The pre-analytical phase – role of EQAS program

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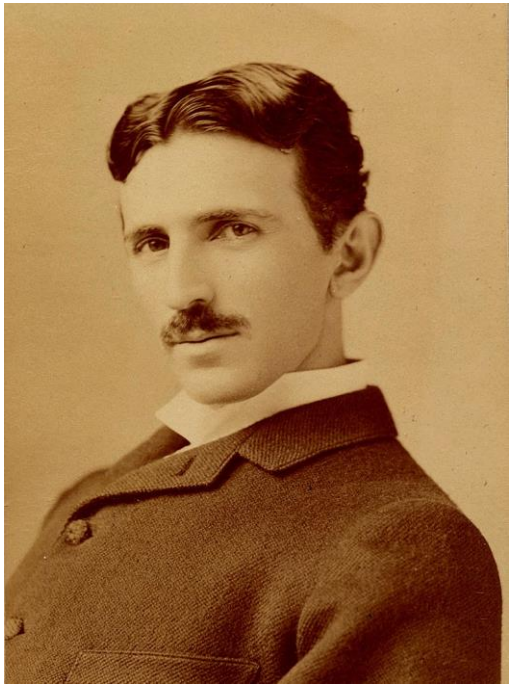
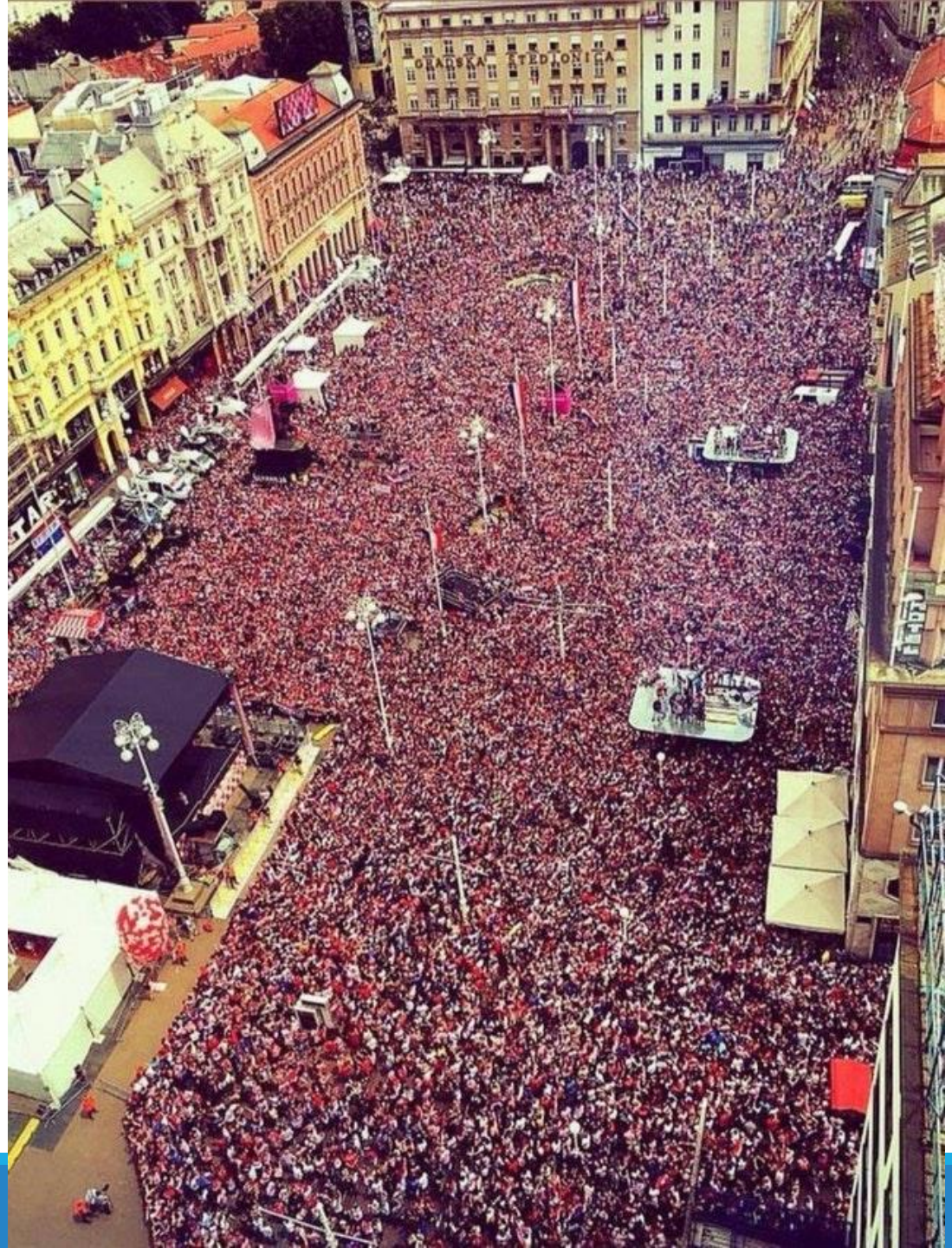
MAMMA MIA!
HERE WE GO AGAIN




