Harmonizacija u predanalitičkoj fazi

Zorica Šumarac

Centar za medicinsku biohemiju

Klinički centar Srbije, Beograd, Srbija

Ana-Maria Šimundić

Klinički bolnički centar Sestre milosrdnice

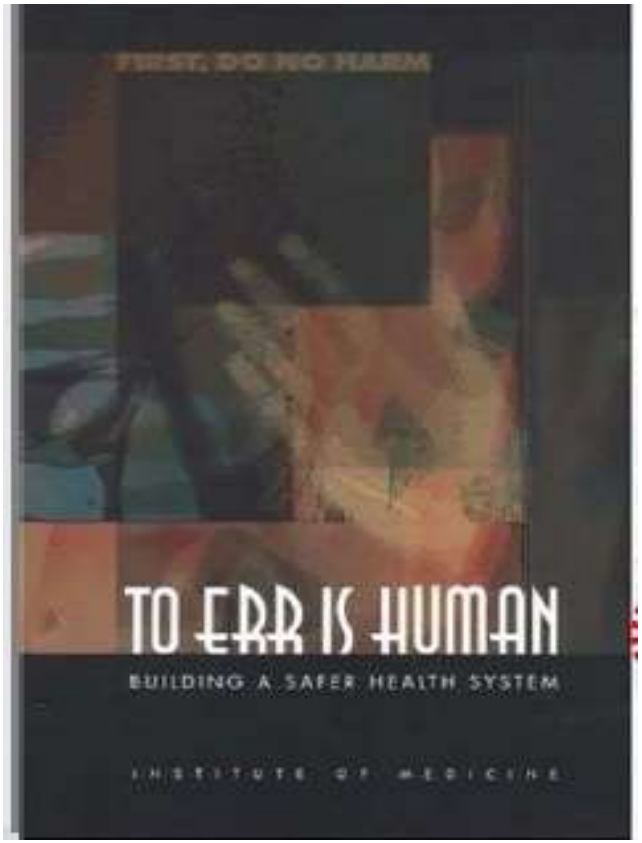
Zagreb, Hrvatska

"Prescribe regimens for the good of my patients according to my ability and my judgment and never do harm to anyone."

Hippocratic Oath, 4 th Century B.C

Primum non nocere ("first do not harm")

Greek physician treating a patient, ca. 480-470 BC (Louvre Museum, Paris, France)



Institute of Medicine

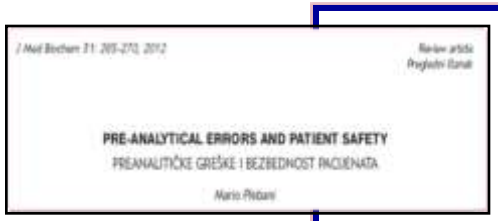
Kohn LT, Corrigan JM, Donaldson MS
National Academy Press, Washington, DC, 2000

44 000–98 000 godišnje smrtnih ishoda usled medicinskih grešaka koje su mogle biti prevenirane.

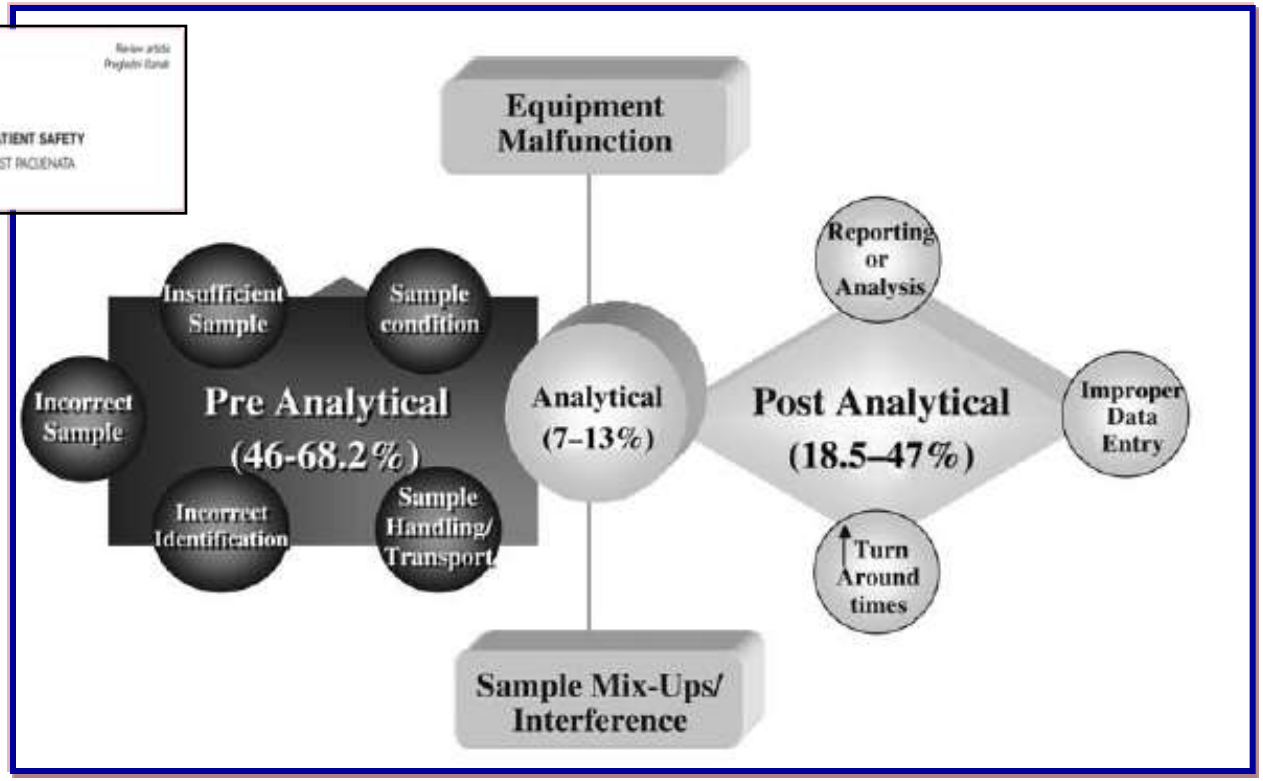
"Err is human, but errors can be prevented and safety is a critical first step in improving the quality of care."

70%-80% svih medicinskih dijagnoza postavlja se na osnovu laboratorijskih rezultata

Maurice O'Kane. The reporting, classification and grading of quality failure in the medical laboratory. Clinica Chimica Acta 404 (2009) 28–31.


PRE-ANALYTICAL ERRORS AND PATIENT SAFETY

PREANALITIČKE GREŠKE I BEZBEDNOST PACIJENATA



Mario Plebani. Errors in clinical laboratories or errorrs in laboratory medicine. Clin Chem Lab Med 2006;44(6):750-9.

Submitted 6.17.11 | Revision Received 7.20.11 | Accepted 7.25.11

A Review of Medical Errors in Laboratory Diagnostics and Where We Are Today

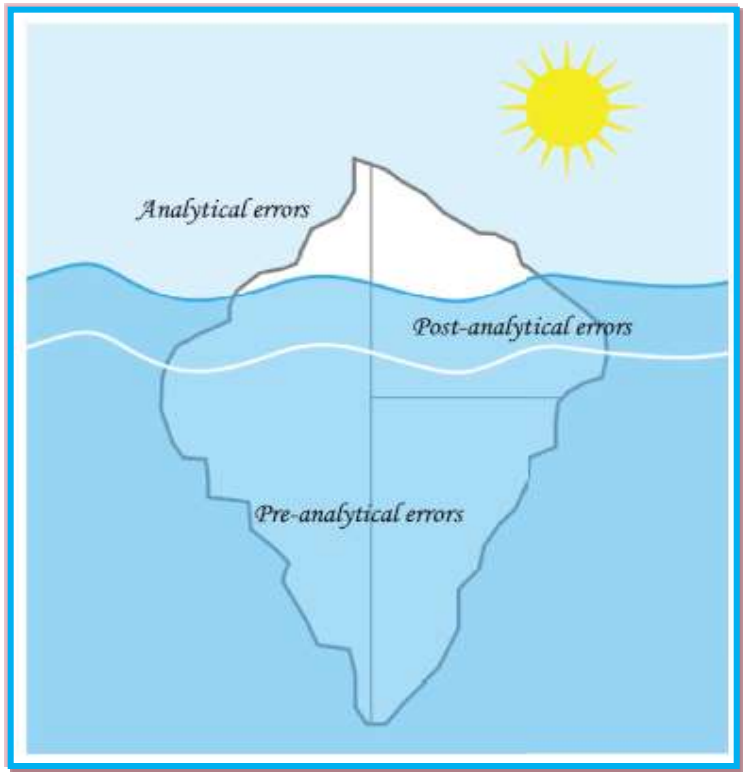
Julie A. Hammerling, MSH, MS, MLS(ASCP)CM
(Division of Health Sciences, Florida Gulf Coast University, Fort Myers, FL)

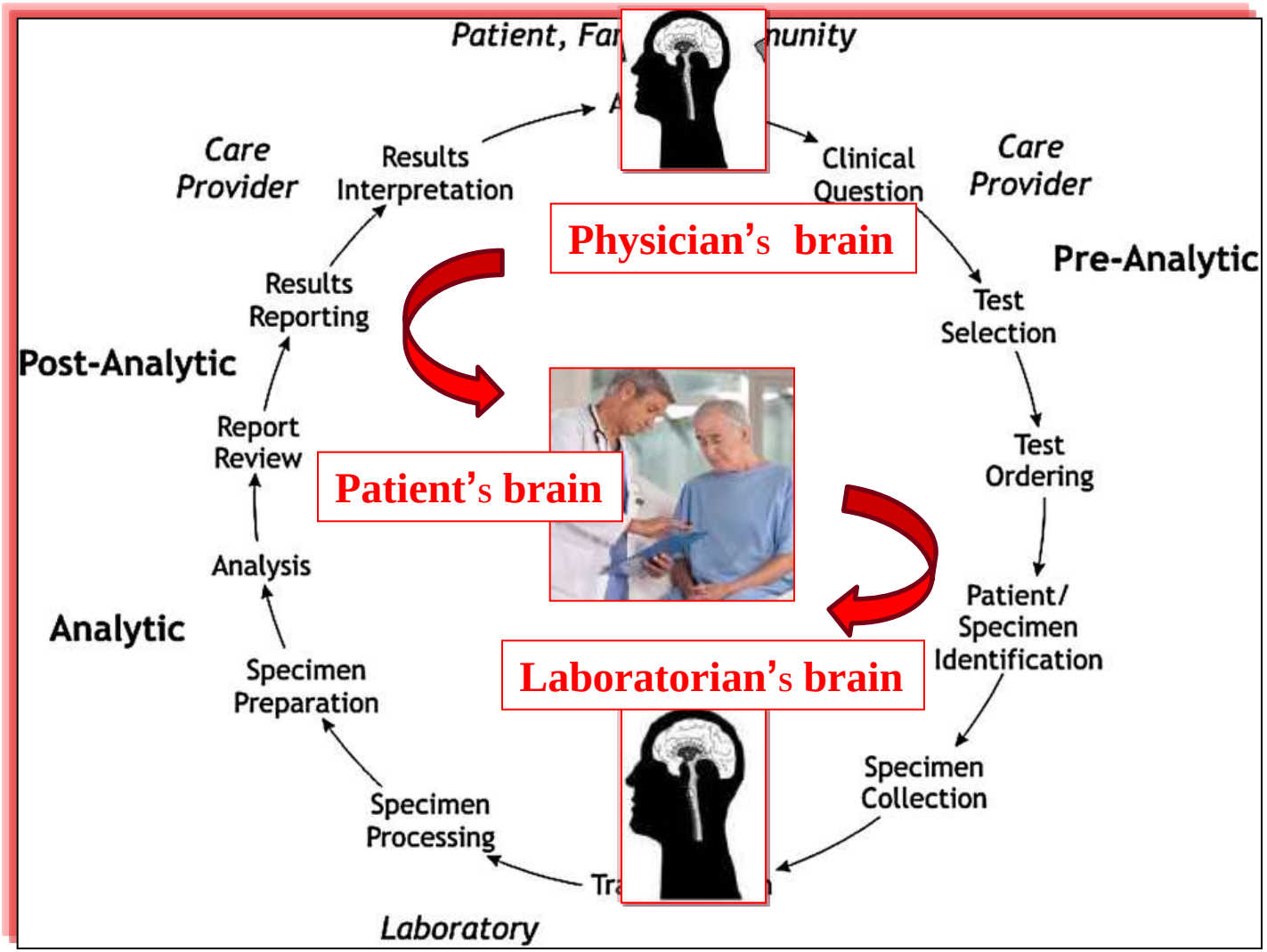
DOI: 10.1309/LMGER9WLER1HGALW

Giuseppe Lippi[b,*], Giuseppe Banfi, Stephen Church[a], Michael Cornes[a], Gabriella De Carli, Kjell Grankvist[a], Gunn B. Kristensen[a], Mercedes Ibarz[a], Mauro Panteghini, Mario Plebani, Mads Nybo[a], Stuart Smellie, Martina Zaninotto and Ana-Maria Simundic[a] on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE)

Clin Chem Lab Med 2015; 53(3): 357–370





George Lundberg (JAMA 1981:245:1762-1763)
The brain-to-brain turnaround time loop

Layla McCay, Claire Lemer, Albert W. Wu. Laboratory safety and the WHO World Alliance for Patient Safety. Clinic Chimica Acta 404; (2009) 6-11.

