Why harmonisation?

- **Improved patient service**
  - The right test, correctly performed, on the right material, reported and commented on adequately = substantial contribution to an improved patient outcome.

- **Improved patient safety**
  - Different names for the same test, different units of measurement, different reference intervals may lead to erroneous interpretations of the laboratory test results by the clinician.

- **Improved data comparability among laboratories and with time**
  - Patients mobility, patient empowerment, electronic patient records
  - Application of clinical guidelines, common reference intervals or decision limits
  - Data collection in clinical trials
Why harmonisation?

- **Savings**
  - Many tests repetitions are caused by the poor comparability among laboratories.
  - Costs of further referrals and investigations for tests (i.e. tumor markers) which may have been requested unnecessarily in the first instance and produce false positive results.

- **Credibility and reliability of the clinical laboratories**
  - Non homogeneous pre-analytical instructions, poor comparability of results, different reporting way challenge the quality of our service.

- **Accreditation programs**

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![Harmonisation Diagram](image-url)

**Improved patient outcome**

- **Test request**
  - Test appropriate for the diagnostic problem

- **Sample collection and transportation**
  - Standardized pre-analytical conditions

- **Analysis**
  - Use of recommended and traceable methods

- **Reporting**
  - Test names, units of measurement, reference intervals
Working Group: Harmonisation of Total Testing Process

Terms of reference

- Survey and summarize National European and Pan European harmonization initiatives.
- Promote and coordinate the diffusion of at least two especially promising harmonization initiatives among the EFLM member societies.
- Take initiatives to harmonize nomenclature, units and reference intervals on a European level.
Plan of action for the first two years

- The WG will act as a **collector of the harmonisation initiatives** arising from other WGs or Task and Finish Groups of EFLM and from National Member Societies active in the field, and will **disseminate** them to all the EFLM Member Societies attempting to **monitor** their application and effects.
- The WG will survey and promote the use of harmonised **nomenclature** for measurands and promote the use of **amount of substance units** in the European countries.
- The WG will **promote the implementation of common reference intervals** for the measurands where this approach is feasible.

EFLM survey on Harmonisation in Total Testing Process

- Covered the 3 main phases of the process: pre-analytical (8 questions), analytical (5 questions) and post-analytical (8 questions).
- The questionnaire was distributed in 2 phases: 1st, end of March (complete version, 21 questions) sent to the National representatives of the 40 Nations of EFLM. **Received 22 replies** (+ Kazakhstan); 2nd, a reduced version (9 questions) to focalize on the most relevant aspects of the pre- and post-analytical phases, sent in July only to the remaining 18 countries. **Received 14 replies, so only 4 countries are missing.**
Questions of the pre-analytical phase

1. Is it common practice in your country to use “profiles” (e.g. liver function, electrolytes, etc.) for test requesting?
   • 20 Yes
   • 17 No

2. If YES, did/does your society produce some document on harmonization of test requesting profiles?
   • 7 Yes, but only 3 sent documents (Russia, Kazakhstan, The Netherlands) all not readable (language!)

3. Did/Does your society, alone or in collaboration with clinical societies, elaborate guidelines for diagnostic approaches to specific diseases? (e.g. myocardial infarction, coeliac disease, etc.)
   • 18 Yes
   • 19 No
Existing guidelines

- Gestational Diabetes
- Diabetes
- CKD
- Tumor markers
- Thyroid disease
- Thyroid disease in pregnancy
- Autoimmune disease
- Proteinuria
- Coeliac disease
- Ref val of lipoproteins
- Dyslipidemia
- Myocardial infarction

- Very heterogeneous material
- Most of the documents in national languages
- Several topics covered in multiple countries (AMI, CKD, diabetes, tumor markers)

Should we try to prepare European guidelines to avoid 40 times repetition of the same efforts?

pre-analytical phase

4. Did/Does your society publish indications for optimal timing for test repetition or minimal retesting intervals
   - 30 No
   - 6 Yes, but only 1 available document from UK

5. Did/Does your society produce a document on quality of the diagnostic samples or have some activity currently on this topic?
   - 22 No
   - 15 Yes
• **Sample collection and transportation**

  - An example of document from the German Society, EFLM WG-Pre-analytical has some analogous document in preparation.