GRADSKA KAVEDONICA

5th EFLM Conference on Preanalytical Phase

Preanalytical challenges - time for solutions

Zagreb (Croatia), 22-23 March 2019

EFLM
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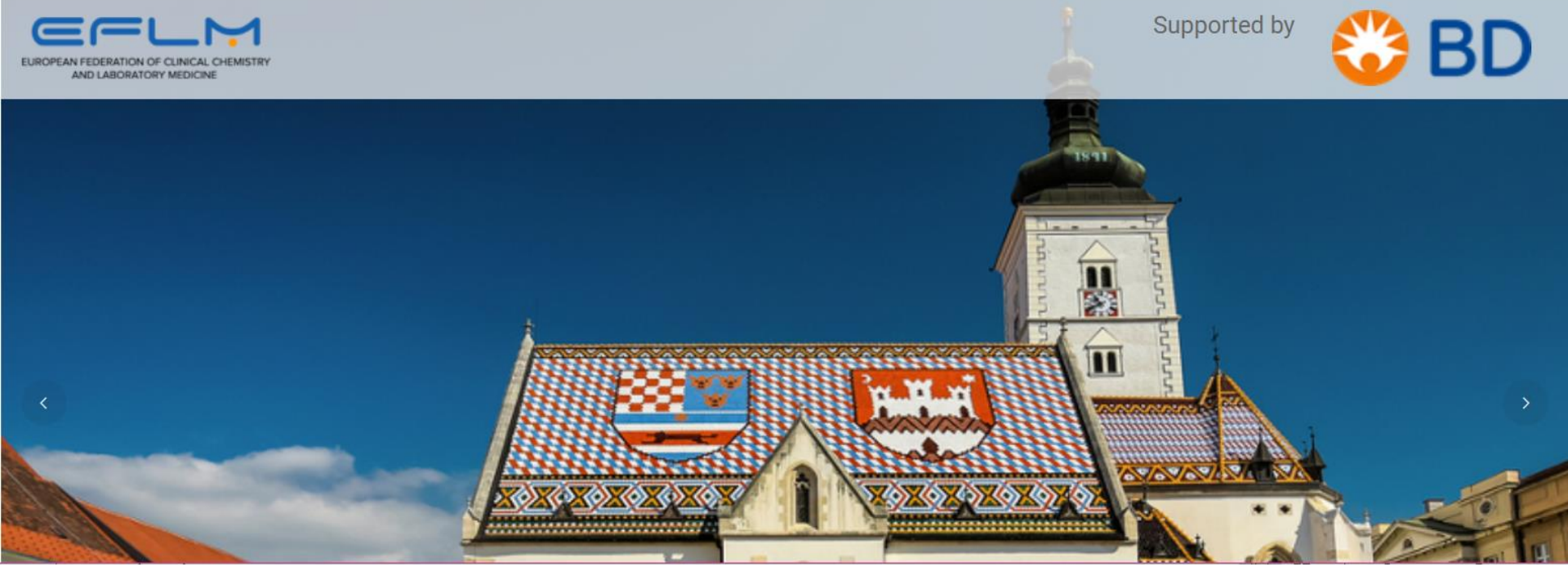