About EFLM
News
Events & Meetings
Publications & Resources
Downloads
Contact Us
COMMITTEES
Science
Quality and Regulations
Education & Training
Profession
Communications
RSS / Atom

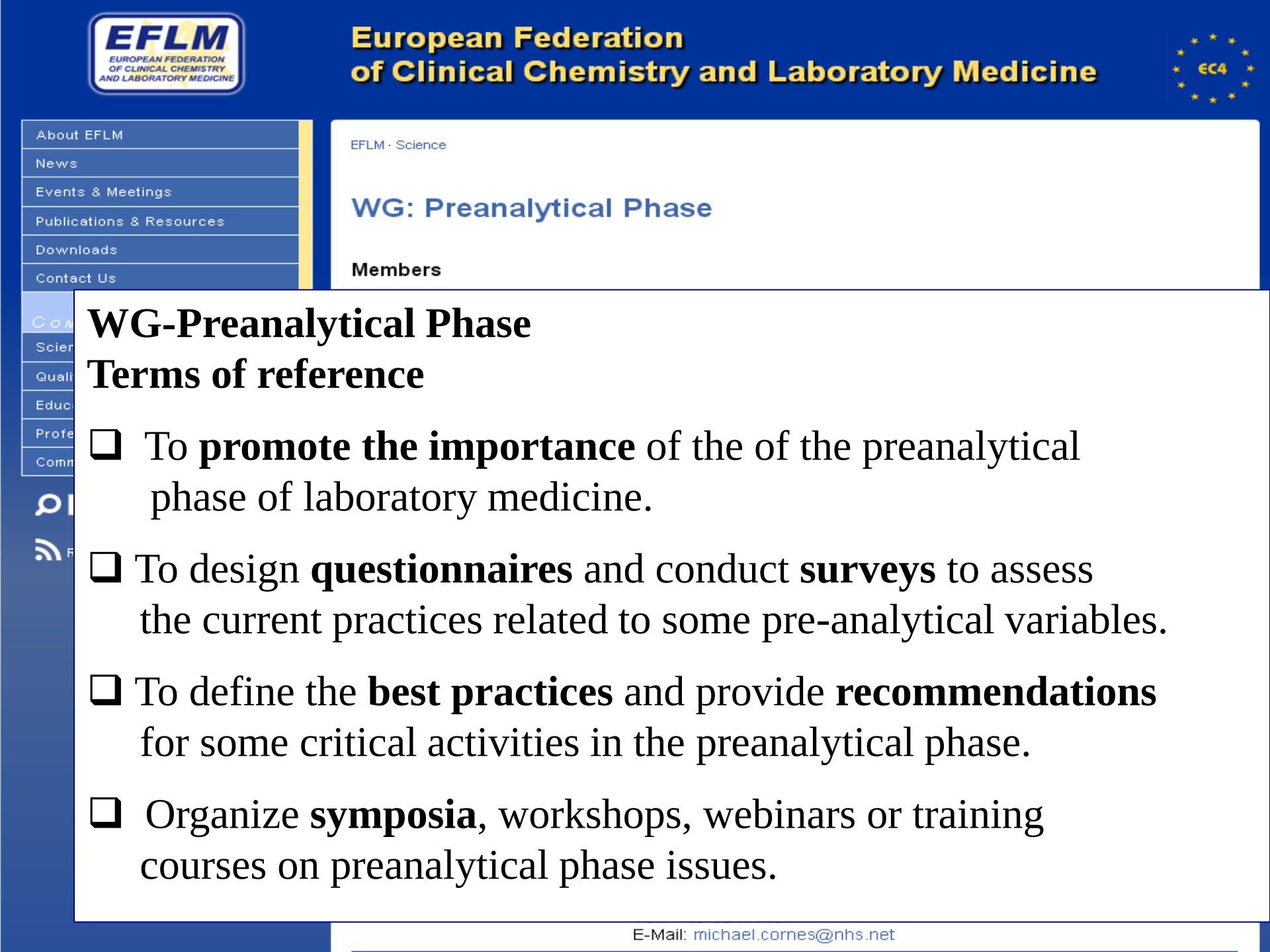
WG: Preanalytical Phase

Members

Name	*Contact*
Chair Ana-Maria Simundic first term 2012-2014	University Dept. of Chemistry University Hospital "Sestre Milosrdnice" Vinogradska 29 10000 Zagreb, Croatia Tel.: +385-1-3787184 Fax: +385-1-3768280 Mobile: +385-99-2554708 E-Mail: am.simundic@gmail.com
Member Giuseppe Lippi first term 2012-2014	Clinical Chemistry and Hematology Laboratory Academic Hospital of Parma, Italy E-Mail: glippi@ao.pr.it
Member Kjell Grankvist first term 2012-2014	Dept. of Medical Biosciences, Clinical Chemistry Umea University Building 6M 2nd Floor S-90185 Umea – Sweden Tel.: +46-907851262, Fax: +46-907854484 E-Mail: kjell.grankvist@medbio.umu.se
Member Mads Nybo first term 2012-2014	Dept. of Clinical Biochemistry and Pharmacology Odense University Hospital Sdr. Boulevard 29 5000 Odense C – Denmark Tel.: +45-65411161 E-Mail: mads.nybo@ouh.regionsyddanmark.dk
Member Young Scientist Michael Cornes first term 2012-2014	The Royal Wolverhampton Hospitals NHS Trust New Cross Hospital Wednessfield Road Wloverhampton WV10 0QP – UK Tel.: +45-65411161 E-Mail: michael.cornes@nhs.net

Corresponding members:
Ludek Sprongl (CZ)
Svjetlana Kovalevskaya (RU)
Zorica Sumarac (SRB)
Gunn B.B. Kristensen (NO)
Pinar Eker (Turkey)
João Tiago Guimarães (PT)
Mercedes Ibarz (Spain)
Edmée van Dongen-Lases (NL)

Corporate members:
Stephen Church (GB)
Christa Seipelt (DE)


EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE
European Federation
of Clinical Chemistry and Laboratory Medicine
About EFLM
News
Events & Meetings
Publications & Resources
Downloads
Contact Us
EFLM · Science
WG: Preanalytical Phase
Members
WG-Preanalytical Phase
Terms of reference
To promote the importance of the of the preanalytical phase of laboratory medicine.
To design questionnaires and conduct surveys to assess the current practices related to some pre-analytical variables.
To define the best practices and provide recommendations for some critical activities in the preanalytical phase.
Organize symposia, workshops, webinars or training courses on preanalytical phase issues.
E-Mail: michael.cornes@nhs.net

Prvi sastanak WG-PRE, Zagreb, april 2012.

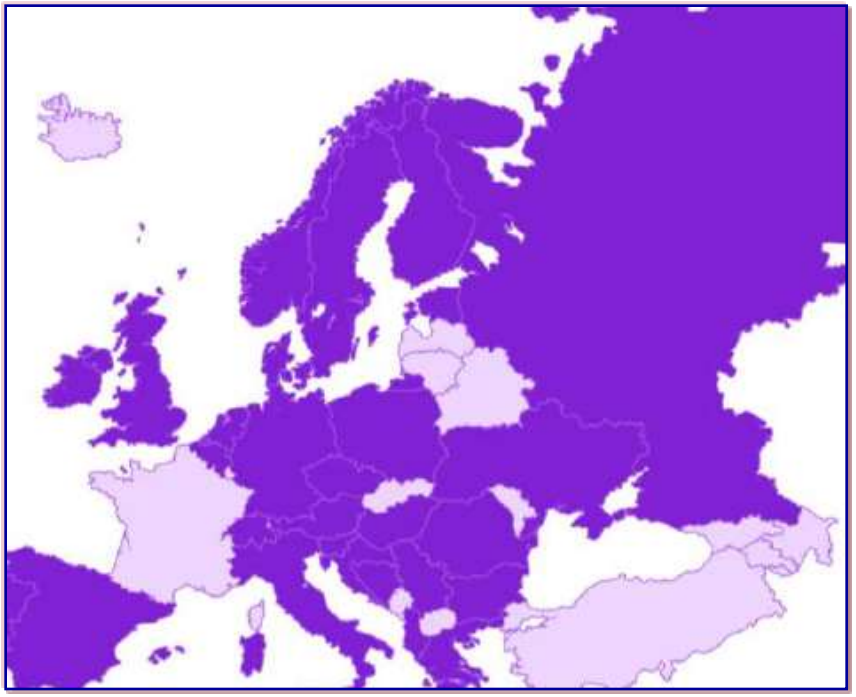
www.preanalytical-phase.org

EFLM WG-PRE
I projekat

DE GRUYTER DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med 2013; 51(8): 1585–1593

Ana-Maria Simundic*, Michael Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Svjetlana Kovalevskaya, Ludek Sprongl, Zorica Sumarac and Stephen Church

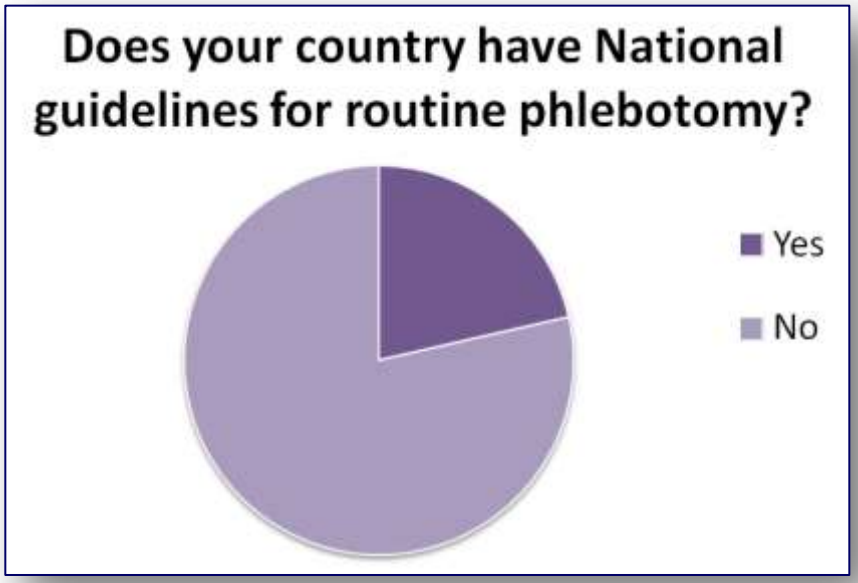
Survey of national guidelines, education and training on phlebotomy in 28 European countries: an original report by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PA)

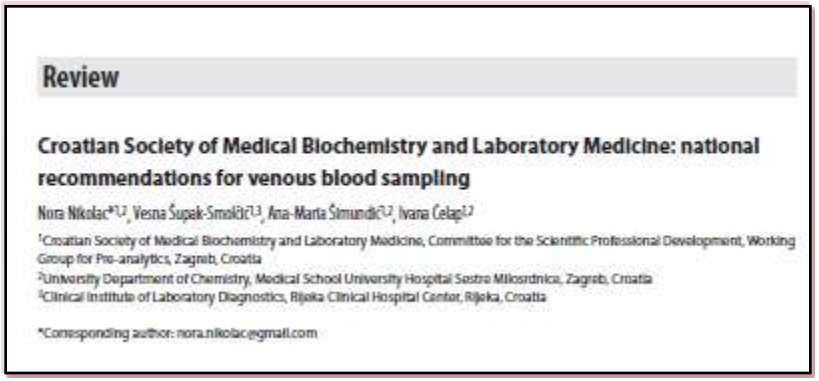


- April-Avgust 2012
- 28/39 (72%) zemalja članica EFLM učestvovalo
- Upinik-20 pitanja

Cilj ?

- ✓ Kako se uzorkovanje krvi sprovodi u zemljama EFLM?
- ✓ Ko obavlja uzorkovanje krvi ?
- ✓ Nivo obrazovanja i edukacije osoba koje uzorkuju krv?
- ✓ Da li postoje nacionalne smernice za uzorkovanje krvi i kakva je njihova usklađenost?




Review

Croatian Society of Medical Biochemistry and Laboratory Medicine: national recommendations for venous blood sampling

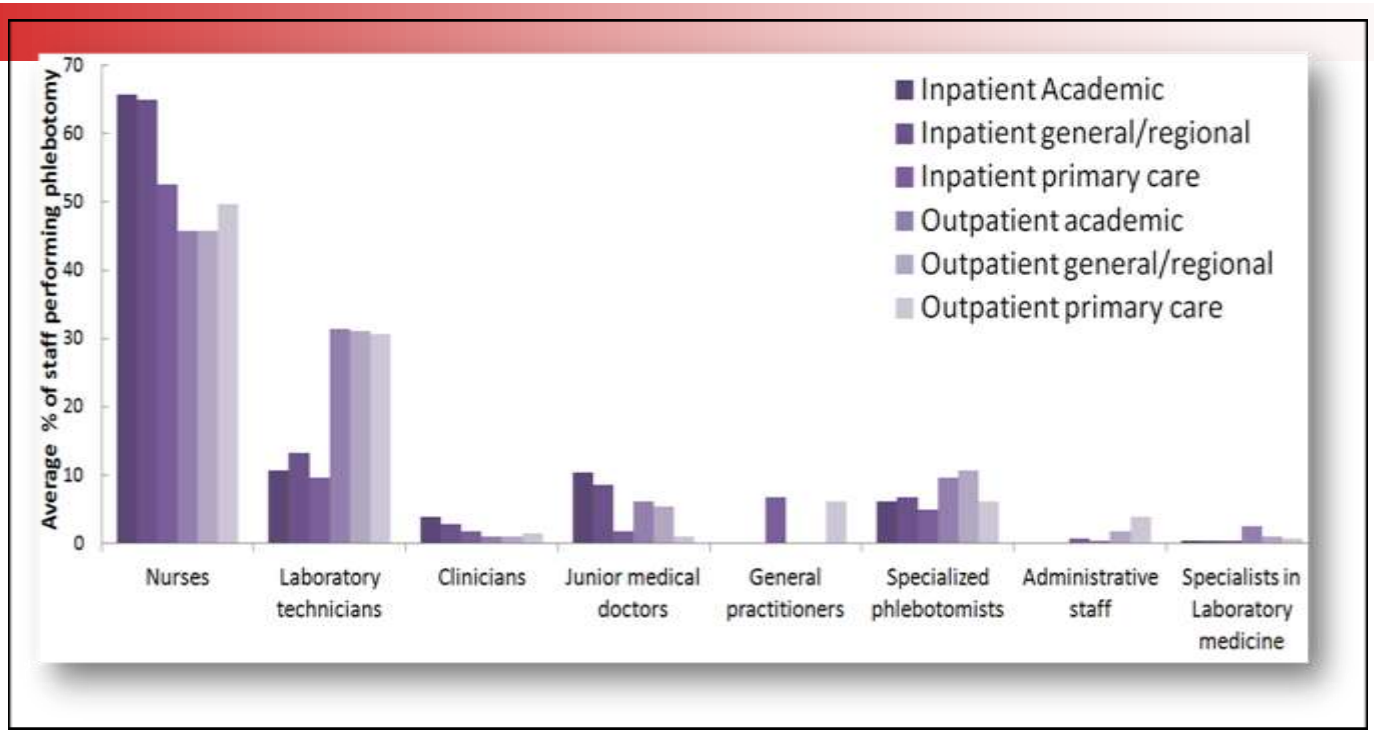
Nora Nikolac[*1,2], Vesna Šupak-Smolčić[1,3], Ana-Maria Šimundić[1,2], Ivana Čelap[1,2]

