µU/mL	mU/L
mU/mL	U/L
AU/mL	KAU/L

(1) **Dybkaer K, Jorgensen R.** *Quantities and Units in Clinical Chemistry. Including Recommendation 1966 of Commission on Clinical Chemistry of IUPAC and IFCC.* København: Munksgaard, 1967

By July 15 2016, all laboratories are asked to have in place this type of reporting.

Step 2: Change to the litre for reporting protein concentration

In the same paper of 1967 (1) Dybkaer and Jorgensen indicated that the "decilitre" (dL) is not a recommended unit. All the laboratories that are still reporting **plasma proteins** in mg/dL or g/dL should change to **mg/L** or **g/L**. In fact the reporting of the same protein (e.g. C-reactive protein) in mg/dL by some laboratories and in mg/L by some others may induce wrong interpretations by the clinicians, posing the patient safety at risk. This change will introduce a 10 or 100-fold modification of the numbers and must be carefully prepared.

There are three groups of possible changes:

1. ***From mg/dL to mg/L: results will increase 10 times***

P- β2 Microglobulin
P-Haemoglobin
P-Free Kappa chain

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P-Free Lambda chain
P-C-reactive protein
P-Transferrin, soluble Receptor
P-Cystatin C

2. From g/dL to g/L: results will increase 10 times

P-Albumin
P-Total protein

3. From mg/dL to g/L: results will decrease by 100-fold (x0.01)

P-Alpha1-Antitrypsin
P-Alpha1-acid glycoprotein
P-Alpha2 Macroglobulin
P-Apolipoprotein AI
P-Apolipoprotein B
P-Complement fraction C3
P-Complement fraction C4
P-Ceruloplasmin
P-Haptoglobin
P-Immunoglobulin A
P-Immunoglobulin G
P-Immunoglobulin G - Subclasses 1-4
P-Immunoglobulin M
P-Lipoprotein (a)
P-Prealbumin (P-Transthyretin)
P-Retinol binding protein
P-Transferrin

In order to minimize the possible confusion, WG-H recommends to performing the changes in two separate phases: those causing a 10-fold increase of the numerical results first, and those causing a 100-fold reduction in a second phase, however it may be considered more practical to do all the changes at the same time.

In any case the following plans and actions should be undertaken by all laboratories when changing level reporting to mg/L or g/L:

1. Synchronized adjustment of analyser and computer systems
2. Communication and liaison with all service users
3. Updating of all documentation and training materials

It is suggested that a standard comment is linked to every report sent out for a period of 12 months and the following wording is suggested: "**Please note new units and the change of the reference intervals**". A message such as that below could be reported with every report for a period of time prior to the change to provide advance notification: "**Please note: From XX.XX.XX, [protein xyz] results will be reported in mg/L (or in g/L) instead of mg/dL in line with national and international guidelines."** If deemed useful an example should be added: "**This means a [C-reactive protein] currently reported as 1.5 mg/dL will be reported as 15 mg/L**" or "**This means a [transferrin] currently reported as 300 mg/dL will be reported as 3.0 g/L**" or "**This means a total protein currently reported as 7.0 g/dL will be reported as 70 g/L**".

4. Communication to hospital users and General Practitioners
   - ➲ The appropriate committees and staff within your Clinical Governance structure should be informed of your intention to change units of measurement.
   - ➲ General Practitioners should be communicated with either directly by a letter or by use of a Newsletter.

By 31 October 2016, all laboratories are asked to have in place this type of reporting.

Focus on the activity of the EFLM Task-and-Finish Group on Standardization of the Colour Coding for blood collection tube closures

by Ana-Maria Simundic
Chair, EFLM TFG-STCC

The European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has recently established a Task-and-Finish Group (TFG) under the title: Standardization of the colour coding for blood collection tube closures (STCC). Representatives of all manufacturers of blood collections systems were invited to appoint their members in the new TFG.

TFG-STCC members

Chair ***Ana-Maria Simundic***	Department for Medical Laboratory Diagnostics Clinical Hospital "Sveti Duh", Zagreb, Croatia
Member **Nuria Barba Meseguer**	CATLAB Viladecavalls - Spain
Member **Michael Cornes**	The Royal Hospitals NHS Trust New Cross Hospital, Wolverhampton – UK
Member **Alberto Dolci**	Clinical Pathology Laboratory University Hospital "Luigi Sacco", Milano, Italy
Member **Edmee van Dongen-Lases**	Dept. of Clinical Chemistry Academic Medical Center Amsterdam - The Netherlands
Company Representative **Stephen Church**	Becton Dickinson
Company Representative **Helene Ivanov**	Greiner-Bio
Company Representative **Christa Seipelt**	Sarstedt

The aim of this TFG is to initiate and manage a dialogue between interested parties in order to achieve the world-wide harmonization of the colour coding for blood collection tube closures and labels.