Why EQA?
Types of EQA?
Benefits and challenges?
Some examples

Laboratory medicine has no borders

- we use same tubes
- we use same methods
- we use same instruments
- we use same/similar reference ranges

Clinical guidelines

Type 2 diabetes in adults: management

NICE guideline
Published: 2 December 2015
nice.org.uk/guidance/ng28

European Heart Journal Advance Access published May 20, 2016

ESC GUIDELINES

European Heart Journal
doi:10.1093/eurheartj/ehw128

2016 ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure

The Task Force for the diagnosis and treatment of acute and chronic heart failure of the European Society of Cardiology (ESC)

ICSI Institute for Clinical Systems Improvement

Health Care Guideline

Venous Thromboembolism Diagnosis and Treatment

JAMA The Journal of the American Medical Association

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February 23, 2016, Vol 315, No. 8 >

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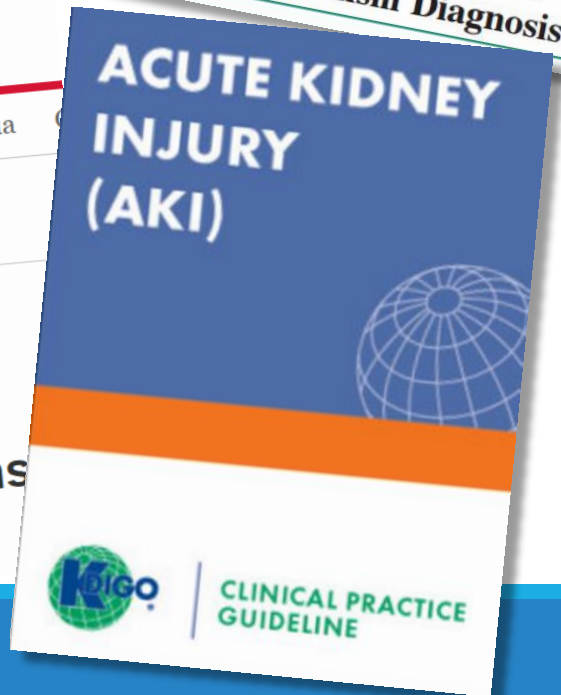
Special Communication | February 23, 2016

CARING FOR THE CRITICALLY ILL PATIENT

The Third International Consensus Definitions for Sepsis and Septic Shock (Sepsis-3)

FREE



Unless all procedures are…

- reliable
- reproducible

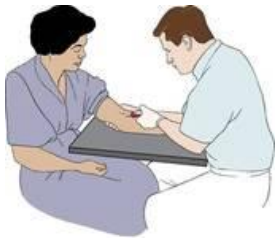
} throughout the total testing process

(How) can we use same cut-off values to diagnose diseases?

Lippi G, Simundic AM, Rodrigues-Manas L, Bossuyt P, Banfi P. Standardizing in vitro diagnostics tasks in clinical trials: a call for action. Ann Transl Med 2016, doi: 10.21037/atm.2016.04.10

Are preanalytical practices comparable?

- between continents?
- between countries?
- between labs?
- between invdividuals?



