How can EFLM WG-PRE help you to improve your phlebotomy practies?

on behalf of the EFLM-WG-PRE

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Phlebotomy facts

Most common invasive procedure in the healthcare

Available worldwide (Hospitals, Primary Health Care, Home Based Care)

Huge variations in technique, safety devices, disposal methods, reuse of devices and availability of postexposure prophylaxis.

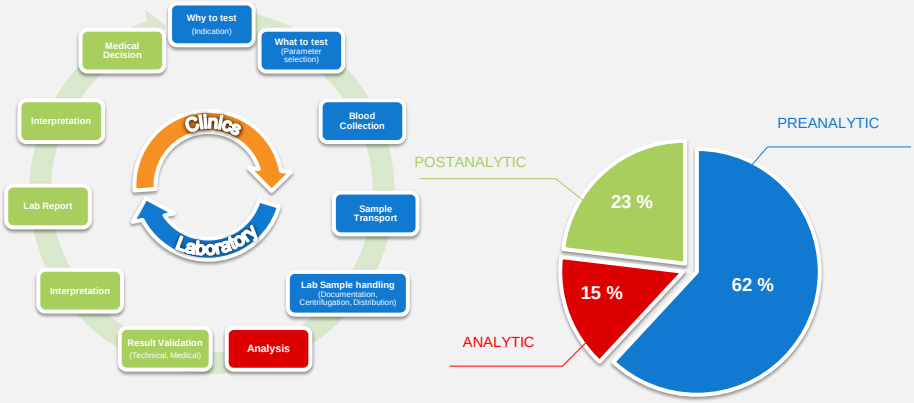
Variations between countries, institutions, individuals

The most common source of preanalytical errors.

Errors often go unrecognized.

Errors within the total laboratory process

Error rate within the total laboratory process:
0.05% - 10 % of all samples



Lippi G,et al Clin Chem Lab Med 2009; 47:143-153; Carraro P, Plebani M. Clin Chem 2007; 53:1338-1342.

Consequences of preanalytical errors

Incorrect test results

Incorrect diagnosis

Unnecessary delays

Harm to the patient and phlebotomist

Unnecessary cost

Who is doing phlebotomy?

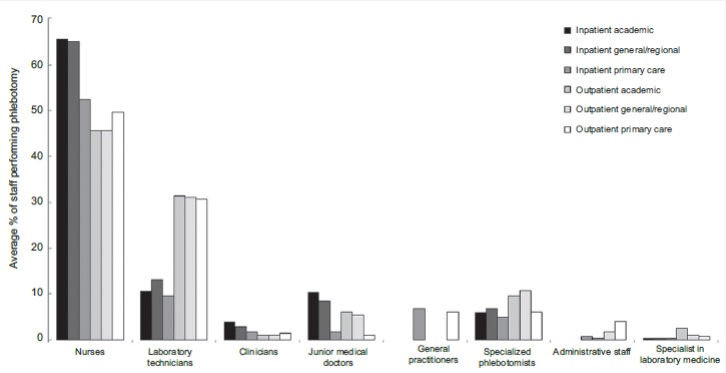


Figure 1 Data showing the responses to questions about who performs phlebotomy in different inpatient and outpatient groups.

Simundic AM, et al. CCLM 2013;51(8):1585-93.

Level of education

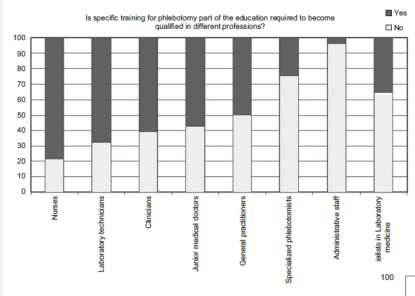


Figure 2 The percentage of countries in each staffing group for which there is specific training in

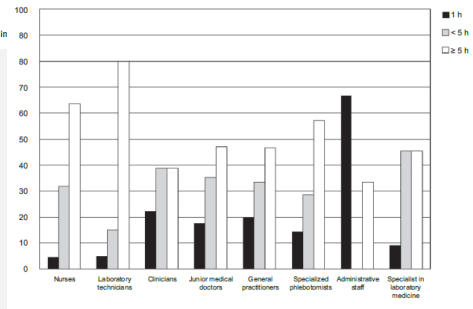


Figure 3 The percentage of countries in each staffing group for which there is specific training in phlebotomy and how many hours of training is typically included.