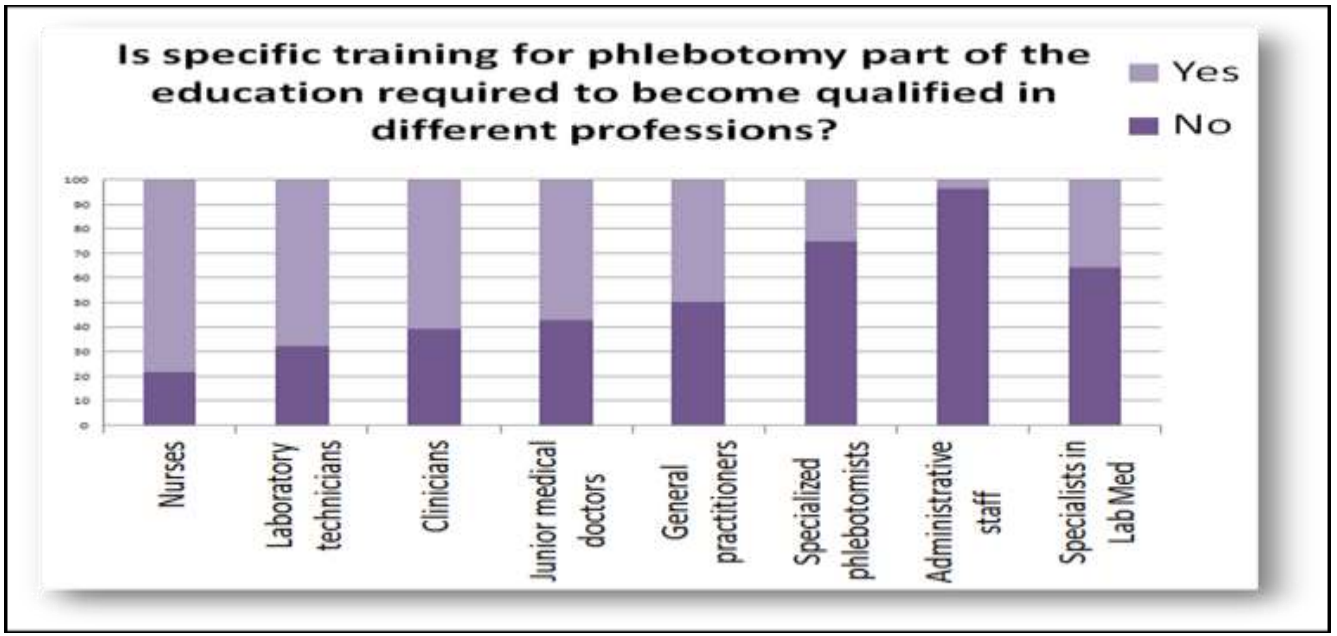
[1]Croatian Society of Medical Biochemistry and Laboratory Medicine, Committee for the Scientific Professional Development, Working Group for Pre-analytics, Zagreb, Croatia
[2]University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice, Zagreb, Croatia
[3]Clinical Institute of Laboratory Diagnostics, Rijeka Clinical Hospital Center, Rijeka, Croatia

*Corresponding author: nora.nikolac@gmail.com

- **7/28 zemalja (25%) ima nacionalne smernice:**

  Irska, UK, Španija, Slovenija, Švedska, Italija i Hrvatska
- **24% koristi CLSI H3-A6**
- **75% vrlo zainteresovano za EFLM smernice**


Average % of staff performing phlebotomy
70
60
50
40
30
20
10
0
Inpatient Academic
Inpatient general/regional
Inpatient primary care
Outpatient academic
Outpatient general/regional
Outpatient primary care
Nurses
Laboratory technicians
Clinicians
Junior medical doctors
General practitioners
Specialized phlebotomists
Administrative staff
Specialists in Laboratory medicine


Is specific training for phlebotomy part of the education required to become qualified in different professions?
Yes
No
Nurses
Laboratory technicians
Clinicians
Junior medical doctors
General practitioners
Specialized phlebotomists
Administrative staff
Specialists in Lab Med

DE GRUYTER DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med 2013; 51(8): 1585–1593

Ana-Maria Simundic*, Michael Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Svjetlana Kovalevskaya, Ludek Sprongl, Zorica Sumarac and Stephen Church

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)

Conclusions and recommendations

Based on the results of this survey we conclude the following: 1) There is a need to assess the quality of current practices, compliance to the CLSI H3-A6 guidelines and to identify some most critical steps which occur during phlebotomy, in different healthcare settings, across Europe; 2) Existing CLSI H3-A6 phlebotomy guidelines should be adapted and used locally in all European countries which do not have their own guidelines; 3) National EFLM societies need to be engaged in basic training program development and continuous education of healthcare phlebotomy staff (implementing the certification of competence).

- **Veliki stepen heterogenosti**
- **Veliki broj zemalja nema nacionalne smernice**
- **Uzorkovanje krvi obavlja medicinski i nemedicinski kadar**
- **Različiti nivo obrazovanja, obuke**
- **Nedovoljno edukacije**
- **Potreba za standardizacijom i harmonizacijom**

EFLM WG-PRE
II projekat

DE GRUYTER

Clin Chem Lab Med 2014; aop

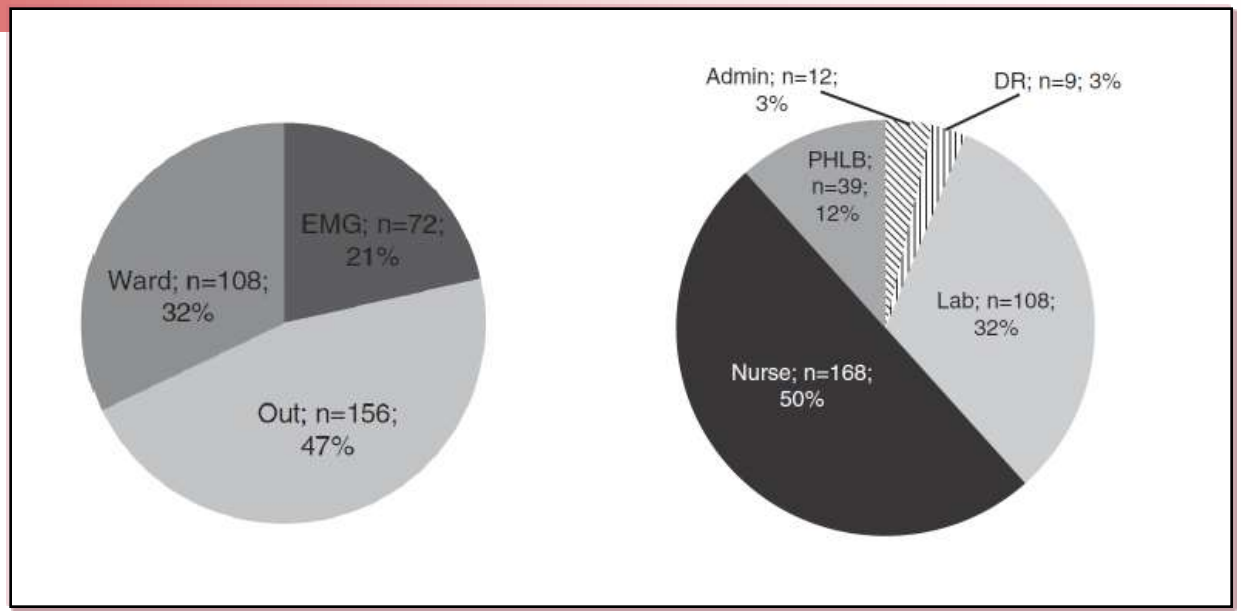
Ana-Maria Simundic*, Stephen Church, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Nora Nikolac, Edmee van Dongen-Lases, Pinar Eker, Svjetlana Kovalevskaya, Gunn B.B. Kristensen, Ludek Sprongl and Zorica Sumarac

Compliance of blood sampling procedures with the CLSI H3-A6 guidelines: An observational study by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE)

Ciljevi

- Ispitivanje nivoa usklađenosti procedura uzorkovanja krvi sa CLSI H3-A6
- Identifikacija najkritičnijih postupaka koji zahtevaju hitnu izmenu i unapređenje

- **Jun 2013-Mart 2014**
- **12 zemalja**
- **3 flebotomičara-**
  3 uzorkovanja krvi
  (N=336)



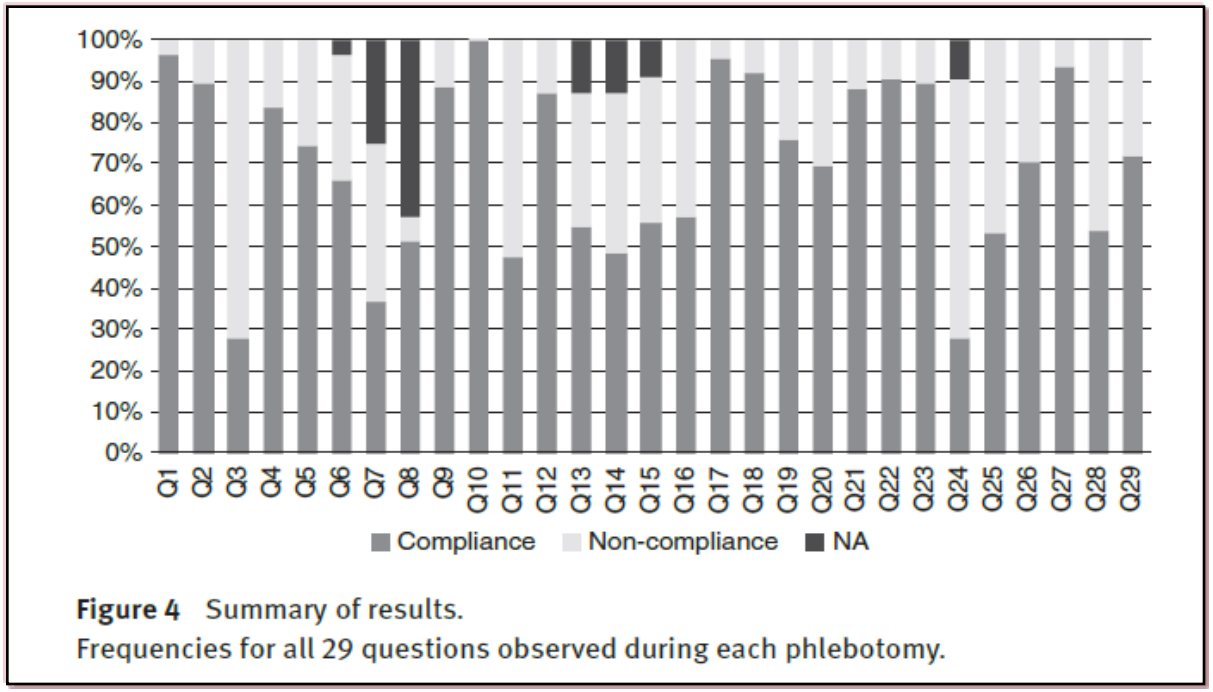


Figure 4 Summary of results.
Frequencies for all 29 questions observed during each phlebotomy.

Question 1																			
Did the collector assemble all necessary supplies prior to collection?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 2																			
Does the collector have an identified request form?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 3																			
Did the collector check the expiry dates of devices in use?	Yes			No	X		Yes			No	X		Yes			No	X		
Question 4																			
Did the collector identify the patient according to CLSI or local guidelines	Yes	X		No			Yes	X		No			Yes	X		No			
Question 5																			
Did the collector appropriately sanitize hands?	Yes			No	X		Yes			No	X		Yes			No	X		
Question 6																			
Has the collector verified that the patient is properly prepared for phlebotomy?	Yes			No	X		Yes			No	X		Yes			No	X		
Question 7																			
Was the chair used for venipunture specific to the task?	Yes	X	No		N/A		Yes	X	No		N/A		Yes	X	No		N/A		
Question 8																			
If lying, did the collector ensure the arm was appropriately positioned?	Yes			No			Yes			No			Yes			No			
Question 9																			
Did the collector place the tourniquet 4 finger widths (10cm) above the venipuncture site?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 10																			
Did the collector select a suitable venipuncture site according to standard pract	Yes	X		No			Yes	X		No			Yes	X		No			
Question 11																			
Did the collector put on a new, fresh clean pair of gloves?	Yes			No	X		Yes			No	X		Yes			No	X		
Question 12																			
Did the collector clean the venipuncture site?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 13																			
Did the collector leave the venipuncture site to dry (30secs)?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 14																			
Did the collector leave the venipuncture site untouched post cleaning?	Yes			No	X		Yes			No	X		Yes	X		No			
Question 15																			
Did the collector ensure a fist was released when blood flow commenced?	Yes			No	X		Yes	X		No			Yes	X		No			
Question 16																			
Did the collector release the tourniquet when blood flow commenced?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 17																			
Was the collector using a closed system for venipuncture?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 18																			
Did the collector follow the correct order of draw according to the guidelines?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 19																			
Were any of the sample tubes clearly under or over filled?	Yes			No	X		Yes			No	X		Yes			No	X		
Question 20																			
Were all sample tubes immediately and appropriately mixed according to manufacturers specifications?	Yes	X		No			Yes	X		No			Yes	X		No			
Question 21																			

Table 4 Risk occurrence chart for various phlebotomy steps.