Perspective

Standardizing in vitro diagnostics tasks in clinical trials: a call for action

Giuseppe Lippi[1,2], Ana-Maria Simundic[1,3], Leocadio Rodrigues-Manas[4], Patrick Bossuyt[5], Giuseppe Banfi[6]

A call for:

Standardization of preanalytical practices for clinical trials is essential

Lippi G, Simundic AM, Rodrigues-Manas L, Bossuyt P, Banfi P. Standardizing in vitro diagnostics tasks in clinical trials: a call for action. Ann Transl Med 2016, doi: 10.21037/atm.2016.04.10

Standardization

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.

http://www.businessdictionary.com

Harmonization

The process of

recognizing, understanding, and explaining differences

while taking steps to achieve uniformity of results,

or at a minimum, a means of conversion of results

such that

different groups can use the data interchangeably.

Clinical and Laboratory Standards Institute

External quality assessment (EQA)

- provides confidence that the results are comparable.
- is a tool for:
  - achieving comparability and reducing variation
  - monitoring laboratory performance and maintaining quality
  - identifying gaps and targeting training needs

Medical laboratories - Particular requirements for quality and competence (ISO 15189:2012)

5.6.4.

External quality assessment programmes should, as far as possible, provide clinically relevant challenges that mimic patient samples and have the effect of checking the entire examination process, including pre-and post-examination procedures.

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

- Type I: Registration of procedures
- Type II: Circulation of samples simulating errors
- Type III: Registration of errors/adverse events

Kristensen GB, Aakre KM, Kristoffersen AH, Sandberg S. How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochem Med (Zagreb). 2014;24(1):114-22.

Type I preanalytical EQA

Surveys (questionnaires)

- questions about policies and procedures,
- preanalytical cases

Advantages

- low cost
- easy to distribute widely

Table 1. Examples of ongoing pre-analytical EQAS.

Method	Pre-analytical issues studied	Frequency	Performed by
	Type I. Registration of procedures		
Registration of procedures *via* web-based multiple choice questionnaire	Clinical chemistry: Hemolysis, stability of samples (2011) Hemostasis testing: Phlebotomy, sample handling and sample acceptance (2012) Glucose: Sample handling and sample treatment (2013)	1 x year	Norwegian Clinical Chemistry EQA program (NKK) Not published
Registration of procedures *via* web-based multiple choice questionnaire	Hemostasis testing	2 x year	ECAT/INSTAND 2011 (25)
Clinical case-based European EQAS covering pre-analytical, analytical and post-analytical phase. Five sets of multi-specimen samples	Porphyria: Case history based test ordering	2 x year	Norwegian Porphyria Centre (NAPOS)/The European Porphyria Network (EPNET (26)
Registration of procedures *via* web-based multiple choice questionnaire	5 general pre- and post-analytical questions, 5 questions within specific disciplines (i.e. coagulation, hematology, immunology, microbiology)	2 x year	* Quality Control Center Switzerland (CSCQ)
Registration of procedures *via* multiple choice questionnaire	Urine chemistry, clinical chemistry	4 x year	* WEQAS
Registration of procedures *via* web-based multiple choice questionnaire	Hematology, sample handling	1 x year	* INSTAND

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PREANALYTICAL EXTERNAL QUALITY ASSESSMENT SURVEY

*The Prenanalytical EQA Survey is **FREE** to all biorepositories.*

This is a **Preanalytical External Quality Assessment** scheme for the **pre-analytical phase in biorepositories**. It is based on collection of information about pre-analytical biorepository procedures (Biochemia Medica 2014;24:114-122). It has been developed by the **ISBER Biospecimen Science Working Group**, and approved by the ISBER Education and Training Committee. The scheme is applicable to all biorepositories, both clinical and environmental.