Simundic AM, et al. CCLM 2013;51(8):1585-93.

ISO 15189:2012


INTERNATIONAL STANDARD **ISO 15189**

Third edition
2012-11-01

Medical laboratories — Requirements for quality and competence

4.11 Preventive action

The laboratory shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.

4.14.7 Quality indicators

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes.

Qualityindicators

IFCC Working Group: Laboratory Errors and Patient Safety (WG-LEPS)
(Chair: Laura Sciacovelli)

www.ifcc-mqi.com

Year	Indicator Code	Indicator	Report	Document
2016	Pre-MisR	Percentage of: Number of misidentified requests/ Total number of: requests.	Statistics.pdf	Download
2015	Pre-MisS	Percentage of: Number of misidentified samples/ Total number of samples.	Statistics.pdf	Download
2014	Pre-UnlS	Percentage of: Number of unlabelled samples/ Total number of samples.	Statistics.pdf	Download
2013	Pre-OutpMT	Percentage of: Number of outpatients requests with erroneous data entry (missed test)/ Total number of outpatients requests.	Statistics.pdf	Download
2012	Pre-InpMT	Percentage of: Number of inpatients requests with erroneous data entry (missed test)/ Total number of inpatients requests.	Statistics.pdf	Download
2011	Pre-WroTy	Percentage of: Number of samples of wrong or inappropriate type (i.e. whole blood instead of plasma)/ Total number of samples.	Statistics.pdf	Download
2010	Pre-WroCo	Percentage of: Number of samples collected in wrong container/ Total number of samples.	Statistics.pdf	Download
2009	Pre-InsV	Percentage of: Number of samples with insufficient sample volume/ Total number of samples.	Statistics.pdf	Download
	Pre-NotRec	Percentage of: Number of samples not received/ Total number of samples.	Statistics.pdf	Download
	Pre-NotSt	Percentage of: Number of samples not properly stored before analysis / Total number of samples.	Statistics.pdf	Download
	Pre-InTem	Percentage of: Number of samples transported at inappropriate temperature/Total number of samples.	Statistics.pdf	Download
	Pre-ExcTim	Percentage of: Number of samples with excessive transportation time/ Total number of samples.	Statistics.pdf	Download
	Pre-Hem	Percentage of: Number of samples with free Hb>0.5 g/L (clinical chemistry)/ Total number of samples (clinical chemistry)*	Statistics.pdf	Download
	Pre-Clot	Percentage of: Number of samples clotted/ Total number of samples with an anticoagulant.	Statistics.pdf	Download
	Post-OutTime	Percentage of: Number of reports delivered outside the specified time/ Total number of reports.	Statistics.pdf	Download

ISO 15189:2012


INTERNATIONAL STANDARD **ISO 15189**

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Medical laboratories — Requirements for quality and competence

5.4 Pre-examination processes

5.4.2 Information for patients and users

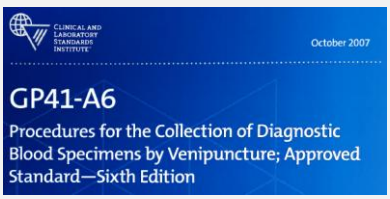
The laboratory shall have information available for patients and users of the laboratory services. The information shall include as appropriate:

- f) instruction for preparation of the patient;
- g) instructions for patient-collected samples;

5.4.4 Primary sample collection and handling

- **5.4.4.1 General**
  The laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff.
- **5.4.4.2 Instructions for pre-collection activities**
- **5.4.4.3 Instructions for collection activities**

Current Guidelines



WHO guidelines on drawing blood:

best practices in phlebotomy

National - Only 7/28 European countries
(Ireland, UK, Spain, Slovenia, Sweden, Italy and Croatia)

Simundic AM, et al. Clin Chim Acta. 2014;432:33-7.