Occurrence probability	Severity of harm				
	None	Limited	Moderate	Severe	Life threatening
	S1	S2	S3	S4	S5
Frequent O6					
Probable O5		Q7, Q11, Q24	Q3		
Occasional O4		Q5, Q13, Q28, Q29	Q6, Q14, Q15, Q16, Q19, Q20, Q23		Q25, Q26
Remote O3		Q8, Q9, Q21	Q12	Q2	Q4
Improbable O2	Q1	Q27, Q18	Q17	Q22	
Rare O1					

Q3: Did the collector check the expiry dates of devices in use?

Procedure identifikacije i obeležavanja!!

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

Zaključci:

- Nivo usklađenosti procedure uzorkovanja venske krvi sa CLSI H3-A6 u 12 zemalja EFLM je veoma nizak.
- Postupci koji zahtevaju hitno unapređenje su: identifikacija pacijenata i obeležavanje uzoraka (*tube labelling*) tokom procedure uzorkovanja krvi.
- Neophodna revizija CLSI H3-A6

EFLM WG-PRE
III projekat

The role of EFLM in standardization and harmonization of the preanalytical phase in Europe

Cornes M , Simundic AM et al. The role of EFLM in standardization and harmonization of the preanalytical phase in Europe. *Manuscript under preparation.*

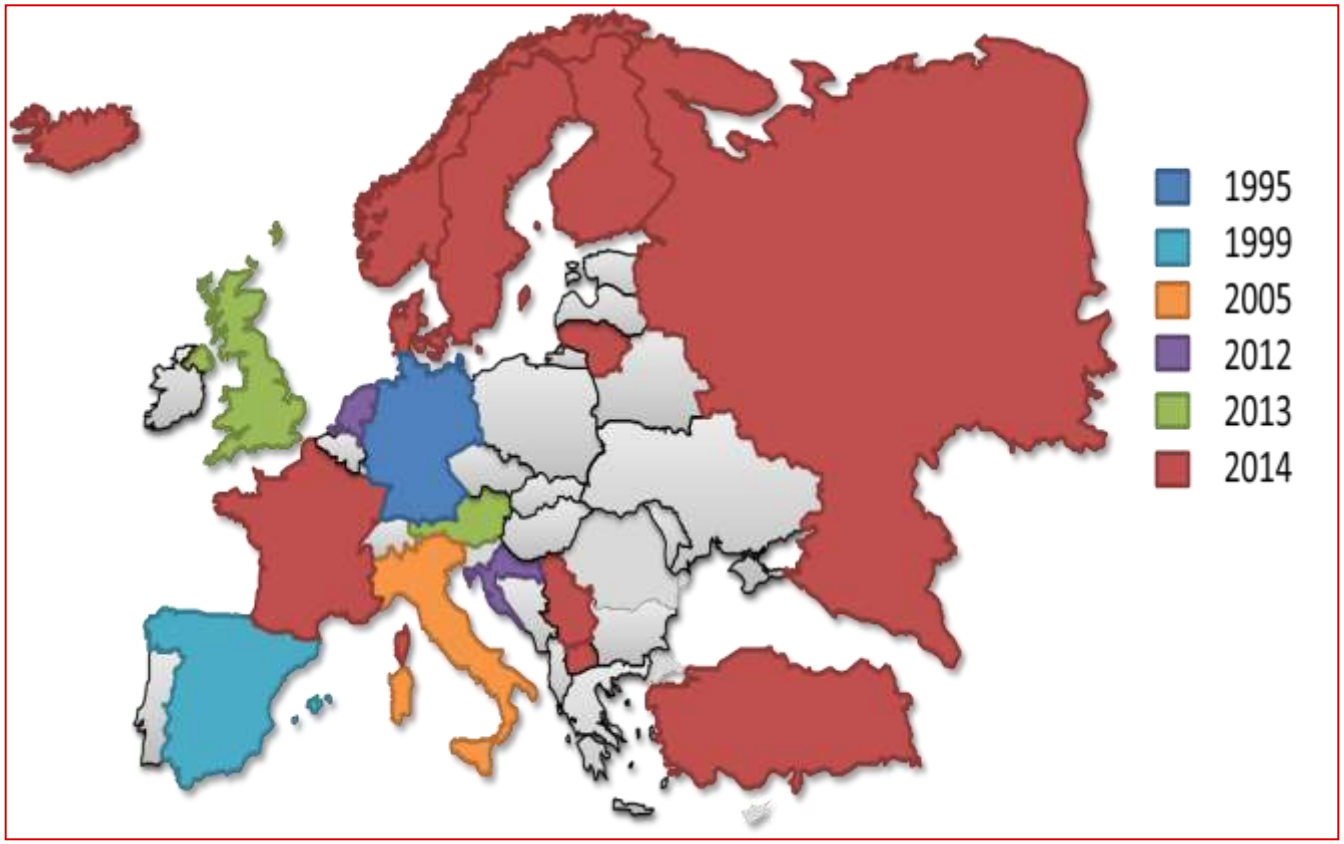
- **Osvrt na sve dosadašnje aktivnosti kao i viziju i misiju EFLM WG-PRE u standardizaciji i harmonizaciji preanalitičkih postupaka i regulative.**

Uloga nacionalnih društava:

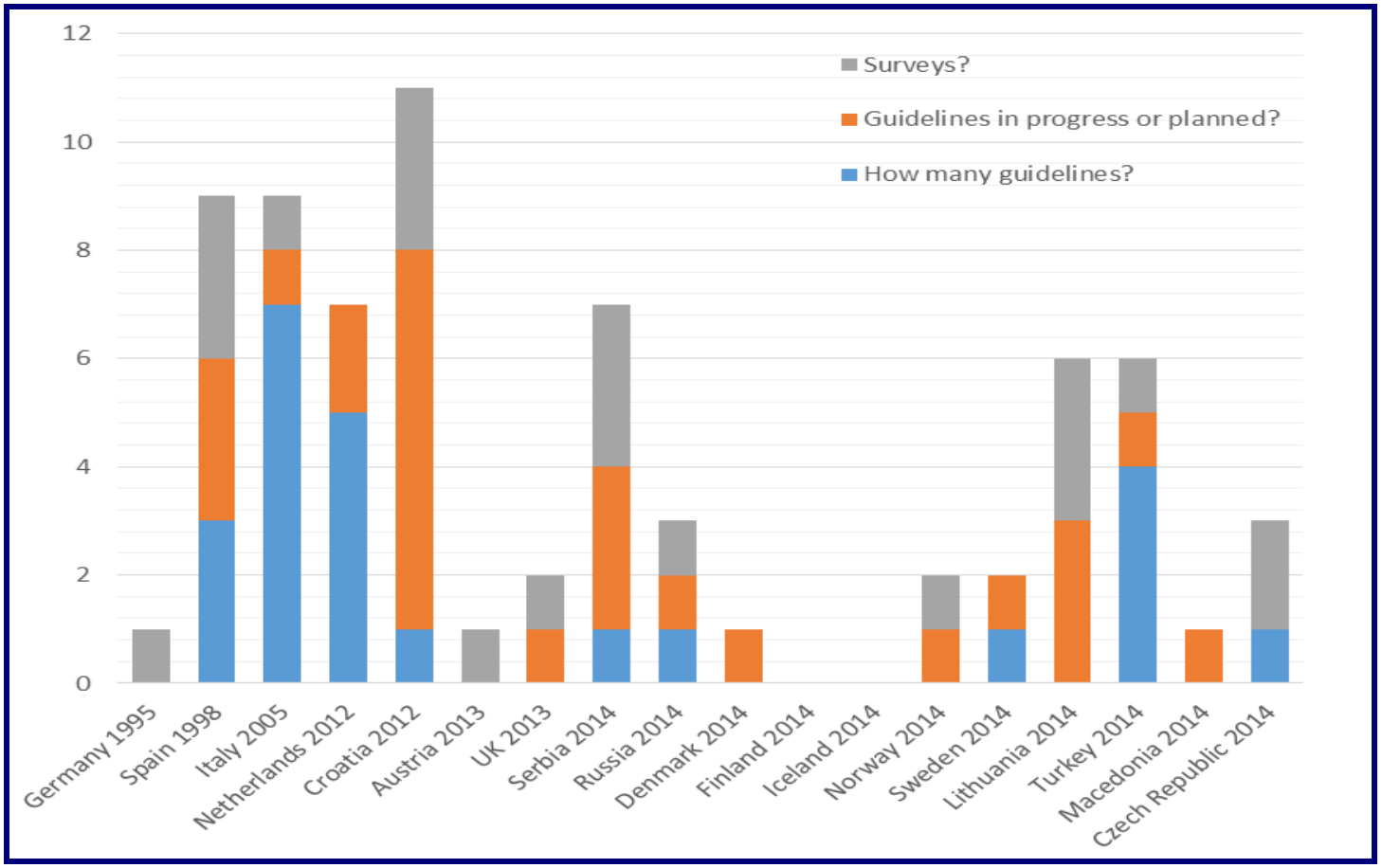
- Formiranje radnih grupa za pre-analitiku
- Promocija i podizanje svesti o značaju pre-analitike
- Edukacija, organizacija skupova, webinara
- Aktivnost na standardizaciji na nacionalnom nivou
- Izrada smernica, uticaj na donošenje regulative
- Saradnja sa EFLM/EFLM WG-PRE i drugim ND

Izlaganje predstavnika EFLM Nacionalnih društava (22) o aktivnostima na polju preanalitike, kroz sledeća postavljena pitanja:

1. Da li postoje radne grupe/komiteti za preanalitiku?
2. Da li su izradili i objavili smernice iz oblasti preanalitike?
3. Da li su organizovali edukativne skupove posvecene preanalitici?
4. Da li su sprovodili i objavili rezultate upitnika iz oblasti preanalitike?
5. Da li postoji EQAP u oblasti preanalitike?
6. Da li smatraju da je harmonizacija u oblasti preanalitike neophodna i moguća na nacionalnom nivou?
7. Da li smatraju da je harmonizacija u oblasti preanalitike neophodna i moguća na internacionalnom nivou?
8. Da li smatraju da je njihovo nacionalno društvo spremno da radi sa EFLM na harmonizaciji pre-analitičke faze i pomogne u izradi međunarodnih smernica i preporuka kao i njihovoj implementaciji na nacionalnom nivou?

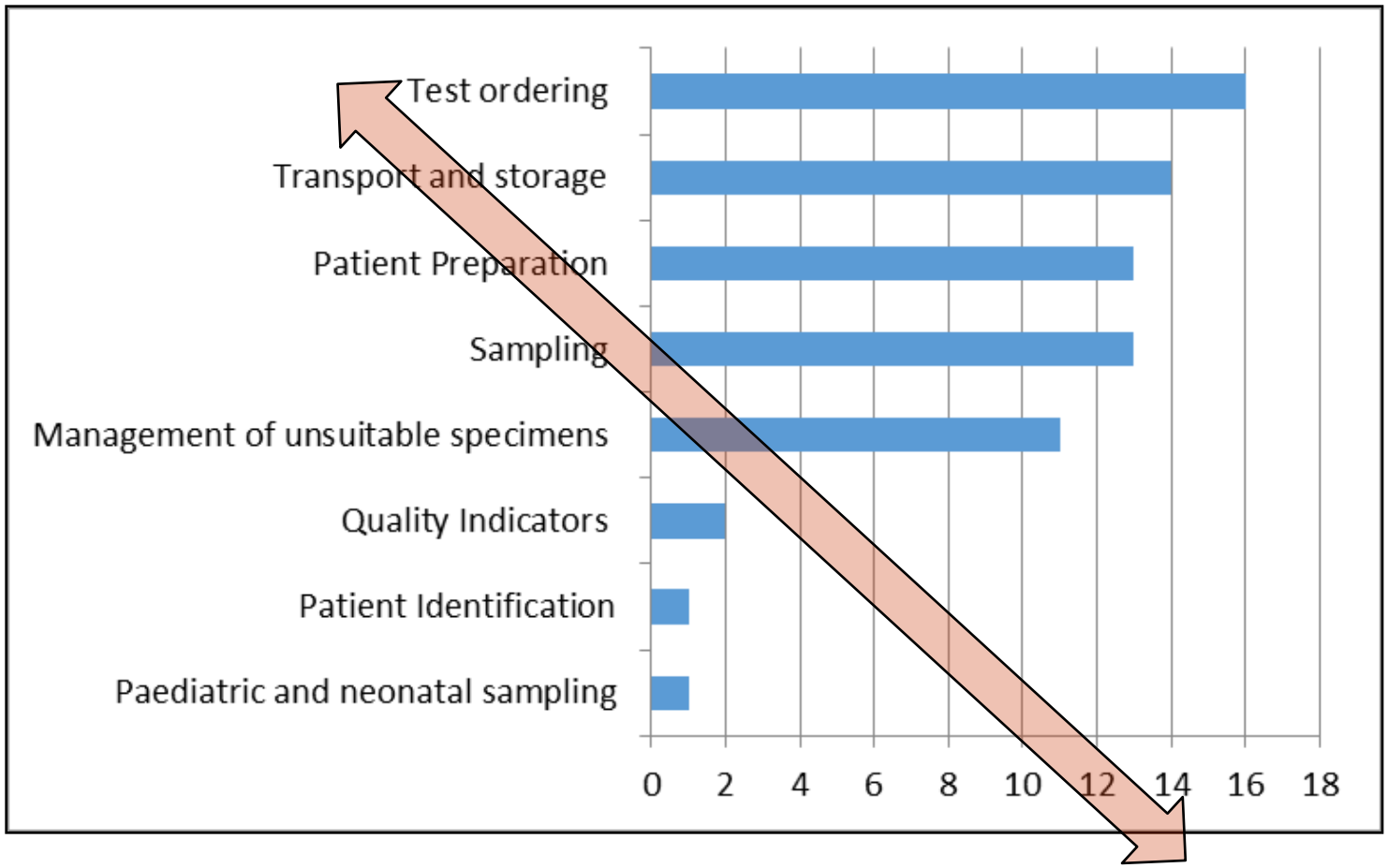


Postojanje radnih grupa za preanalitiku u zemljama Evrope.