PROCEDURES

2. Do you have written procedures to **define default pre-analytical conditions**?

"*Default*": A particular setting for a pre-analytical variable that is assigned in a standard way and remains in effect unless canceled or modified by the operator (e.g. default tissue fixation time being 24 hrs)

- Yes
- No

3. Do you have written procedures to **record pre-analytical variables**? (eg SPREC or in any other way)?

- Yes
- No

4. Do you have written procedures to **track and report pre-analytical non-conformities?**

"*Non-Conformities*": any procedure or step in a procedure which does not conform to the standard procedure

- Yes
- No

5. Do you have written procedures to **track temperature excursions during storage?**

- Yes
- No

Type I Preanalytical EQA in Croatia – *the origins*

Izvorni znanstveni članak **Original scientific article**

Učestalost pojedinih postupaka izvananalitičke faze laboratorijske dijagnostike u Hrvatskoj - presječno anketno istraživanje

Self reported routines and procedures for the extra-analytical phase of laboratory practice in Croatia - cross-sectional survey study

Lidija Bilić-Zulle[1,2*], Ana-Maria Šimundić[3], Vesna Šupak Smolčić[1], Nora Nikolac[3], Lorena Honović[4]

Bilic Zulle L, Simundic AM, Supak Smolcic V, Nikolac N, Honovic L. Biochem Med 2010;20:64-74

Type I Preanalytical EQA in Croatia – *the origins*

Question	N	Never (%)	Rarely (%)	Often (%)	Always (%)
Questions on criteria of sample acceptance					
*Already coagulated samples are centrifuged shorter than required.	143	64	26	8	2
The sample for analysis will not be accepted, unless the tube containing anticoagulant is filled up to the mark.	143	4	26	20	50
*If potassium concentration in a slightly hemolytic serum is normal, new blood sampling will not be requested.	143	29	29	24	18
Blood samples for serum are centrifuged at least 10 minutes at 3500 rpm.	144	4	0	9	87
*Complete blood cells count from a slightly coagulated sample will be performed carefully observing that the coagulum is not aspirated.	140	84	9	2	5
If the samples for the potassium measurement are even slightly hemolytic, new sampling will be requested.	142	8	21	24	47

Bilic Zulle L, Simundic AM, Supak Smolcic V, Nikolac N, Honovic L. Biochem Med 2010;20:64-74

Type I Preanalytical EQA in Croatia – *the origins*

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Lidija Bilić-Zulle[1,2*], Ana-Maria Šimundić[3], Vesna Šupak Smolčić[1], Nora Nikolac[3], Lorena Honović[4]

Conclusions:

Results indicate the **urgent need for improving activities in the extra-analytical** phase, especially phlebotomy procedures. Reinforced education of all the personnel involved, **appropriate recording and monitoring** of extra-analytical phase is necessary to reach high quality standards.

Bilic Zulle L, Simundic AM, Supak Smolcic V, Nikolac N, Honovic L. Biochem Med 2010;20:64-74

2014 - First preanalytical EQA

In 2014 - 1 pilot round per year:

- Modul 10 - pre-analytical
- Modul 11 - post-analytcal

From 2015 - 3 rounds per year:

- Modul 10 - pre-analytical
- Modul 11 - post-analytcal

Preanalytical EQA (2014)

3 preanalytical cases:

- incorrect collection of 24h urine
- incorrect sampling time for the OGTT - prolonged fasting.
- request for potassium in slightly hemolyzed sample

- questions related to sample acceptance criteria

Preanalytical EQA (2014)

- Questions
  - multiple choice
  - only one answer was correct according to current recommendations and standards of good laboratory practice in Croatia.

- Individualized reports:
  - absolute numbers and percentages of respondents.
  - educative comments.