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**Questions present only in the first survey**

- Did/Does your society validate and promote any sort of reflex testing?
  - 7 YES (out of 22 replies), but no documents.
- Has your society officially declared the obsolescence of any laboratory test?
  - Only 2 YES, but no documents.
Other pre-analytical harmonization activities

- Documents regarding how to perform phlebotomy or collection of other samples (urine, CSF etc.)

<table>
<thead>
<tr>
<th>Country</th>
<th>Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Croatia</td>
<td><a href="http://www.biochemia-medica.com/2013/23/242">http://www.biochemia-medica.com/2013/23/242</a></td>
</tr>
<tr>
<td>Slovenia</td>
<td>Venous blood, capillary blood, urine collection, CSF</td>
</tr>
<tr>
<td>Italy</td>
<td>Blood sampling / Urine collection</td>
</tr>
<tr>
<td>Norway</td>
<td>Blood sampling instructions</td>
</tr>
<tr>
<td>The Netherlands</td>
<td>Correct way of carrying out phlebotomy</td>
</tr>
</tbody>
</table>


Harmonisation of blood sampling

- Effective implementation of EU Directive on needlestick injury prevention (2010/32/EU)
  - Use of safety-engineered devices (SED)
- Patient preparation
  - Definition of fasting requirements
  - Requirements for physical activity
  - Order of draw
  - Colour codes of the test tubes

Colour coding for blood collection tube closures

Road map
- All stakeholders, including all manufacturers working in the field, have been invited to join a dialogue to establish a universally acceptable colour coding standard for blood collection tube closures;
- Standard writing bodies (ISO, CLSI) should add the colour coding standard agreed on to the existing recommendations;
- Manufacturers should implement the agreed colour coding standard.
Harmonisation / standardisation of the analytical phase

- Creation of reference measurement systems: IFCC task
- Quality goals: EFLM Task Force on Performance Specifications in Laboratory Medicine

Post-analytical phase

1. Did/Does your society make documents or guidelines on use or definition of autovalidation rules?
   - 6 Yes, but only 1 document from Switzerland
2. Rules for reporting “critical values”
   - EFLM has a Task and Finish Group on Critical Results (TFG-CR) that will soon release a paper
3. Do you have any data on the diffusion of the use of SI unit (amount of substance units, e.g. mmol/L) in your country?
4. Did/Does your society promote officially the use of SI units?
5. Would your society be in favour of initiatives devoted to the introduction of SI units (mmol/L)?
Units of measurement

- In 8 European countries less than 10% of the results are reported in SI units.
- Six societies do not promote officially the use of SI units: Belgian, Czech, Italian, Greek, Macedonian and Norwegian, but only in 2 of them (Italy and Greece) the use of SI unit is <10%.
- 3 societies (Albania, Cyprus and Portugal) declare to be against a campaign for their implementation
- **Use of katal.** Only in 5 countries: Czech republic, Slovenia, Slovakia, Sweden and Ukraine. Should we suggest to abandon it?
- WG-H will start a campaign within the EFLM members for:
  - **Moving to SI units for all the electrolytes**
  - **Using only Liter (L) as denominator for all the measures where SI units are not available (proteins)**
Considerations on the results of the survey

- Not harmonised harmonisation activities!!
- Several initiatives, but difficult to spread among countries also for the problems related to different languages
- Reference interval problem not yet touched

Harmonisation as a three-level process

- **International**: standardization and among methods harmonization, definition of best practice standards, preparation of clinical practice guidelines for test requesting and result interpretation;
- **National**: Diffusion of internationally developed guidelines; release of laboratory practices for standardization and harmonization of all TTP steps, including communication of test results and critical values;
- **Local**: Adoption of international and national recommendations; implementation of measurement units, reference intervals, decision limits and Standard Operating Procedures for the pre- and post-analytical phases.

Thanks for your attention!