Broj smernica i upitnika objavljenih od strane EFLM Nacionalnih društava: 22 upitnika; 19 izrađenih smernica, 22 u planu; 8 EQAS

EFLM WG-PRE



Ključni pre-analitički postupci koji zahtevaju hitnu harmonizaciju

Nacionalna društva


Porto
2015
BD
Conference on Preanalytical Phase
Closing remarks
21 03 2015

Budući projekti EFLM WG-PRE u oblasti pre-analitičke faze

1. Izbor testova

The three rules of laboratory test utilization:

1. "If you ask a stupid question, you get a stupid answer"
2. "Laboratory testing is for sick people"
3. "Too many good tests are the same as one bad test"

Review

The laboratory test utilization management toolbox

Geoffrey Baird

Biochemia Medica 2014;24(2):223–34

Inappropriate test
Unnecessary test
Appropriate test

Nepotrebni laboratorijski testovi:

4,5%-95% - van Walraven C, JAMA, 1998.
23-67% - Lippi G, Semin Thromb Hemost 2014.

A. A. Fryer and W. S. A. Smellie
Managing demand for laboratory tests: a laboratory toolkit.
J. Clin. Pathol. 2013 66:62-72

Clin Chem Lab Med 2012;50(7):1249–1252 © 2012 by Walter de Gruyter • Berlin • Boston. DOI 10.1515/cclm-2011-0611

Opinion Paper

Reflective testing: adding value to laboratory testing

Clinical Chemistry / Utilization Management

Utilization Management in a Large Urban Academic Medical Center

A 10-Year Experience

Ji Yeon Kim, MD, MPH, Walter H. Dzik, MD, Anand S. Dighe, MD, PhD, and Kent B. Lewandrowski, MD

Table 4
Test Ordering Guidelines Established for the SICU at MGH

A physician order is required for all laboratory tests. An RN is accountable for all tests sent.
Retroactive physician orders are acceptable during acute clinical events. An RN should discuss with the physician and obtain order before the shift is over.
Routine AM laboratory tests are defined as CBC, Na, K, Cl, bicarbonate, BUN, creatinine, glucose, magnesium, and phosphorus. Duplicate laboratory tests are not acceptable. Additional routine AM laboratory tests include TPN laboratory tests as ordered on the TPN template and blood bank samples every 72 h.
Routine AM laboratory tests and patient-specific laboratory tests are ordered on SICU rounds and sent on the night shift if possible.
Postrepletion electrolyte laboratory tests can be sent as needed and are ordered on the POE laboratory screen or using the SICU electrolyte template.
Arterial blood gases are *not* routine and require a physician order.
PT, PTT, and troponin-T are *not* routine admission laboratory tests.
Admission laboratory tests are generally *not* STAT and may be done at any appropriate time within the first hour of admission.
MGH guidelines for diagnosing acute myocardial infarction
Time 0: Troponin-T, CPK, CK-MB
Time 8 h: Troponin-T

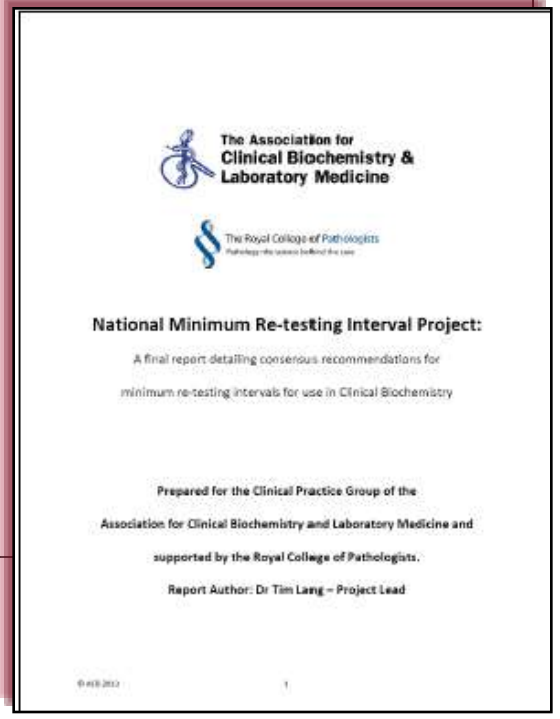
...um) urea nitrogen; CK-MB, creatine kinase MB
..., creatine kinase; K, potassium; MGH, Massachusetts
..., sodium; POE, provider order entry; PT, prothrombin
...stin time; RN, registered nurse; SICU, surgical
... parenteral nutrition.

Table 5
A Framework for Approaching Utilization Management Problems

	Low-Volume Testing	High-Volume Testing
Overutilization	Focused physician education and/or establishing group practice standards (in conjunction with leadership of the specialty group) Physician profiling, with utilization profiling Addition of a gatekeeper (require approval before test can be obtained)	Change to CPOE screen(s) design, redesign paper requisition forms, eliminate standing orders Banning tests Limit ordering privileges to specialists Find cheaper alternatives, and promote
Underutilization	Test interpretation services, with recommendation of additional tests, if necessary	Reflex testing using laboratory information system Use of disease- or syndrome-specific templates
Examples	Electronic mail sent to select clinicians about free-text orders; interpretation services for hypercoagulation testing	Remove lactate dehydrogenase, uric acid from requisition/ CPOE screen; ban 5-h oral glucose tolerance test; use templates for cardiac markers; reflex testing for evaluation of prolonged partial thromboplastin time

CPOE, computerized provider order entry.

- **Standardizovati mehanizme koji omogućavaju pravilan odabir testova**
- **Obrazovanje kadrova**
- **Revizija dokumenata**
- **Izrada smernica sa ciljem smanjenja korišćenja testova** (klinički vodiči, reflex testovi, određivanje intervala za ponavljanje testova)
- **Redizajniranje uputa** (izbacivanje zastarelih testova, pravljenje panela, klinički algoritmi, cene testova)
- **Modeli finansiranja**


The Association for Clinical Biochemistry & Laboratory Medicine

The Royal College of Pathologists

National Minimum Re-testing Interval Project:

A final report detailing consensus recommendations for minimum re-testing intervals for use in Clinical Biochemistry

Prepared for the Clinical Practice Group of the Association for Clinical Biochemistry and Laboratory Medicine and supported by the Royal College of Pathologists.

Report Author: Dr Tim Lang – Project Lead

QOF - UK Quality and Outcomes Framework

Unos zahteva preko kompjutera
(Computerized Physician Order Entry, CPOE)

Prednosti:

- ❑ **Efektivnost**
- ❑ **Lični odabir testova od strane lekara**
- ❑ **Prethodni rezultati pacijenta**
- ❑ **Ograničavanje ponavljanja zahteva**
- ❑ **Usklađenost sa smernicama, kliničkim algoritmima**
- ❑ **Podrška softvera**
- ❑ **On-line komunikacija sa laboratorijom**
- ❑ **Cena testova**
- ❑ **Broj analiza po pacijentu**
- ❑ **Linkovi za baze podataka**

2. Transport i stabilnost uzoraka

- Transport i rukovanje unutar laboratorije
- Transport uzoraka do centralne (*core*) laboratorije
- Poznavanje stabilnosti analita
- Praćenje uslova transporta (vreme, temperatura)

Zahtevi ISO 15189:2012

Verifikacija:

1. Vremenskog perioda između uzorkovanja i analiziranja
2. Temperature i vremena čuvanja uzoraka od uzorkovanja do analiziranja
3. Uslova pakovanja i pozicioniranja u transportne kutije/torbe prilikom transporta
4. Identifikacija i evidencija odbacivanja uzoraka

Transport i stabilnost uzoraka

Opinion Paper

Giuseppe Lippi[a,*], Giuseppe Banfi, Stephen Church[b], Michael Cornes[c], Gabriella De Carli, Kjell Grankvist[d], Gunn B. Kristensen[e], Mercedes Ibarz[c], Mauro Panteghini, Mario Plebani, Mads Nybo[e], Stuart Smellie, Martina Zaninotto and Ana-Maria Simundic[a] on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine Working Group for Preanalytical Phase

Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working group for Preanalytical Phase (WG-PRE)

Monitoring the time and temperature conditions of sample transport

J Med Biochem 2012; 31 (4) DOI: 10.2478/v10011-012-0014-1

UDK 577.1 : 61 ISSN 1452-8258

J Med Biochem 31: 265–270, 2012 Review article
Pregledni članak

PRE-ANALYTICAL ERRORS AND PATIENT SAFETY

PREANALITIČKE GREŠKE I BEZBEDNOST PACIJENATA

Mario Plebani

Department of Laboratory Medicine, University Hospital, Padova, Italy

Quality in sample transportation

Clinical Biochemistry 44 (2011) 1028–1029

Contents lists available at ScienceDirect

Clinical Biochemistry

journal homepage: www.elsevier.com/locate/clinbiochem

Case Report

Suitability of a transport box for blood sample shipment over a long period

Giuseppe Lippi [a,*], Gabriel Lima-Oliveira [b,c,d,e], Sandro Coutino Nazer [d], Maria Luiza Lopes Moreira [d], Rodrigo Pagnez Mosele Souza [d], Gian Luca Salvagno [a], Martina Montagnana [a], Daniela Scartezini [b], Geraldo Picheth [b], Gian Cesare Guidi [a]

[a] U.O. Diagnostica Ematochimica, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy
[b] Program of Pharmaceutical Sciences, Department of Medical Pathology, Federal University of Paraná, Curitiba, Paraná, Brazil
[c] Sezione di Chimica Clinica, Dipartimento di Scienze della Vita e della Riproduzione, Università degli Studi di Verona, Verona, Italy
[d] MERCOSUL Sector Committee of Clinical Analyses and In Vitro Diagnostics – CSM 20, Rio de Janeiro, Brazil
[e] Brazilian Society of Clinical Analysis on São Paulo State, Brazil

ARTICLE INFO

Article history:
Received 12 April 2011
Received in revised form 25 May 2011
Accepted 27 May 2011
Available online 13 June 2011

Keywords:
Preanalytical variability
Laboratory errors
Storage
Transportation
Quality

ABSTRACT

Background: Safety transport boxes are increasingly used to ship laboratory specimens but there is little information on their capacity to maintain suitable transportation temperatures.
Materials and methods: Inner temperature was assessed using a commercially available transport box during an 8-h transportation period in the heat.
Results: Temperature stability was unsatisfactory during approximately 6/8 of the transportation time (i.e., from 125 to 450 min).
Conclusions: Transport boxes might be unsuitable for shipping specimens over long periods.

Introduction

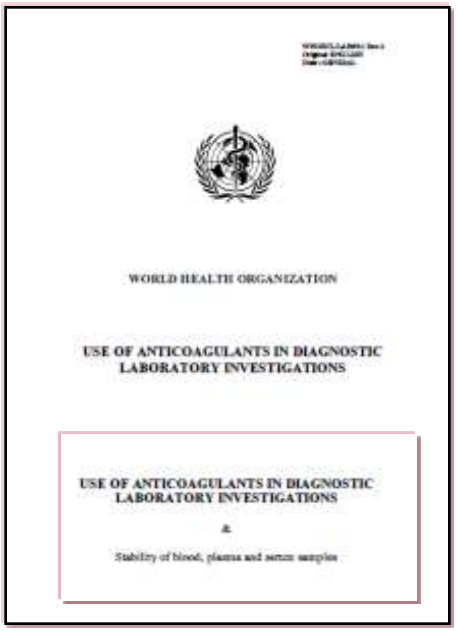
Although laboratory diagnostics strongly contributes to the screening, diagnosis, follow-up and therapeutic monitoring of most – if not all – human disorders, diagnostics errors can occur at any step of the total testing process, i.e., from the appropriateness of the test request to the interpretation of test results [1]. Within this cycle (i.e., the foremost Lundberg's "brain to brain turnaround cycle"), errors arising from the manually intensive preanalytical activities are prevailing, representing up to 70% of all laboratory errors. Preanalytical errors are mostly due to incorrect, inappropriate or mishandled procedures for collection, handling, preparation and – last but not least – transportation and storage of the specimens [2–4]. In particular, due to the widespread networking, centralization of laboratory diagnostics within large facilities (e.g., huge, totally automated and focused factories) and the consequent need to transport a large number of specimens from peripheral collections sites to the core laboratories, the problem of appropriate conditions of sample transportation (i.e., time, temperature and humidity) is critically emerging [5,6]. Moreover, temperature monitoring is considered one of the leading issues in transfusion medicine, since routine blood components' transportation should not exceed 10 °C during transport at a maximum transit time of 24 h, as established by most guidelines [7]. Safety transport boxes, that are products designed to maintain the inner environment at a constant temperature notwithstanding temperature changes outside the container, are increasingly developed and used to store and ship laboratory specimens as well as other biological materials. Nevertheless, little information is available as yet on the effectiveness of these devices to maintain suitable conditions of temperature, which would not affect sample quality during long transportation times.

