How is EFLM WG-PRE contributing to the improvement of preanalytical phase quality in Europe

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Working group for Preanalytical Phase (WG-PRE)
European federation of Clinical Chemistry and Laboratory Medicine (EFLM)

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<th>Role</th>
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<td>Portugal</td>
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<td>Janne CADAMURO</td>
<td>Austria</td>
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Terms of reference (WG-PRE)

• To **promote the importance** of the quality of the preanalytical phase of laboratory medicine;

• To **conduct surveys** using validated questionnaires with the aim to assess the current pre-analytical practices;

• To **define the best practices and provide recommendations** for some critical activities in the preanalytical phase;

• Organize preanalytical **educational events**

What have we done so far?
Phlebotomy practices – our first project

Why?

- Phlebotomy is the most common invasive procedure in the healthcare - available worldwide (hospitals, PHC, home based care)
- Phlebotomy is the most common source of preanalytical errors. Errors often go unrecognized.
- Consequences:
  - Incorrect test results
  - Unnecessary delays
  - Harm to the patient and phlebotomist

Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA)

Aim:

- who performs phlebotomy in EFLM countries?
- differences in personnel?
- level of education and skills?
- are guidelines available?
National guidelines for routine phlebotomy

- Only 7/28 countries (25%) have national guidelines for phlebotomy
- Ireland, UK, Spain, Slovenia, Sweden, Italy, Croatia.
  - 5/7 were issued by national societies,
  - 2/7 were provided by the government.

Health care personnel categories

- Phlebotomy is performed in the majority of countries by nurses and laboratory technicians regardless of the patient population
Specific training for phlebotomy

Is specific training for phlebotomy part of the education required to become qualified in different professions?

Training time to qualify as phlebotomist in each profession

- 1 hour
- < 5 hours
- ≥ 5 hours
### Conclusion

- large heterogeneity!
- many countries do not have guidelines
- phlebotomy is performed by medical and nonmedical personnel
- different level of education and life long training

**patients should receive the same level of care across Europe!**

### Our 2nd project – observational study

- compliance with CLSI H3-A6 standard was assessed through witness audits (3 phlebotomies per each phlebotomist)

Some examples....

Q11 Did the collector put on a new, fresh clean pair of gloves?
Replies relative to the profession

Q12 Did the collector clean the venipuncture site

Some examples....

Q14 Did the collector leave the venipuncture site untouched post cleaning?
Replies relative to the profession

Q26 were the tubes labeled in the presence of the patient?
ID procedure → immediate action is required to lower the probability of an error.

What have we learned from this study?

- level of compliance is low
- some critical phlebotomy steps are not followed
  - safety issue
  - patient harm
  - sample quality
- sample and patient ID procedure – the most critical!
- room for improvement for all involved in phlebotomy

Q3: Did the collector check the expiry dates of devices in use?
Q25: When were the sample tubes labeled?
Q26: Were the tubes labeled in the presence of the patient?
Q4: Did the collector identify the patient according to CLSI or local guidelines
To underline the importance of the proper identification procedure...

- A minimum 2 and preferably 3 unique identifiers should be used for patient identification;
- Patient and sample identity should always be checked in the presence of the patient;
- Barcoded labels whenever possible

*CLSI GP33-A  Accuracy in Patient and Sample Identification*
Healthcare institutions should:

- have **zero tolerance** to patient ID errors;
- have a **policy** and a written **standard operating procedure** for patient and sample identification,
- ensure a **continuous education** for all professions involved in phlebotomy;
- have a system in place to **continuously monitor** and reduce the ID error frequency;

EFLM member societies:

- should **adopt these recommendations**
- Should **encourage their implementation** among healthcare institutions at their national level;
Observational study & self declared facts

Primary care medical laboratory (N=150)

Results:

- 40% of patients did not come properly prepared for laboratory testing
- 52% of patients did not receive any information about how to prepare themselves for blood testing
- Patients are not well informed about the fasting requirements for laboratory blood testing

Biochemia Medica 2013;23(3):326–31

The lack of a uniform definition of fasting in scientific papers

Table 1. Evaluation of articles published in relevant journals in 2002.