Proper sampling and sample additives are essential and may substantially affect the quality of the sample. Tubes and additives are identified not only in writing on the tubes but also by the colour of the tube closures. Unfortunately these colours have not been standardized. The background of the problem and possible solution have recently been described in details in the EFLM Opinion paper published in CCLM (Simundic AM, et al. Colour coding for blood collection tube closures – A call for harmonization. Clin Chem Lab Med. 2015;53(3):371-6).

TFG-STCC has had its first meeting during the EuroMedLab 2015 conference in Paris, where a preliminary agreement was reached between manufacturers and laboratory professionals and operational plan of the project was drafted.


Ana-Maria Simundic

Furthermore, TFG-STCC has recently started a close collaboration with the ISO TC76/WG1 on *'Transfusion, infusion and injection, and blood processing*

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equipment for medical and pharmaceutical use', which is currently working on the revision of the ISO 6710 standard: *'Single-use containers for venous blood specimen collection'*. This revision of ISO 6710 would also replace the current European standard EN 14820. TFG-STCC and ISO TC76/WG1 have agreed to include (as an Informative Annex) a colour code based on the Swedish standard in the new incoming version of the ISO 6710. This is already a first encouraging result.

In order to identify barriers and obstacles which could put this important project at risk of full implementation, TFG-STCC has recently set up a short survey in order to learn whether EFLM National Societies would be willing to accept an EFLM proposal for the colour coding of the blood tube caps as the European standard. Moreover, if there are institutions, laboratories or individuals which are not in favour of such standardization we would be very interested to understand possible reasons for this.

The outcome of this survey is very important and will guide TFG-STCC in their efforts to identify the best solution for all stakeholders and achieve our goal, the world-wide harmonization of the colour coding for blood collection tube closures and labels.

EFLM TFG-STCC Proposal for the color coding standard of the blood tube closures

Specimen type	Additive	IS0 4822 (1981) ≠	BS 4851 (1982)	IS0 6710 (1995)	CLSI H1-A5 (2003)	CLSI GP41-A6* (2007)	Swedish standard SS-872805 (2011)	EFLM proposal (color)
Serum	Clot activator	Z (no aditive)	White (no additive)	Red	Red	Red	Red	
Serum with gel	Gel, clot activator	NA	NA	NA	NA	Red	Yellow	
Plasma	Li-Heparin	LH (Li- heparin)	Orange (Li-heparin)	Green	Green	Green	Dark green	
Plasma with gel	Gel, Li-heparin	NA	NA	NA	NA	Green	Light green	
Plasma	Citrate (1:9)	9 NC	Indigo	Light blue	Blue	Blue	Light blue	
Whole blood	Citrate (1:4)	4 NC	Mauve	Black	Black	NA	Black	
Whole blood	EDTA	KE (K salt) LE (Lithium salt) NE (Sodium salt)	Pink	Lavender	Lavender	Lavender or Pearl	Lavender	
Plasma EDTA with gel	Gel, EDTA	NA	NA	NA	NA	Lavender or Pearl	White or pearl	
Plasma	Glycolytic inhibitor	FX	Yellow	Grey	Grey	Grey	Grey	

≠ - ISO 4822 standard had suggested a letter coding for different anticoagulants (the standard did not contain color coding proposal)
** - (former H03-A6)*

News from the IFCC Website

Foundation for Emerging Nations

IFCC is pleased to announce the Foundation for Emerging Nations (FEN), a non-profit Charitable Trust devoted to supporting programmes that help to improve the quality and delivery of laboratory medicine services, particularly in emerging nations.

Read more

Focus on the activity of the EFLM Working Group on Patient Focused Laboratory Medicine

by Ian D. Watson

Chair, EFLM Working Group on Patient Focused Laboratory Medicine

Ian D. Watson

The term Patient Focused Laboratory Medicine (PFLM) was coined by me for a presentation I was invited to give in Reykjavik at the 33rd Nordic Congress on Clinical Biochemistry in June 2012. My premise is, that patients are increasingly engaged with their own health and well-being, but access and understanding of laboratory investigations was limited. Internet sites vary in quality from excellent to misleading. In addition there were service, legal and patient specific factors that had to be considered should one wish to enable patients to make best use of any laboratory information provided to them.

The theme was further developed by me in other presentations in Europe and the audiences were encouraging in their responses, leading to the decision to form a Working Group within EFLM on PFLM. I was particularly delighted to share thoughts with Wytze Oosterhuis as he had similar views and had been trying to investigate options for his own hospital. So what are the issues we think are important?