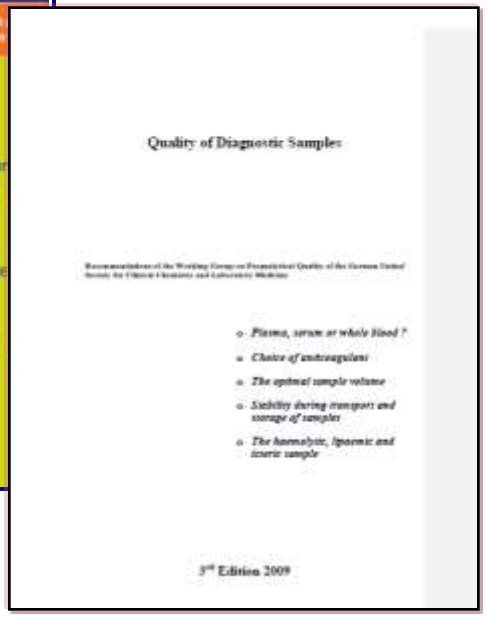
Materials and methods

Suitability of sample transportation was assessed using a commercially available transport box, purchased from Gilsenan® (Wichita, Kansas-United States) with external size: 10.63"L × 7.87"W × 8.27"H, and interior size: 9.45"L × 6.89"W × 7.09"H. To warrant the correct temperature range, four ice reusable dry gel packs with carbopol gel inside (2 × 200 mL and 2 × 500 mL) were accurately placed inside the transport box at a private peripheral blood collection facility. A calibrated temperature recorder (Trix-8 Temperature Recorder®, LogTag recorders, Adaveo®, Brazil) was also inserted. The temperature monitoring was started immediately after closure of the box and repeated every 5 min through an 8-hour study period. According to manufacturer's instruction, the suitable transportation temperature (i.e., below 10 °C) is reached ~30 min after

* Corresponding author at: U.O. Diagnostica Ematochimica, Azienda Ospedaliero-Universitaria di Parma, Via Gramsci, 14, 43126 Parma, Italy. Fax: +0039 0521 703761.
E-mail addresses: giuseppe.lippi@ao.pr.it (G. Lippi).

0009-9120/$ – see front matter © 2011 The Canadian Society of Clinical Chemists. Published by Elsevier Inc. All rights reserved.
doi:10.1016/j.clinbiochem.2011.05.018





Clinical and Laboratory Standards Institute. Procedures for handling and processing of blood specimens for common laboratory tests. H18-A4; approved guideline – 4th ed. CLSI: Wayne, PA, 2010.

Guder WG, Ehret W, da Fonseca-Wollheim F, Heil W, Müller Plathe O, Töpfer G, et al. 1. Auflage Deutsche Gesellschaft für Clinische Chemie und Deutsche Gesellschaft für Laboratoriumsmedizin, 1999. Heidelberg: Becton Dickinson GmbH; [Die Qualität diagnostischer Proben]

3. Priprema pacijenata

Clinica Chimica Acta 432 (2014) 33–37

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Standardization of collection requirements for fasting samples For the Working Group on Preanalytical Phase (WG-PA) of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM)

A.M. Simundic [a,b,*], M. Cornes [b,c], K. Grankvist [b,d], G. Lippi [b,e], M. Nybo [b,f]

Clinical Chemistry

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

Journal	Articles with a group of fasting patients,[a] n	Well-defined fasting, n (%)	Insufficient definition, n (%)	No definition, n (%)
Clinical Chemistry	20	1 (5)	5 (25)	14 (70)
Clinical Chemistry and Laboratory Medicine	24	0 (0)	6 (25)	18 (75)
Scandinavian Journal of Clinical and Laboratory Investigation	18	3 (17)	4 (22)	11 (61)
Diabetes	94	7 (7)	36 (38)	51 (54)

[a] If the term "fasting patient" was used in the Materials and Methods, Results, or Discussion, the publication was considered as using fasting patients.

Hrvatsko društvo za medicinsku biokemiju 2015

Original papers

Are patients well informed about the fasting requirements for laboratory blood testing?

Sanja Kackov[1*], Ana-Maria Simundic[2], Ani Gatti-Drnic[3]

[1]Medical biochemistry laboratory, Policlinic Bonifarm, Zagreb, Croatia
[2]University Department of Chemistry, Medical School University Hospital Sestre Milosrdnice, Zagreb, Croatia
[3]Medical biochemistry laboratory, Public Health Centre Zagreb-Centar, Zagreb, Croatia

Biochemia Medica 2013;23(3):326–31

Institution: ☐ Interviewed by: ☐ Questionnaire №: ☐

Date: ☐

Patient age (years):

☐ ≤ 25 ☐ 26 - 45 ☐ 46 – 65 ☐ ≥ 65

Gender:

☐ male ☐ female

1) Are you taking regularly any of the following products? If yes, please state for how long?

Products	≤ 7 days	8-30 days	≥ 30 days	No
1. Acetylsalicylic acid (Aspirin) (not ordered by physician)				
2. Aloe vera (Aloe Barbadensis Miller)				
3. Cranberry (tea, capsules)				
4. Red yeast rice				
5. Ginkgo Biloba				
6. Minerals (Ca, Mg, Zn, Se, Fe, etc.)				
7. Noni juice				
8. Omega-3 fatty acids				
9. Propolis				
10. Caraway oil (Carum carvi)				
11. Silymarin (Silybum marianum)				
12. Vitamins (A, B, C, D, E, etc.)				
13. Green coffee bean extract				
14. Weight loss supplements				
15. other (please specify):*				

** other: apple cider vinegar (capsules), guarana (Paullinia cupana), royal jelly, papaya enzyme (chewable tablets) echinacea, Green magma (Hordeum vulgare) beta-glucan, hyaluronic acid, garlic capsules, evening primrose oil (Oenothera biennis), neem (Azadirachta indica) etc.*

2) Does your physician know that you take these products?

☐ yes ☐ no ☐ not applicable

3) Is it important to inform your physician that you are taking* some of the listed products?
(*patients who are not taking any of the listed products should simply give their opinion about the statement)

☐ yes ☐ no

4) Is it important to inform the laboratory staff that you are taking* some of the listed products?
(*patients who are not taking any of the listed products should simply give their opinion about the statement)

☐ yes ☐ no

5) What do you think, could the below listed factors affect the laboratory tests results?

Factor	yes	no	I don't know
Intense physical activity on the day before the blood sampling**			
Alcohol consumption on the day before the blood sampling			
Consumption of coffee on the day before the blood sampling			
Consumption of grapefruit on the day before the blood sampling			
Consumption of broccoli 3 days before the blood sampling			
Consumption of any of the products from the Table 1.			

*** cycling, tennis, running*

PREPORUKE EFLM WG-PRE

1. Neophodna revizija CLSI H3-A6 –pripema pacijenata
   - uzorkovanje krvi 07-09h
   - gladovanje 12h, dozvoljeno uzimanje vode
   - alkohol izbegavati 24h
   - pred vađenje krvi ne konzumirati kafu, čaj i cigarete
2. IFCC, EFLM-harmonizacija preporuka
3. Na nacionalnom nivou laboratorije treba da implementiraju standardizovane procedure uzorkovanja krvi i pripreme pacijenata.
4. Kriterijumi za prihvatanje uzoraka na osnovu pripreme pacijenata.
5. Laboratorijsko osoblje odgovorno za informisanost doktora i pacijenata.

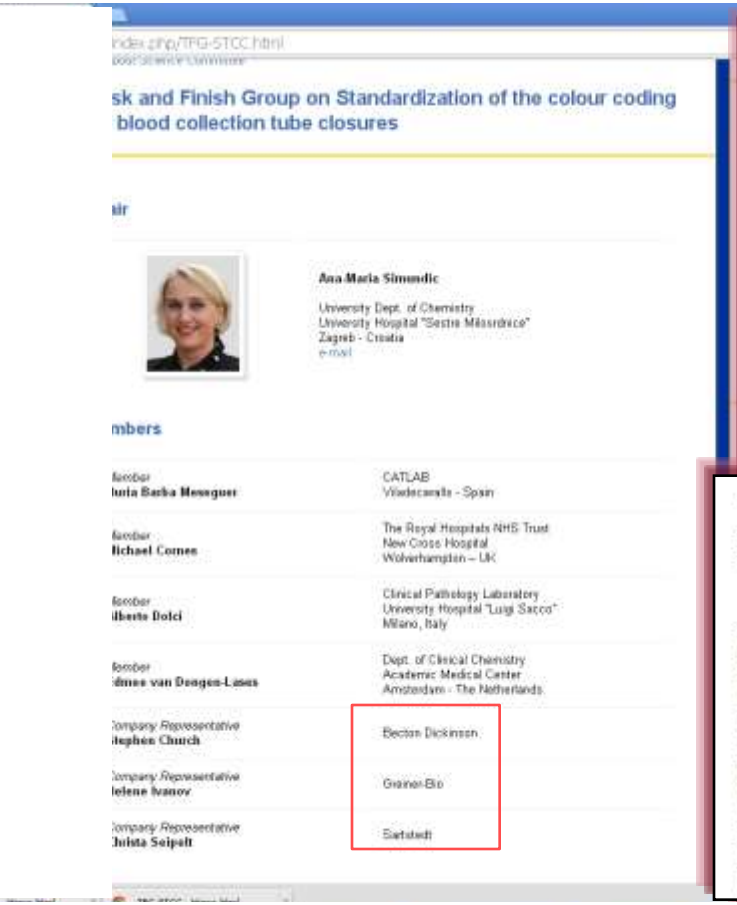
4. UZORKOVANJE KRVI

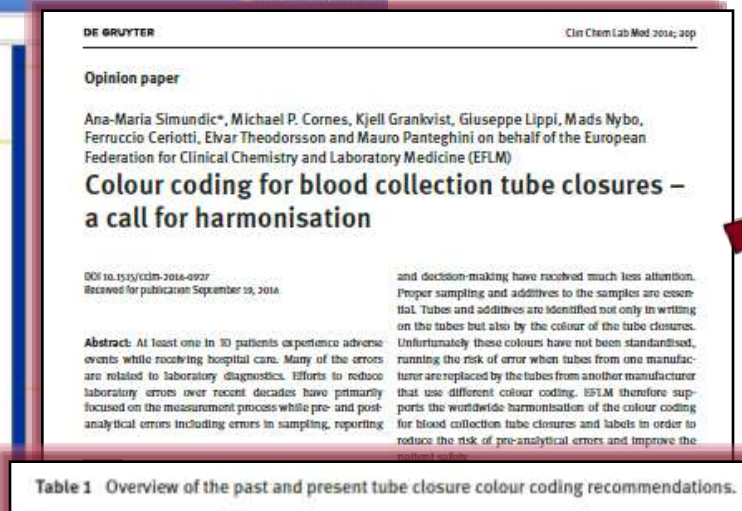
EFLM WG-PRE

- Započeta izrada (konsenzus) smernica za proceduru venepunkcije
- Rezultati rada: *AM Simundic et al. Compilance of blood sampling procedures with the CLSI H3-A6 guidelines. CCLM 2014.*
- CLSI H3-A6, WHO, preporuke nacionalnih društava
- Re-evaluacija postupaka zasnovana na dokazima
- Opservacione studije
- Uključivanje industrije-proizvođača sistema za venepunkciju
- Uključivanje udruženja sestara i laboratorijskih tehničara iz zemalja EFLM
- Sastanak EFLM WG-PRE-Zagreb, novembar 2015

EFLM WG-PRE je inicirala formiranje:

EFLM Task and Finish Group on Standardization of the colour coding for blood collection tube closures




DE GRUYTER

Clin Chem Lab Med 2014; aop

Opinion paper

Ana-Maria Simundic*, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Ferruccio Ceriotti, Elvar Theodorsson and Mauro Panteghini on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM)

Colour coding for blood collection tube closures – a call for harmonisation

DOI 10.1515/cclm-2014-0927
Received for publication September 19, 2014

Abstract: At least one in 10 patients experience adverse events while receiving hospital care. Many of the errors are related to laboratory diagnostics. Efforts to reduce laboratory errors over recent decades have primarily focused on the measurement process while pre- and post-analytical errors including errors in sampling, reporting and decision-making have received much less attention. Proper sampling and additives to the samples are essential. 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 standardised, running the risk of error when tubes from one manufacturer are replaced by the tubes from another manufacturer that use different colour coding. EFLM therefore supports the worldwide harmonisation of the colour coding for blood collection tube closures and labels in order to reduce the risk of pre-analytical errors and improve the patient safety.

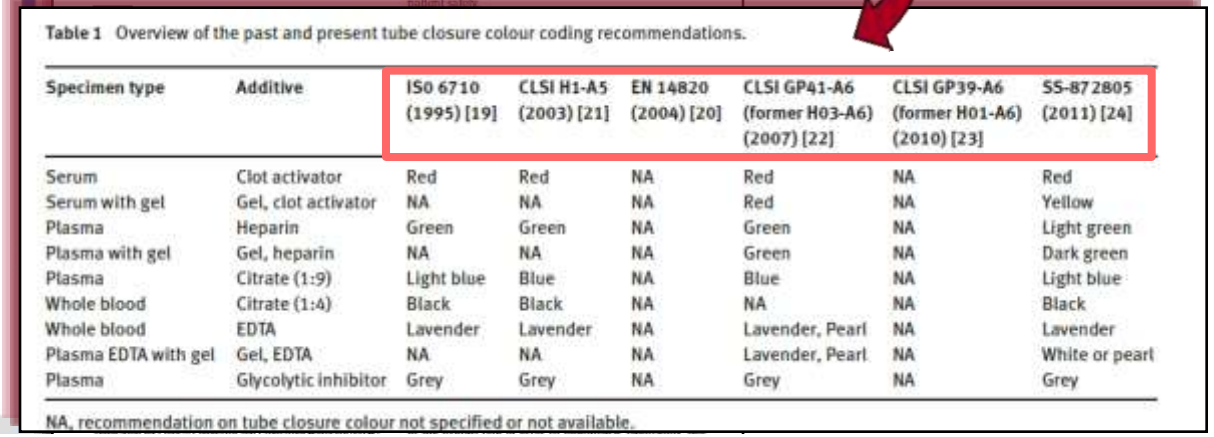


Table 1 Overview of the past and present tube closure colour coding recommendations.