Case 1 – description (2014)

- patient arrives to the lab in the morning (8:00 am).
- creatinine clearance is requested.
- patient brings 24h urine (1500 mL) in a clean plastic bottle
- patient says that he had collected entire urine with the exception of the first morning urine on the day of arrival to the lab (1 - 2 dL) because the urine container was full

Possible choices

Please select response which best describes the policy and procedure with a sample in your laboratory:

Number of participants (N=151) Listed responses:		Frequency of response: N (%)
a)	the sample is accepted for testing, and the result be issued without note	0 (0)
b)	the sample is not acceptable, but is accepted for testing, and the result be issued with the note	9 (6)
c)	the sample is not acceptable and is not accepted for testing	136 (90)
d)	although the sample is not acceptable, in exceptional situations may be accepted if the user* explicitly requires it	6 (4)

With courtesy of Jasna Leniček Krleža, CROQALM Chair

Hrvatsko društvo za medicinsku biokemiju i laboratorijsku medicinu
Croatian society of medical biochemistry and laboratory medicine

Hrvatski centar za vrednovanje kvalitete u laboratorijskoj medicini
Croatian Centre for Quality Assessment in Laboratory Medicine

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E-mail: hdmblm@hdmblm.hr • www.hdmblm.hr, OIB/VAT: 37373470182

CASE 1

Listed responses	N= 151		Your respond	Preferred response
	number	%		
the sample is accepted for testing, the result be issued without note	0	0,00		
the sample is accepted for testing, the result be issued with the note	9	5,96		
the sample is not acceptable and is not accepted for testing	136	90,07		●
although the sample is not acceptable, in exceptional situations may be accepted if the user* explicitly requires it	6	3,97	●	