Inconsistency

Table 1
Recommendations available at several national LTO Internet sites for fasting requirements for some serum/plasma blood tests.

	Glucose	ALP	Triglycerides	Bilirubin
USA	8 h fast is recommended (nothing to eat or drink except water)	Fasting is preferred but not required for this test.	9–12 h fasting is recommended (only water is permitted, alcohol should not be consumed for 24 h before the test)	Fasting requirements vary by laboratory. Ask your lab or health care provider for instructions. You may need to fast (nothing but water) for several hours before the test.
UK	8 h fast is recommended	Fasting is preferred but not required for this test	9–12 h fasting is recommended (only water is permitted, alcohol should not be consumed for 24 h before the test)	No requirements
Australia	8–10 h fast is recommended	Fasting overnight is recommended[a]	10–16 h fasting is recommended (only water is permitted, alcohol should not be consumed for 24 h before the test)	No requirements
Germany	12 h fast is recommended	Fasting overnight is recommended[a]	12–14 h fasting is recommended (only water is permitted, alcohol should not be consumed for 24 h before the test)	No requirements
Czech Republic	8–10 h fast is recommended	Fasting is recommended	12–14 h fasting is recommended (only water is permitted, alcohol should not be consumed for 24 h before the test)	No requirements
Italy	8 h fast is recommended (nothing to eat or drink except water)	No requirements	8 h fast is recommended.	No requirements

[a] Eating a meal can increase alkaline phosphatase (ALP) slightly for a few hours in some people.

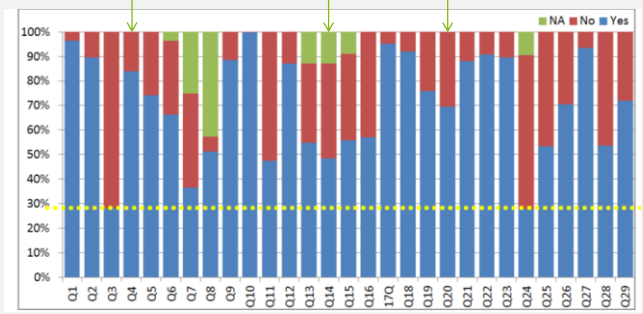
Compliance

Study over 12 countries (n=336)

Did the collector identify the patient according to CLSI or local guidelines? (No: 16.1 %!)

Did the collector leave the venipuncture site untouched post cleaning? (No or N/A: 44.5 %!)

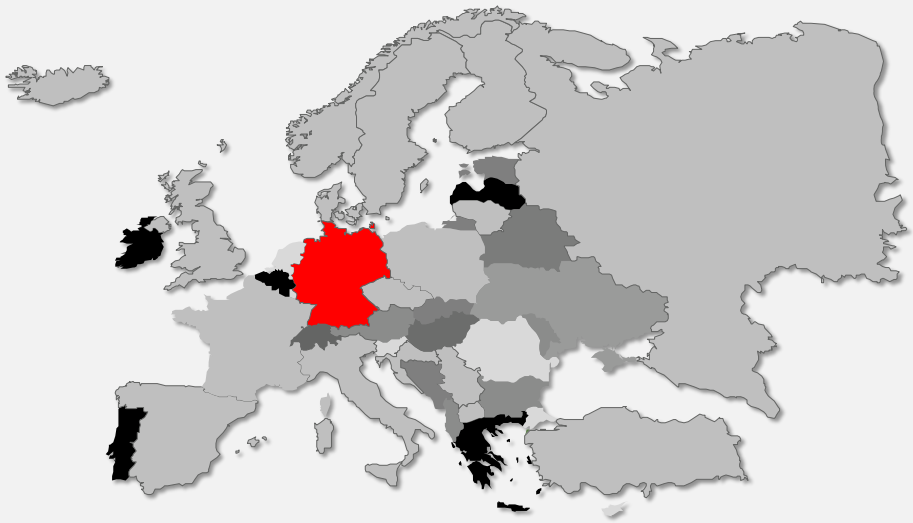
Were all sample tubes immediately and appropriately mixed according to manufacturer's specifications? (No: 30.4 %!)