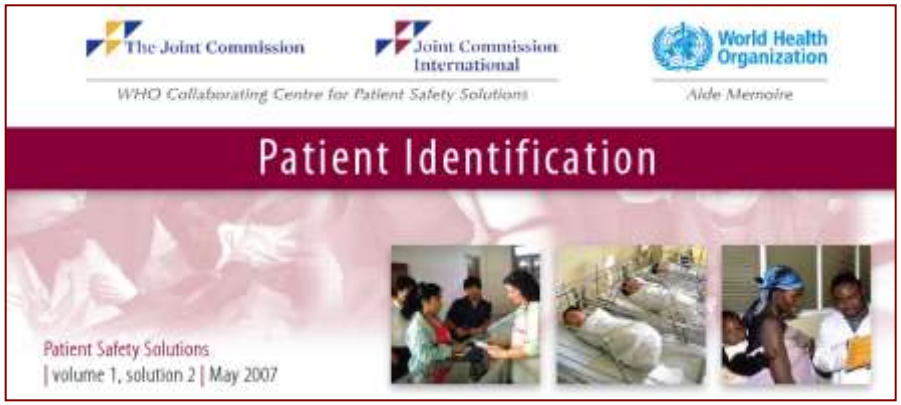
Specimen type	Additive	ISO 6710 (1995) [19]	CLSI H1-A5 (2003) [21]	EN 14820 (2004) [20]	CLSI GP41-A6 (former H03-A6) (2007) [22]	CLSI GP39-A6 (former H01-A6) (2010) [23]	SS-87 2805 (2011) [24]
Serum	Clot activator	Red	Red	NA	Red	NA	Red
Serum with gel	Gel, clot activator	NA	NA	NA	Red	NA	Yellow
Plasma	Heparin	Green	Green	NA	Green	NA	Light green
Plasma with gel	Gel, heparin	NA	NA	NA	Green	NA	Dark green
Plasma	Citrate (1:9)	Light blue	Blue	NA	Blue	NA	Light blue
Whole blood	Citrate (1:4)	Black	Black	NA	NA	NA	Black
Whole blood	EDTA	Lavender	Lavender	NA	Lavender, Pearl	NA	Lavender
Plasma EDTA with gel	Gel, EDTA	NA	NA	NA	Lavender, Pearl	NA	White or pearl
Plasma	Glycolytic inhibitor	Grey	Grey	NA	Grey	NA	Grey

NA, recommendation on tube closure colour not specified or not available.

AM Šimundic-član ISO TC 76/WG -revizija ISO 6710:1995, ***Single-use containers for venous blood specimen collection.***

5. Identifikacija pacijenata

- ✓ **CLSI H3-A6: ime i prezime, adresa, ID i/ili datum rodjenja (svesni)**
- ✓ **Politika ustanove: odstupanja, pacijenti bez svesti, hitni pacijenti**
- ✓ **Različita zakonska regulativa u zemljama Evrope (usklađivanje)**
- ✓ **Rezultati EFLM WG-PRE II projekta (*Compilance of blood sampling procedures with the CLSI H3-A6*): kritični postupci: identifikacija pacijenata i obeležavanja**
- ✓ **EFLM WG-PRE: konsenzus smernice-procedura venepunkcije (*patient identification, specimen labeling*)**
- ✓ **Neophodna harmonizacija**



EFLM WG-PRE

Opinion Paper: Edmée C. van Dongen-Lases, Michael P. Cornes, Kjell Grankvist, Mercedes Ibarz, Gunn B.B. Kristensen, Giuseppe Lippi, Mads Nybo and Ana-Maria Simundic. **Patient identification and tube labelling – a call for harmonisation by the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) working group for the preanalytical phase (WG-PRE).** Clin Chem Lab Med.

6. Uzorkovanje kapilarne krvi; Uzorkovanje krvi kod dece i novorođenčadi

CLSI document H4-A6. Procedures and Devices for collection of Diagnostic Capillary Blood specimens; approved guideline, 6th ed. 2008.

WHO guidelines on drawing blood: best practices in phlebotomy (WHO, 2010).

Original papers

Nationwide survey of policies and practices related to capillary blood sampling in medical laboratories in Croatia

Jasna Lenicek Krleza

Children's Hospital Zagreb, Department of Laboratory Diagnostics, Zagreb, Croatia

- ✓ Ograničena primena
- ✓ Teškoće u izvođenju, mešanju; pravilan izbor lanceta-prst-peta/starost bebe
- ✓ Posebna pažnja na mesto punkcije u zavisnosti od starosi (peta, prst)!
- ✓ Mali volumen uzorka
- ✓ Problem detekcije hemolize i lipemije
- ✓ Neophodne preporuke zasnovane na dokazima

7. Upravljanje neprihvatljivim uzorcima

- **Neprihvatljivi uzorci:**
  - ◊ Pogršna identifikacija (pacijent, uzorak, uput)
  - ◊ Hemolizirani, lipemični uzorci
  - ◊ Koagulisani uzorci
  - ◊ Nepravilno izvađeni uzorci (pogrešna epruveta)
  - ◊ Neodgovarajući odnos krv-antikoagulans
  - ◊ Nedovoljno uzorka
  - ◊ Nepravilno transportovani i/ili čuvani uzorci
- **Nedostatak preporuka**
  - ◊ Prate se preporuke proizvođača za hemolizu, lipemiju, ikterus
- **Uvođenje EQA za pre-analitiku**
- **EFLM WG-PRE Pilot EQA za pre-analitiku u saradnji sa EQALM**

Review

Recommendations for detection and management of unsuitable samples in clinical laboratories

Giuseppe Lippi[1,*], Giuseppe Banfi[2], Mauro Buttarello[3], Ferruccio Ceriotti[4], Massimo Daves[5], Alberto Dolci[6], Marco Caputo[7], Davide Giavarina[8], Martina Montagnana[1], Valentino Miconi[9], Bruno Milanesi[10], Andrea Mosca[11], Margherita Morandini[12] and Gian Luca Salvagno[1] for the Italian Intersociety SIBioC-SIMeL-CISMEL Study Group on Extra-analytical Variability

[1] Sezione di Chimica Clinica, Dipartimento di Scienze Morfologico-Biomediche, Università degli Studi di Verona, Verona, Italy
[2] Istituto Galeazzi, Università di Milano, Milan, Italy
[3] Servizio di Medicina di Laboratorio, Azienda Ospedaliera di Padova, Padova, Italy
[4] Laboratorio Analisi, Istituto Scientifico H.S. Raffaele, Milan, Italy
[5] Laboratorio di Biochimica Clinica, Azienda Sanitaria di Bolzano, Bolzano, Italy
[6] Laboratorio Analisi Chimico Cliniche, A.O. Luigi Sacco, Milan, Italy
[7] Laboratorio di Patologia Clinica, Azienda Ospedaliera, Russolengo (VR), Italy
[8] Laboratorio di Chimica Clinica ed Ematologia, Ospedale S. Bortolo, Vicenza, Italy
[9] Laboratorio di Patologia Clinica, Ospedale di Arzignano, Vicenza, Italy
[10] Dipartimento di Medicina di Laboratorio, Azienda Ospedaliera, Desenzano del Garda (BS), Italy
[11] Dipartimento di Scienze e Tecnologie Biomediche, Università degli Studi di Milano, Milan, Italy
[12] Laboratorio di Patologia Clinica, Dipartimento di Medicina di Laboratorio, AOSMA, Pordenone, Italy

Abstract

A large body of evidence attests that quality programs developed around the analytical phase of the total testing process would only produce limited improvements, since the large majority of errors encountered in clinical laboratories still prevails within extra-analytical areas of testing, especially in manually intensive preanalytical processes. Most preanalytical errors result from system flaws and insufficient audit

*Corresponding author: Prof. Giuseppe Lippi, MD, Sezione di Chimica Clinica, Dipartimento di Scienze Morfologico-Biomediche, Università degli Studi di Verona, Ospedale Policlinico G.B. Rossi, Piazzale Scuro, 10, 37134 Verona, Italy
Phone: +39-049-8124388, Fax: +39-049-8201988,
E-mail: ...

of the operators involved in specimen collection and handling responsibilities, leading to an unacceptable number of unsuitable specimens due to misidentification, in vitro hemolysis, clotting, inappropriate volume, wrong container or contamination from infusive routes. Detection and management of unsuitable samples are necessary to overcome this variability. The present document, issued by the Italian Intersociety SIBioC-SIMeL-CISMEL (Society of Clinical Biochemistry and Clinical Molecular Biology – Society of Laboratory Medicine-Italian Committee for Standardization of Hematological and Laboratory Methods) Study Group on Extra-analytical Variability, reviews the major causes of unsuitable specimens in clinical laboratories, providing consensus recommendations for detection and management.
Clin Chem Lab Med 2007;45:728–36.

Keywords: audit; detection of unsuitable specimens; extra-analytical variability; guidelines and consensus recommendations; laboratory errors; specimen collection.

Introduction

Remarkable advances in biotechnology and informatics over recent years have contributed to revolutionizing the role and organization of clinical laboratories. Owing to a lack of operating procedures based on reliable scientific evidence or evidence-based laboratory medicine (EBLM), innovative tools were developed to allow broad diffusion of knowledge and experience in daily clinical practice, including systematic reviews, meta-analyses, decisional systems based on clinical models and economic analyses. The Italian legislative decree 229/99 and the 1998–2000 Italian National Healthcare Plan (NHP) both include clear recommendations to develop guidelines for more effective resource allocation and to guide physicians towards more appropriate utilization of laboratory resources. According to the indications of the Italian Istituto Superiore di Sanità (ISS), there are at least four potential approaches to produce valid recommendations: (a) guidelines, (b) recommendations issued by consensus conferences, (c) recommendations developed through principles of technology assessment, and (d) recommendations developed through the evaluation of clinical appropriateness and outcome.

Programs expressly developed to improve quality in the analytical phase of the total testing process, implementation of innovative and automated analytic techniques, development of specific

NKK
Norsk Klinisk-kjemisk Kvalitetssikring

http://www.nkk-ekv.com/

Review

How to conduct External Quality Assessment Schemes for the pre-analytical phase?

Gunn B.B. Kristensen[1*], Kristin Moberg Aakre[1,2], Ann Helen Kristoffersen[2,3], Sverre Sandberg[2,3]

[1]The Norwegian EQA Program (NKK), Bergen, Norway
[2]Laboratory of Clinical Biochemistry, Haukeland University Hospital, Bergen, Norway
[3]Noklus (Norwegian Centre for Quality Improvement of Primary Care Laboratories), University of Bergen, Bergen, Norway

*Corresponding author: gunn.kristensen@noklus.no

Biochemia Medica 2014;24(1):114–22

Norwegian EQA-program

RCPA Quality Assurance Programs Pty Limited

Key Incident Monitoring & Management Systems KIMMS

Quality Assurance Scientific and Education Committee (QASEC) of the Royal College of Pathologists of Australasia (RCPA) The Key Incident Monitoring & Management Systems (KIMMS) Available at: http://dataentry.rcpaqap.com.au/kimms/. Accessed November 4, 2013.

8. Indikatori kvaliteta

- **Objektivno merilo** kojim se procenjuju kritični zdravstveni segmenti: sigurnost pacijenata, efektivnost, nepristrasnost, pravovremenost, efikasnost.
- Usklađeni sa zahtevima **ISO 15189** i nacionalnim standardima; primenljivost na TTP.
- Praćenje kvaliteta TTP, identifikacija potencijalnih rizika, identifikacija postupaka koji zahtevaju dalja ispitivanja i unapređenja.
- **Karakteristike**: značajnost, primenljivost, izvodljivost, pravovremenost, naučna osnova, usmerenost ka pacijentu.

60th Anniversary 1952 - 2012

IFCC International Federation of Clinical Chemistry and Laboratory Medicine

Home | About us | IFCC Newsletter | eJIFCC | Press Room | Sitemap

Leading the fields of Clinical Chemistry and Laboratory Medicine worldwide

Executive Board and Council | Scientific Activities | **Education and Management** | Communications and Publications | Congresses and Conferences | Index by Subject

You are here: FrontpageHome » Education and Management » EMD Working Groups and Special Projects

Education and Management

- EMD Committees
- **EMD Working Groups and Special Projects**
- Visiting Lecturer Progamme (VLP)
- IFCC Professional Exchange Programmes (PEPs)
- Speaker's Bureau
- Webinars and Distance Learning Modules

EMD Working Groups and Special Projec

- Laboratory Errors and Patient Safety (WG-LEPS)
- Flow Cytometry (WG-FC)
- Developing Quality Competence in Medical Laboratorie

International Federation of Clinical Chemistry and Laboratory Medicine
Working Group "Laboratory Errors and Patient Safety"

Model of Quality Indicators: Key Processes

The Model of Quality Indicators has been updated on the basis of the recent Consensus Conference "Harmonization of Quality indicators in Laboratory Medicine: Why, How and When?", held in Padova in the October 2013, and a priority score was designed to highlight the value of the individual QI for assessing not only the quality of the service and possible effects on patient safety, but also the feasibility of data collection (order of priority: 1 = mandatory; 2 = important; 3 = suggested; 4 = valued).