PFLM is recognised through a range on international projects recognizing the key role of Information Technology (IT) in medicine, such as: the Digital Agenda for Europe; ITFoM (IT Future of Medicine). Patients can have their DNA checked for disease risk with no referral through a physician, yet it is often impossible for patients to access commonly utilized disease markers e.g. thyroid function HbA1c for diagnosis and monitoring purposes, etc: Why?

Patients are only vaguely aware of the laboratory, they get their information from their physician; feedback may be poor; patients being told e.g. “the results are normal” but not the what and why of investigations being performed.

Patients are increasingly being given right of access to their results; in this “Age of Information” they want to know what the tests are for and what they mean, they can access general information through e.g. LabTests Online. The better informed patient will be better capable to take up an active role in the decision making process and be empowered to do so. The term “shared decision making” has been introduced for this aspect. As this becomes more widespread, could patient’s physician cope with demand: maybe there is a role for the Specialist in Laboratory Medicine?

Use of internet, phone apps, increases access, but only for patients able and willing to use these approaches. Dr Amir Hannan in Manchester, has a current uptake of around 25% of his patients. However there are other issues; some patients have an ‘I don’t want to know’ approach to their results (1), yet for others, even when they have been told their results and what they mean, their recall is poor though they express satisfaction with their treatment (2). Decision aids help retention, but the effect last around 12 months and worsens with time (3).

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Numeracy and literacy are significant factors: the way numeric data is expressed can confuse, so of: 1 in 100, 10 in 1000 and 1%, percentage was significantly better understood whether innumerate, numerate or highly numerate (4), better yet was to provide information pictorially (5), particularly so for elderly (>75y) patients. Health literacy is impaired particularly in those for whom the native language is their second language, but issues of culture, gender, and age all come in to play in different ways (6).

Patients must recognize that errors can occur, so all involved with collection, analysis and interpretation make every effort to minimize errors of any kind and to act promptly when they are detected. It should be noted that it has been shown that patients themselves can play an important role in the detection and mitigation of errors (7).

So, patients receive their results, but may not be reassured by them, nor understand them, indeed may have negative emotional responses to them. There is clearly a complex issue to address and limited resource; can Specialists in Laboratory Medicine address this? The EFLM Working Group on Patient Focused Laboratory Medicine sought the views of European professionals: the majority were in favour of providing support to patient's understanding of their results. A recent survey by the same group of patients views in several European countries demonstrated that patients too were in favour of the proposition that Specialists in Laboratory Medicine provided them with support.

There is no doubt that such a change in role will be fundamental and challenging, yet in the information age where knowledge is key this is the direction Laboratory Medicine must go if it is to remain relevant to the patient experience.

For this to happen requires your active engagement!

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News from the IFCC Website

IFCC Annual Report 2015

The 2015 IFCC Annual Report is now available.

Peruse all the activities performed in 2015 by the IFCC, at a glance.

Read More

Recognition of Specialists in Laboratory Medicine at the EU Commission

by Gilbert Wieringa
EFLM Profession Committee Chair
EC4 Foundation Board chair

IMPORTANT INFORMATION NEEDED

To whom it may concern:

As you may be aware, EU Directive 2013/55/EU (The recognition of professional qualifications) was transposed into EU member states national laws on 18th January 2016. As well as allowing free professional migration across EU borders, it affords opportunities for "specialist" practice to be recognised under Common Training Frameworks. For Specialists in Laboratory Medicine the opportunity arises to present a Common Training Framework that has been developed by our colleagues in EC4 (the European Register of Specialists in Laboratory Medicine) and EFLM's Profession Committee but it needs to have the support of at least one third of EU member states.

EU Member States are now supposed to have completely updated their national legislations to the provisions of the said Directive. Some of the governments are issuing guides, organising conferences or meetings in order to inform stakeholders on the changes the application of 2013/55 brings.

If this has happened already in your Country, could you kindly share the documents/information with the EFLM Office (*eflm@eflm.eu*)?

This information has been requested by the European Council of the Liberal Professions (CEPLIS) who are leading on our behalf in presenting the case for recognition of Specialists in Laboratory Medicine at the EU Commission.

With thanks and best regards,
Gilbert Wieringa

IFCC'S CALENDAR OF CONGRESSES, CONFERENCES & EVENTS

Calendar of IFCC Congresses/Conferences and Regional Federations' Congresses

Nov 26 - 29, 2016	*14th Asia-Pacific Federation for Clinical Biochemistry and Laboratory Medicine Congress*	Taipei, TW
Jun 11 - 15, 2017	*IFCC-EFLM EuroMedLab 2017*	Athens, GR

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