<table>
<thead>
<tr>
<th>Journal</th>
<th>Articles with a group of fasting patients, n (%)</th>
<th>Well-defined fasting, n (%)</th>
<th>Insufficient definition, n (%)</th>
<th>No definition, n (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Chemistry</td>
<td>20</td>
<td>1 (5)</td>
<td>5 (25)</td>
<td>14 (70)</td>
</tr>
<tr>
<td>Clinical Chemistry and Laboratory Medicine</td>
<td>24</td>
<td>0 (0)</td>
<td>6 (23)</td>
<td>18 (73)</td>
</tr>
<tr>
<td>Scandinavian Journal of Clinical and Laboratory Investigation</td>
<td>18</td>
<td>3 (17)</td>
<td>4 (22)</td>
<td>11 (61)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>94</td>
<td>7 (7)</td>
<td>36 (38)</td>
<td>51 (54)</td>
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* If the term ‘fasting patient’ was used in the Materials and Methods, Results, or Discussion, the publication was considered as using fasting patients.

The AIM: To propose a definition of fasting procedure

Fasting was not well defined in the literature and across healthcare

Available definitions differ regarding the
- definition of fasting time
- whether fasting is required or not for a certain analyte
- whether water is allowed during the fasting period

Blood should be drawn between 7 to 9 a.m.
Fasting should last for 12 h
Water consumption is permitted
Alcohol should be avoided for 24 h before blood sampling.
In the morning before blood sampling, patients should refrain from cigarette smoking and caffeine containing drinks (tea, coffee, etc.).
Professional associations should support standardized recommendations for fasting

Laboratories should adopt the definition of fasting

Laboratories should have policies for sample acceptance criteria related to fasting samples.

Definition of fasting should be used in scientific studies.


Based on our 1st and 2nd study we felt that...

- heterogeneity in practices and policies should be reduced
- common guidelines are needed
- phlebotomy staff needs education in order to improve the compliance to guidelines

- room for improvement – task for EFLM WG-PRE
Our 3rd project: European recommendation for venous blood sampling

- Collaboration on joint guidelines would:
  - Save the effort for many
  - Facilitate implementation across Europe

- Consensus meeting (March 2015, Porto)
  - 20/40 EFLM NS have been present
  - NSs have presented their activities at the national level (10 min PPT)
  - Interactive panel discussion
  - The aim was to share views about necessity and the possibility of harmonization of preanalytical phase across Europe.

What have we learned?

- There has been a rapid growth in the number of NS with preanalytical working group, in the past several years.

- In 2015 there are at least 19 countries in Europe that have a preanalytical working group.
1998 --> Spain.

2005 --> Italy.
2012 --> Netherlands and Croatia.

2013 --> Austria and UK
2014 -> France, Serbia, Russia, Denmark, Finland, Iceland, Norway, Sweden, Lithuania, Turkey, Macedonia, Czech Republic

NS representatives
20-21 March 2015, Porto
EFLM Consensus statement (2015, Porto)

- Harmonization of preanalytical phase policies and practices is possible and necessary:
  - at national level in each individual country in Europe
  - at international level

- EFLM NS are willing to work with EFLM to:
  - harmonize preanalytical phase in Europe
  - develop and implement preanalytical guidelines and recommendations
Key preanalytical issues identified which require urgent harmonization

- Test ordering
- Transport and storage
- Patient Preparation
- Sampling
- Management of unsuitable specimens
- Quality Indicators
- Patient identification
- Paediatric and neonatal sampling