Key Processes
Quality Indicators - Priority 1

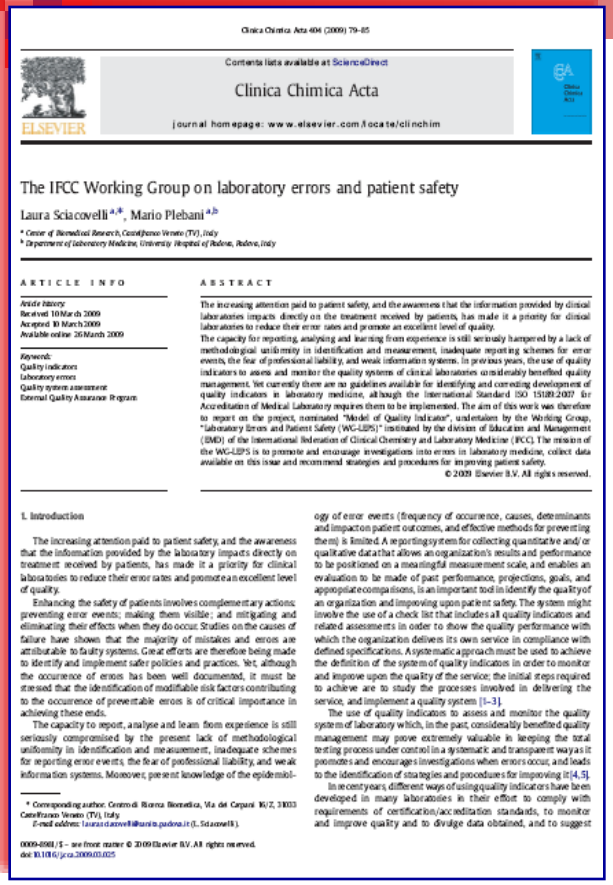
Quality Indicator	Code	Reporting Systems	Data Collection	Time
PRE-ANALYTICAL				
Misidentification errors	Pre-MisR	Percentage of: Number of misidentified requests/ Total number of requests.	a) count misidentified requests b) count total number of requests c) calculate percentage	Data collection: Every day; Input data: Monthly
	Pre-MisS	Percentage of: Number of misidentified samples/ Total number of samples.	a) count misidentified samples b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly
	Pre-Iden	Percentage of: Number of samples with fewer than 2 identifiers initially supplied/ Total number of samples.	a) count samples with fewer than 2 identifiers initially supplied b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly
	Pre-UnlS	Percentage of: Number of unlabelled samples/ Total number of samples.	a) count unlabelled samples b) count total number of samples c) calculate percentage	Data collection: Every day; Input data: Monthly
Test transcription errors	Pre-OutpTN	Percentage of: Number of outpatients requests with erroneous data entry (test name)/ Total number of outpatients requests.	a) count outpatients requests with errors concerning test name (misinterpreted test) b) count total number of outpatients requests c) calculate percentage	Data collection: A week per month; Input data: Monthly
	Pre-OutpMT	Percentage of: Number of outpatients requests with erroneous data entry (missed test)/ Total number of outpatients requests.	a) count outpatients requests with errors concerning missed tests (required tests but not registered) b) count total number of outpatients requests	Data collection: A week per month; Input data: Monthly

KEY PROCESSES: 45

OUTCOME MEASURES: 3

SUPPORT PROCESSES: 4

Nivo prioriteta: 1-4



Clinica Chimica Acta 404 (2009) 79–85

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

The IFCC Working Group on laboratory errors and patient safety

Laura Sciacovelli [a,*], Mario Plebani [a,b]

[a] Center of Biomedical Research, Casalpusterlengo (TV), Italy
[b] Department of Laboratory Medicine, University Hospital of Padova, Padova, Italy

ARTICLE INFO

Article history:
Received 10 March 2009
Accepted 10 March 2009
Available online 26 March 2009

Keywords:
Quality indicators
Laboratory errors
Quality system assessment
External Quality Assurance Program

ABSTRACT

The increasing attention paid to patient safety, and the awareness that the information provided by clinical laboratories impacts directly on the treatment received by patients, has made it a priority for clinical laboratories to reduce their error rates and promote an excellent level of quality.
The capacity for reporting, analysing and learning from experience is still seriously hampered by a lack of methodological uniformity in identification and measurement, inadequate reporting schemes for error events, the fear of professional liability, and weak information systems. In previous years, the use of quality indicators to assess and monitor the quality systems of clinical laboratories considerably benefited quality management. Yet currently there are no guidelines available for identifying and correcting development of quality indicators in laboratory medicine, although the International Standard ISO 15189:2007 for Accreditation of Medical Laboratory requires them to be implemented. The aim of this work was therefore to report on the project, nominated "Model of Quality Indicator", undertaken by the Working Group, "Laboratory Errors and Patient Safety (WG-LEPS)" instituted by the division of Education and Management (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The mission of the WG-LEPS is to promote and encourage investigations into errors in laboratory medicine, collect data available on this issue and recommend strategies and procedures for improving patient safety.

1. Introduction

The increasing attention paid to patient safety, and the awareness that the information provided by the laboratory impacts directly on treatment received by patients, has made it a priority for clinical laboratories to reduce their error rates and promote an excellent level of quality.

Enhancing the safety of patients involves complementary actions: preventing error events; making them visible; and mitigating and eliminating their effects when they do occur. Studies on the causes of failure have shown that the majority of mistakes and errors are attributable to faulty systems. Great efforts are therefore being made to identify and implement safer policies and practices. Yet, although the occurrence of errors has been well documented, it must be stressed that the identification of modifiable risk factors contributing to the occurrence of preventable errors is of critical importance in achieving these ends.

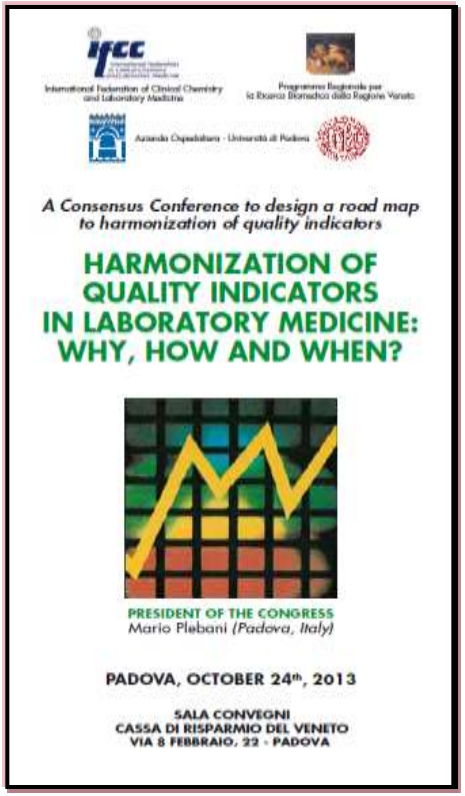
The capacity to report, analyse and learn from experience is still seriously compromised by the present lack of methodological uniformity in identification and measurement, inadequate schemes for reporting error events, the fear of professional liability, and weak information systems. Moreover, present knowledge of the epidemiology of error events (frequency of occurrence, causes, determinants and impact on patient outcomes, and effective methods for preventing them) is limited. A reporting system for collecting quantitative and/or qualitative data that allows an organization's results and performance to be positioned on a meaningful measurement scale, and enables an evaluation to be made of past performance, projections, goals, and appropriate comparisons, is an important tool in identify the quality of an organization and improving upon patient safety. The system might involve the use of a check list that includes all quality indicators and related assessments in order to show the quality performance with which the organization delivers its own service in compliance with defined specifications. A systematic approach must be used to achieve the definition of the system of quality indicators in order to monitor and improve upon the quality of the service; the initial steps required to achieve are to study the processes involved in delivering the service, and implement a quality system [1–3].

The use of quality indicators to assess and monitor the quality system of laboratory which, in the past, considerably benefited quality management may prove extremely valuable in keeping the total testing process under control in a systematic and transparent ways it promotes and encourages investigations when errors occur, and leads to the identification of strategies and procedures for improving it[4,5].

In recent years, different ways of using quality indicators have been developed in many laboratories in their effort to comply with requirements of certification/accreditation standards, to monitor and improve quality and to divulge data obtained, and to suggest

* Corresponding author. Centro di Ricerca Biomedica, Via dei Carpani 10/Z, 31033 Casalpusterlengo (TV), Italy.
E-mail address: laura.sciacovelli@unipd.it (L. Sciacovelli).

0009-8981/$ – see front matter © 2009 Elsevier B.V. All rights reserved.
doi:10.1016/j.cca.2009.03.025



International Federation of Clinical Chemistry and Laboratory Medicine

Programma Regionale per la Ricerca Biomedica della Regione Veneto

Azienda Ospedaliera - Università di Padova

A Consensus Conference to design a road map to harmonization of quality indicators

HARMONIZATION OF QUALITY INDICATORS IN LABORATORY MEDICINE: WHY, HOW AND WHEN?

PRESIDENT OF THE CONGRESS
Mario Plebani *(Padova, Italy)*

PADOVA, OCTOBER 24th, 2013

SALA CONVEGNI
CASSA DI RISPARMIO DEL VENETO
VIA 8 FEBBRAIO, 22 - PADOVA

Clin Chem Lab Med 2011; 49(6):836–844 © 2011 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2011.128

Quality Indicators in Laboratory Medicine: from theory to practice

Preliminary data from the IFCC Working Group Project "Laboratory Errors and Patient Safety"

J Med Biochem 31: 174–183, 2012

Review article
Pregledni članak

QUALITY INDICATORS OF THE PRE-ANALYTICAL PHASE

INDIKATORI KVALITETA PREANALITIČKE FAZE

Nada Majkić-Singh, Zorica Šumarac

Institute of Medical Biochemistry, Clinical Centre of Serbia and Pharmaceutical Faculty, University of Belgrade, Belgrade, Serbia

DE GRUYTER

DOI 10.1515/cclm-2012-0582 — Clin Chem Lab Med 2013; 51(1): 187–195

Mini Review

Mario Plebani*, Maria Laura Chiozza and Laura Sciacovelli

Towards harmonization of quality indicators in laboratory medicine

DE GRUYTER

DOI 10.1515/cclm-2014-0342 — Clin Chem Lab Med 2014; 52(7): 951–958

Opinion Paper

Mario Plebani*, Michael L. Astion, Julian H. Barth, Wenxiang Chen, César A. de Oliveira Galoro, Mercedes Ibarz Escuer, Agnes Ivanov, Warren G. Miller, Penny Petinos, Laura Sciacovelli, Wilson Shcolnik, Ana-Maria Simundic and Zorica Sumarac

Harmonization of quality indicators in laboratory medicine. A preliminary consensus

CLSI document GP35-P. Development and Use of Quality Indicators for Process Improvement and Monitoring of Laboratory Quality; Proposed Guideline. 2009.

Giuseppe Lippi et al. Preanalytical quality improvement. In pursuit of harmony, on behalf of European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) ***Working group for Preanalytical Phase (WG-PRE).***
Clin Chem Lab Med 2015; 53(3): 357–370.

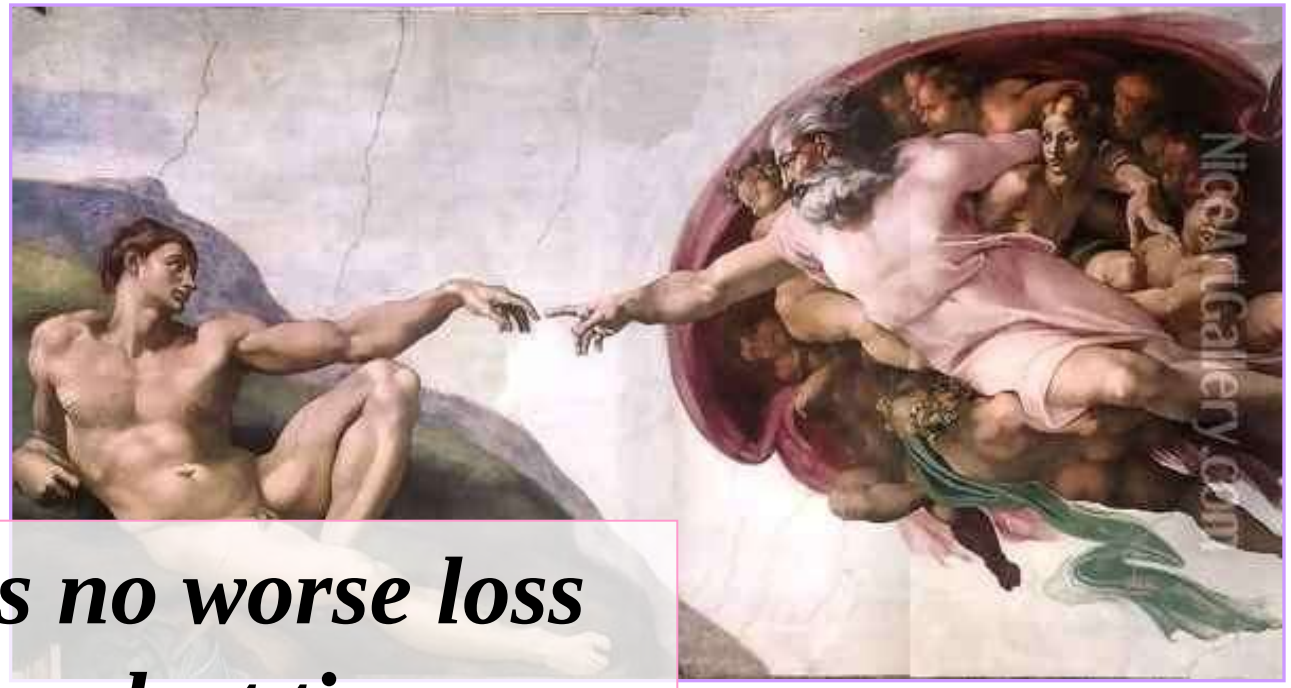
- **Buduće aktivnosti će imati za cilj povećavanje svesti svih učesnika i isticanje značaja indikatora kvaliteta u cilju unapređenja laboratorijske dijagnostike i bezbednosti pacijenata.**

- **Pojednostavljivanje postojećeg modela indikatora kvaliteta identifikovanjem indikatora kvaliteta koji će se pratiti kao obavezujući je razuman kompromis za laboratorije širom sveta.**


EFLM
EUROPEAN FEDERATION
OF CLINICAL CHEMISTRY
AND LABORATORY MEDICINE
3rd EFLM-BD
European Conferen

... dalje aktivnosti EFLM WG-PRE

- Standardizacija i harmonizacija pre-analitičkih postupaka.
- Saradnja sa ostalim EFLM WGs: WG for Harmonization of the Total Testing Process (WG-H), WG-Postanalytical Phase, WG Guidelines, WG-Accreditation and ISO/CEN standards.
- Saradnja sa nacionalnim društvima EFLM.
- Uključivanje svih laboratorijskih profesionalaca, proizvođača opreme i tela koja izdaju standarde kako bi se definisali univerzalno primenljivi standardi za pre-analitičku fazu i implementirali na globalnom nivou.
- Dalja promocija značaja pre-analitičke faze kroz organizaciju skupova i edukaciju svih učesnika zdravstvenog sistema u Evropi i širom sveta...



There is no worse loss than a lost time

Michelangelo Buonarroti (1475-1564)