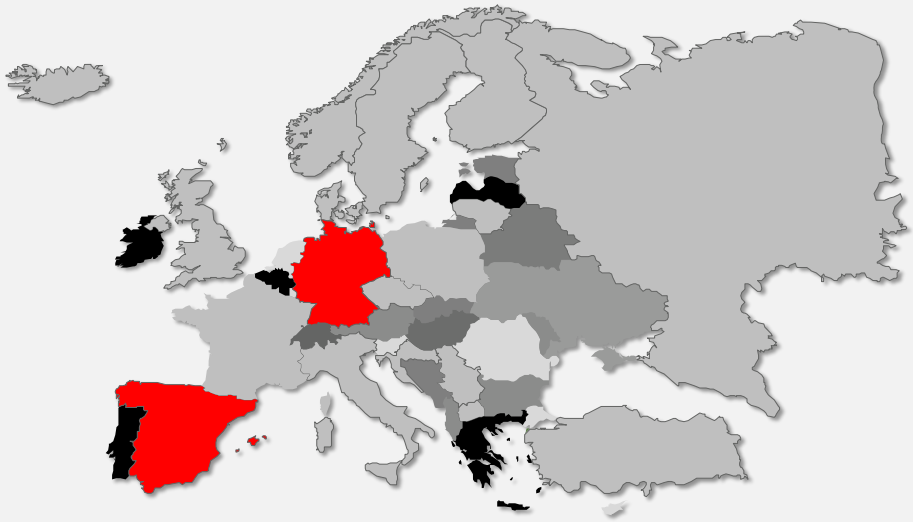
There is a need for continuous education and implementation of existing procedures

Simundic AM et al. CCLM 2015; 53:1321-1331.

