Harmonisation of preanalytical phase in Europe

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Where....

A patient can walk into every lab on Earth and get (almost) the same test results...

This is not possible unless all procedures are...

- reliable
- reproducible throughout the total testing process

Are preanalytical practices comparable?

- between continents?
- between countries?
- between labs?
- between individuals?

- large heterogeneity (variations in blood-sampling technique)
- done mostly by nurses
- phlebotomy is performed by medical and nonmedical personnel (even admin staff)
- different level of knowledge, competence, education and life long training
- few NSs have phlebotomy guidelines (7/28, 25%)
Compliance with the CLSI H3-A6 unacceptably low

The most critical steps were:
- patient identification
- tube labelling

Non compliance leads to errors!

Preanalytical errors

- Harm to the patient
- Unnecessary cost
- Incorrect test results
- Unnecessary delays

Diagnostic errors:
- missed diagnosis
- delayed diagnosis
- misdiagnosis

Standardization throughout the total testing process

- the scope of harmonization should include all aspects of the total testing process
- laboratory tests performed by different laboratories at different times on the same sample and specimen should be comparable.

The role of EFLM WG-PRE?

What have we done so far?

Solution?

Standardization of all procedures within the TTP

Formulation, publication, and implementation of guidelines, rules, and specifications for common and repeated use, aimed at achieving optimum degree of order or uniformity in a given context, discipline, or field.

The scope of harmonization should include all aspects of the total testing process.
Healthcare institutions should:

- have zero tolerance to patient ID errors;
- have a policy and a 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;

To underline the importance of the proper definition of the fasting state:

- 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.).
The effect of different tube additives on blood glucose measurement: systematic overview of the literature.

Giuseppe Lippi, Mads Nybo, Janne Cadamuro, Joao Tiago Guimaraes, Edmée van Dongen-Lases, Ana Maria Simundic, on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of Clinical Chemistry and Laboratory Medicine (EFLM).


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

Our role?

Take the lead and catalyse collaboration on preanalytical issues in 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
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

NS activities
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


EFLM WG-PRE European recommendation for venous blood sampling

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

13 countries represented

Harmonization of venous blood sampling throughout Europe

What makes our document different from other docs?

EFLM EG-PRE recommendation:

- is evidence based
- evidence is graded (quality of evidence and associated risk are assessed for each step)
- offers guidance for successful implementation
- Gives you tools to assist you in implementation
- is free
- shall be translated to local languages

Accompanying tools

- Knowledge test
- Checklist
- PPT presentation
- Posters
- Videos
EFLM-Colabiocli MoU

Signed in October 2017

EFLM-Colabiocli joint recommendation for venous blood sampling
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Demand management
- Background: not known what demand management strategies are in use in European labs; demand management not recognised by clinicians as the responsibility of the laboratory
- Aim:
  - To launch a survey about what demand management strategies are in use in Europe
  - To launch a survey addressed to clinicians and health managers about what should be the laboratory role in demand management and how laboratory could help them.
  - Opinion paper about the Medical Laboratory role in demand management

Stability studies
- Background: stability studies not done in the same way;
- Aim:
  - To develop a standard for stability experiments in the clinical setting
  - To propose a checklist for critical appraisal of stability studies
  - To build a EFLM stability database

Unsuitable samples
- Background: large variations in the way labs detect HIL indices and manage unsuitable samples
- Aim:
  - To assess how laboratories in Europe detect and manage unsuitable samples
  - To propose recommendations.
  - Project started in 2015, ongoing – planned end date – end of 2018
Recommendations

- Lippi G, Cadamuro J, von Meyer A, Simundic AM. Practical recommendations for managing hemolyzed samples in clinical chemistry testing. (Opinion paper, Type III document)
- von Meyer A, Cadamuro J, Lippi G, Simundic AM. Call for more transparency in manufacturers declarations on serum indices. (Opinion paper, Type III document)

Both documents are submitted to EFLM-C5 chair for comments and endorsement.

European survey on unsuitable samples

- aim: to assess how labs in Europe detect and manage unsuitable samples
- done in collaboration with EQALM
- survey launched mid September and closed by the end of November
- 1300 completed answers collected so far
- survey open until the end of November

Blood sampling through catheters

- Background: blood sampling through catheters not standardized, large variations
- Aim: Perform observational study to assess the quality of sampling through catheters
- Perform a survey to assess the nurses’ knowledge and awareness
- Produce recommendation

Project ongoing—planned end date—end of 2018

Tube validation

- Background: Tube validation not done, or not done in the same way (CLSI not widely available; CLSI not free)
- Aim: produce EFLM recommendation for tube validation
- produce EFLM tools (checklist and Excel chart; recommendation on statistical methods and performance criteria)

Awareness raising campaign

- Background: Not all healthcare professionals are aware of the importance of the preanalytical phase
- Aim:
  - To raise awareness of hospital professionals and phlebotomists of the importance of the preanalytical phase in laboratory results
  - To produce a resource focusing on the quality of blood specimens (eg. Website hosted by EFLM, App, Social media campaign, etc.)

Thanks to.....

- EFLM Executive Board
- National Societies
- Laboratory professionals throughout Europe
- Companies (BD, Greiner, Sarstedt, Maksense)
- WG-PRE members for their hard work
Team is the key

@ recent WG-PRE meeting in Munich
Thursday, 9 November 2017 (9:00 – 18:00)

more WG-PRE webinars:

- Zorica Sumarac (Title: EFLM WG-PRE venous blood sampling project), date: 27 January 2018
- Tiago Guimaraes (Title: How to perform tube validation?), date: March 2018
- Michael Cornes (Title: The order of draw), date: May 2018
- Stephen Church (Title: Catheter collection), date: September 2018
- Pieter Vermersch (Title: Pre-analytical mysteries), date: November 2018