Our 3rd project: European recommendation for venous blood sampling

1. **Prepare the consensus recommendation**
   - 2 WG meetings (June 2015 Paris, Dec 2015 Zagreb)
   - draft almost ready
2. **Provide guidance** on how to implement the change
3. **EFLM WG-PRE tools**
   - education (**template PPT**) 
   - observational audit (**checklist**) 
   - assessment of knowledge (**knowledge test**) 

soon available @ EFLM website
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- To define the best practices and provide recommendations for some critical activities in the preanalytical phase;
- Organize preanalytical educational events

www.preanalytical-phase.org
Parma, 2011
Zagreb, 2013
Porto, 2015

Opportunity to share experiences
Exchange resources
Networking

4th EFLM-BD European conference on Preanalytical Phase, Amsterdam (NL)

www.preanalytical-phase.org

- Opportunity to share experiences
- Exchange resources
- Networking

March, 2017

24-25
Aim: standardization of the colour coding for blood collection tube closures and labels.

Terms of reference (TFG-STCC)

- To initiate a dialog and preliminary consensus
- To produce a color coding standard agreed by all major manufacturers
- To achieve the inclusion of the standardized color coding proposal into the ISO and CLSI standards
- To support and enhance the world-wide implementation of the standard.
What have we done so far?

- meeting in June 2015 in Paris
  - strategy agreed
  - companies have reached a consensus about the need for standardization
- EFLM representative has become a member of the ISO TC76/WG1, which is currently working on the revision of the ISO 6710 standard: ‘Single-use containers for venous blood specimen collection’.
- ISO TC76/WG1 has agreed to include a colour code based on the Swedish standard in the new version of the ISO 6710 standard, as an Informative Annex (Dec 2015, Berlin)
- survey is necessary to understand the position of the profession, to see what are the barriers and obstacles
TFG-STCC survey: preliminary results
(open until June 1st)

Do you believe that implementing the standard is necessary to minimize the risk of errors and improve the patient safety?

- Yes: 93%
- No: 7%

TFG-STCC survey: preliminary results

Would you be willing to accept the EFLM proposal for the colour coding as the European standard for the colours of the tube caps (see the below table)?

- No: 5%
- Yes, completely: 85%
- Yes, but with some...: 10%
The way forward

- ISO TC76/WG1 meeting in June in Zagreb
- analysis of the data from the survey
- finalization of the ISO 6710 standard
Science Committee

- WG: Biological Variation
- WG: Cardiac Markers
- WG: Guidelines
- TFG: Laboratory Testing for Dyslipidemia
- WG: Harmonisation of Total Testing Process
- WG: Patient Focused Laboratory Medicine
- WG: Personalized Laboratory Medicine
- WG: Postanalytical Phase
- **WG: Preanalytical Phase**
- TFG: Standardization of the colour coding for blood collection tube closures
- WG: Test Evaluation

All papers are free

Educational material: papers & lectures

3rd EFLM BD European Conference on Preanalytical Phase - Porto, 20-21 March 2015
Speakers presentations - [Click here to download the files]

2nd EFLM BD European Conference on Preanalytical Phase - Zagreb, 1-2 March 2013
Speakers presentations - [Click here to download the files]

1st EFCC BD European Conference on Preanalytical Phase - Parma, 1-2 April 2011
Speakers presentations - [Click here to download the files]

The role of European Federation of Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase in standardization and harmonization of the preanalytical phase in Europe
[Click here to download the paper]

EFLM WG Preanalytical phase opinion paper: local validation of blood collection tubes in clinical laboratories
Lippi G, Correia MP, Granqvist K, Nybo M, Simundic AM
[Click here to download the paper]

Patient identification and tube labelling – a call for harmonisation
van Dongen-Lasee E, Correia MP, Granqvist K, Mercedes Ibarz M, Kristensen GBB, Lippi G et al.
on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical
EFLM WG-PRE shall continue in its effort to improve the preanalytical phase quality in Europe

but...

The real success is possible only through the joined effort at all levels:
- European
- national
- individual

What have I done to improve the quality of preanalytical phase in my lab?

Can I do more?

Policy and written procedures?
Staff education?
Lab? Nursing?
Error rate?
Recommendations implemented?
Compliance?
EFLM WG-Preanalytical Phase, Zagreb 10 May, 2014