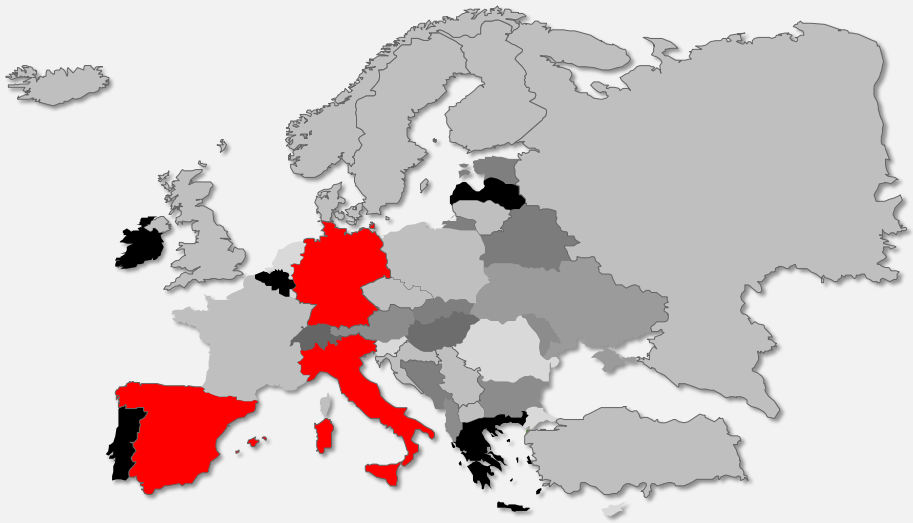
Preanalytical Working groups



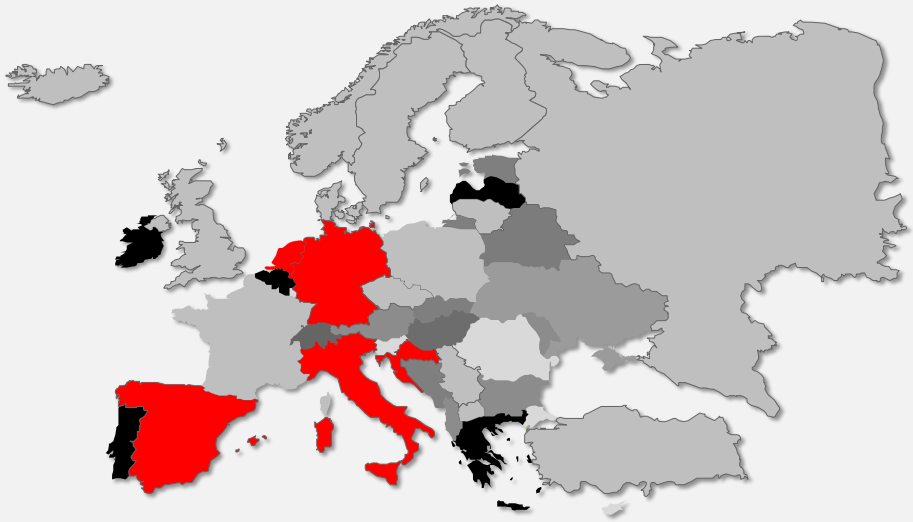
1995 --> Germany.



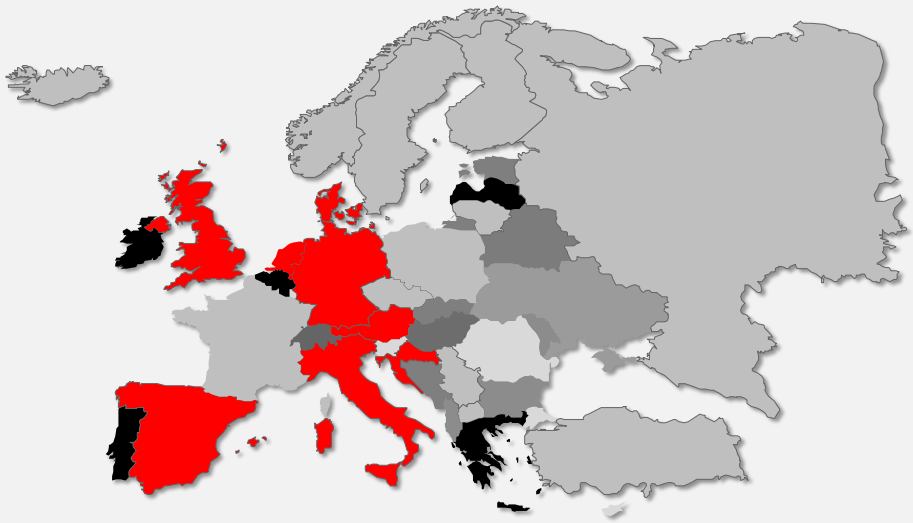
1998 --> Spain.



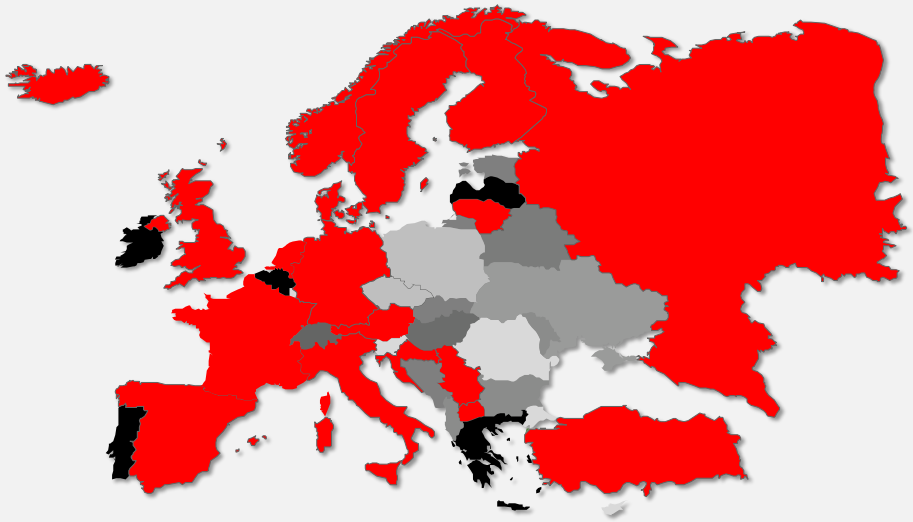
2005 --> Italy.



2012 --> Netherlands and Croatia.



2013 --> Austria and UK



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

EFLM WG-PRE

Chair

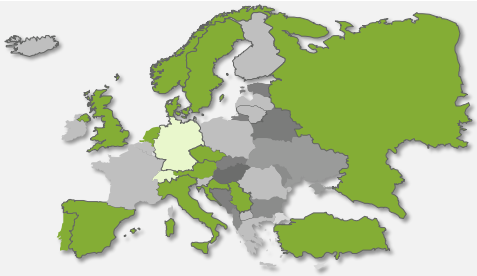
Ana-Maria Simundic	Croatia

Full / Corresponding Members

Kjell Grankvist	Sweden
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Michael Cornes	UK
Janne Cadamuro	Austria
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Expert/Consultant

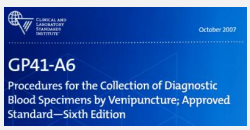
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Helene Ivanov	Greiner Bio-One
Christa Seipelt	Sarstedt





http://www.eflm.eu/index.php/wg-preanalytical-phase.html

EFLM-Guideline on venous blood collection



WHO guidelines on drawing blood:

best practices in phlebotomy

CONSENSUS DOCUMENT ON VENOUS BLOOD COLLECTION AND SAMPLE HANDLING

At disposal for all EFLM countries



EBM

EFLM-Guideline on venous blood collection

Necessary requirements for the blood sampling area and key supplies

- ✓ Required materials
- ✓ Collection facilities requirements
- ✓ Communication with the patient



EFLM-Guideline on venous blood collection

Pre-sampling procedures

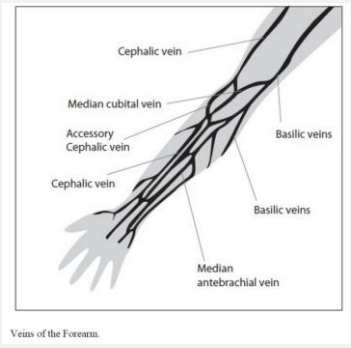
- ✓ Patient identification
- ✓ Fasting requirements
- ✓ Tube labelling



EFLM-Guideline on venous blood collection

Sampling procedure

- ✓ Hygiene (Hand desinfection, PPE)
- ✓ Tourniquet application and release
- ✓ Veinpuncture site selection
- ✓ Cleaning sampling site
- ✓ Vein punture (Vacuum and Aspiration)
- ✓ Order of draw
- ✓ Tube mixing



Veins of the Forearm.

Nikolac N et al. Biochem Med 2013;23(3):242-

EFLM-Guideline on venous blood collection

Post-sampling procedures

- ✓ Disposal
- ✓ Advise the patient



Images with kind permission GBO ©

EFLM-Guideline on venous blood collection

Implementation

- ✓ First time implementation (Requirements, Stakeholder, ...)
  - ✓ Powerpoint-Presentation
  - ✓ Knowledge test
- ✓ Maintaining standards
  - ✓ Observational sheet

Thank you





On behalf of the EFLM Working Group „Preanalytical Phase“

Ana-Maria Simundic; Kjell Grankvist; Giuseppe Lippi; Mads Nybo; Michael Cornes; Janne Cadamuro; Pinar Eker; João Tiago Guimarães; Mercedes Ibarz; Svetlana Kovalevskaya; Gunn B.B. Kristensen; Ludek Sprongl; Zorica Sumarac; Edmée van Dongen-Lases; Stephen Church; Helene Ivanov; Christa Seipelt

http://www.eflm.eu/index.php/wg-preanalytical-phase.html

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Save the Date



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