*user: physician who requested testing or patient

With courtesy of Jasna Leniček Krleža, CROQALM Chair

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MODUL: **MODUL 10 - PREDANALITIČKA FAZA LABORATORIJSKOG RADA**

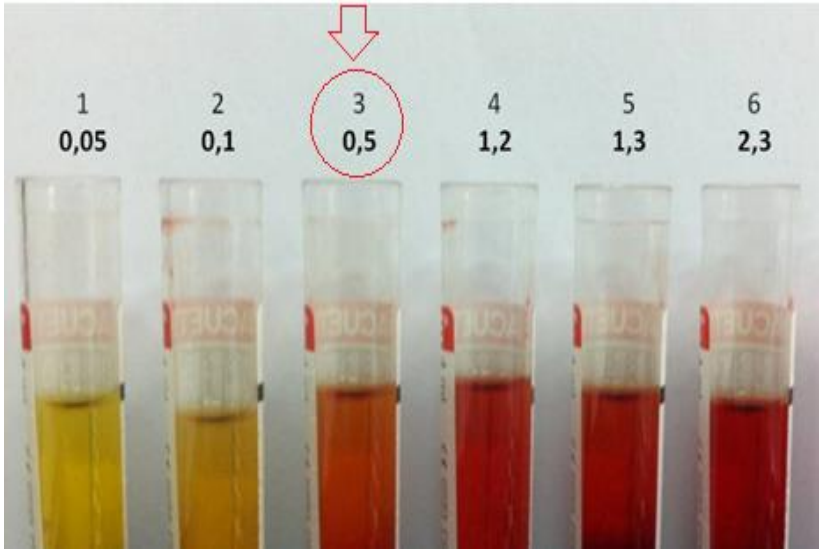
ANALIZA REZULTATA

U modulu 10 sudjelovalo je 161/180 laboratorija što iznosi 89,44%.
U prvom slučaju poželjni odgovor c) odabralo je 136/151 = 90,07% laboratorija. Pravilno prikupljanje uzorka, koje uključuje cjelokupnu količinu mokraće izmokrenu unutar 24 sata, neophodno je za izdavanje rezultata za klirens kreatinina. Odstupanje od definiranog protokola sakupljanja 24-satne mokraće može dovesti do značajnih varijacija u rezultatu.
U drugom slučaju poželjni odgovor c) odabralo je 134/160 = 83,75% laboratorija. Prema svim važećim preporukama stručnih društava, OGTT se izvodi ujutro između 7.00 i 9.00 sati. Izvođenje ovog testa nakon produljenog gladovanja može dovesti do značajnih varijacija u rezultatu.
U trećem slučaju poželjni odgovor c) odabralo je 134/159 = 85,53% laboratorija. Kalij je jedan od parametara čija je koncentracija promijenjena čak i pri najmanjoj hemolizi uzorka. S obzirom da stupanj hemolize nije u linearnom odnosu s promjenom koncentracije kalija, nemoguće je iz koncentracije slobodnog hemoglobina procijeniti kolika će biti promjena koncentracije kalija. Stoga se preporučuje odbacivanje hemolitičnog uzorka za mjerenje koncentracije kalija. Koncentracija kalija u hemolitičnom uzorku je nepouzdana.
Za postupanje s hemolitičnim uzorcima, većina laboratorija koristi preporuke HKMB (134/161 = 83,23%), a tek manji broj preporuke proizvođača (24/161 = 14,91%) ili vlastite rezultate verifikacije interferencija (2/161 = 1,24%). Za neke parametre (K, LD, AST) interferencija hemolize neovisna je o metodi, dok su za pojedine parametre (kolesterol, trigliceridi, bilirubin, magnezij) jačina i stupanj interferencije ovisni o uporabljenom reagensu. Utjecaj hemolize na mjerenje koncentracije ovakvih parametara različit je kod različitih proizvođača reagensa.
Rezultati prvog modula za predanalitičku fazu laboratorijskog rada pokazuju vrlo dobro slaganje postupaka s važećim preporukama i stručnim standardima. Laboratoriji se potiču da postupanje s uzorcima s interferencijama prilagode specifičnim metodama koje koriste u laboratoriju te da za granične vrijednosti za odbacivanje nesukladnih uzoraka koriste podatke dobivene od proizvođača. Zbog mogućeg neslaganja deklariranih vrijednosti i rezultata dobivenih u laboratoriju, poželjno je napraviti verifikaciju deklariranih podataka.

With courtesy of Jasna Leniček Krleža, CROQALM Chair

Case 3 – description (2014)

The laboratory has received the blood sample with a request for serum potassium measurement. After centrifugation, sample is slightly hemolyzed (free hemoglobin concentration of 0.5 g/L; Figure 1: tubes No. 3).



Possible choices

Please select response which best describes the policy procedure with a sample in your laboratory:

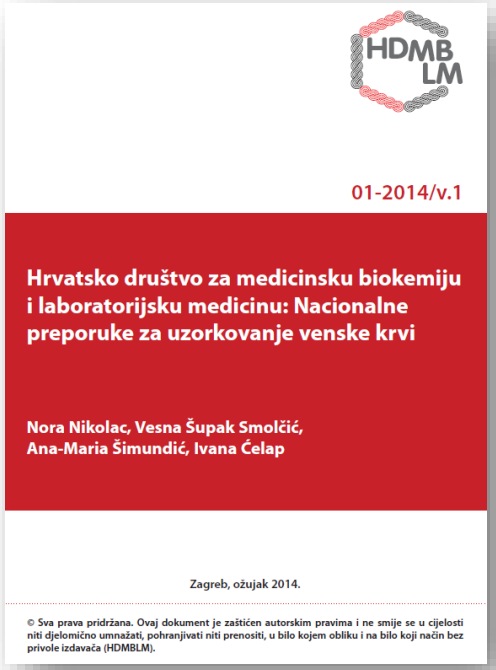
Number of participants (N=159) Listed responses:		Frequency of response: N (%)
a)	the sample is accepted for testing, and the result be issued without notice	0 (0)
b)	the sample is not acceptable, but is accepted for testing, and the result be issued with the note	15 (9)
c)	the sample is not acceptable and is not accepted for testing	136 (86)
d)	although the sample is not acceptable, in exceptional situations may be accepted if the user* explicitly requires it	8 (5)

With courtesy of Jasna Leniček Krleža, CROQALM Chair

Preanalytical EQA (2015)

Compliance with National recommendation for venous blood sampling (published 2014):

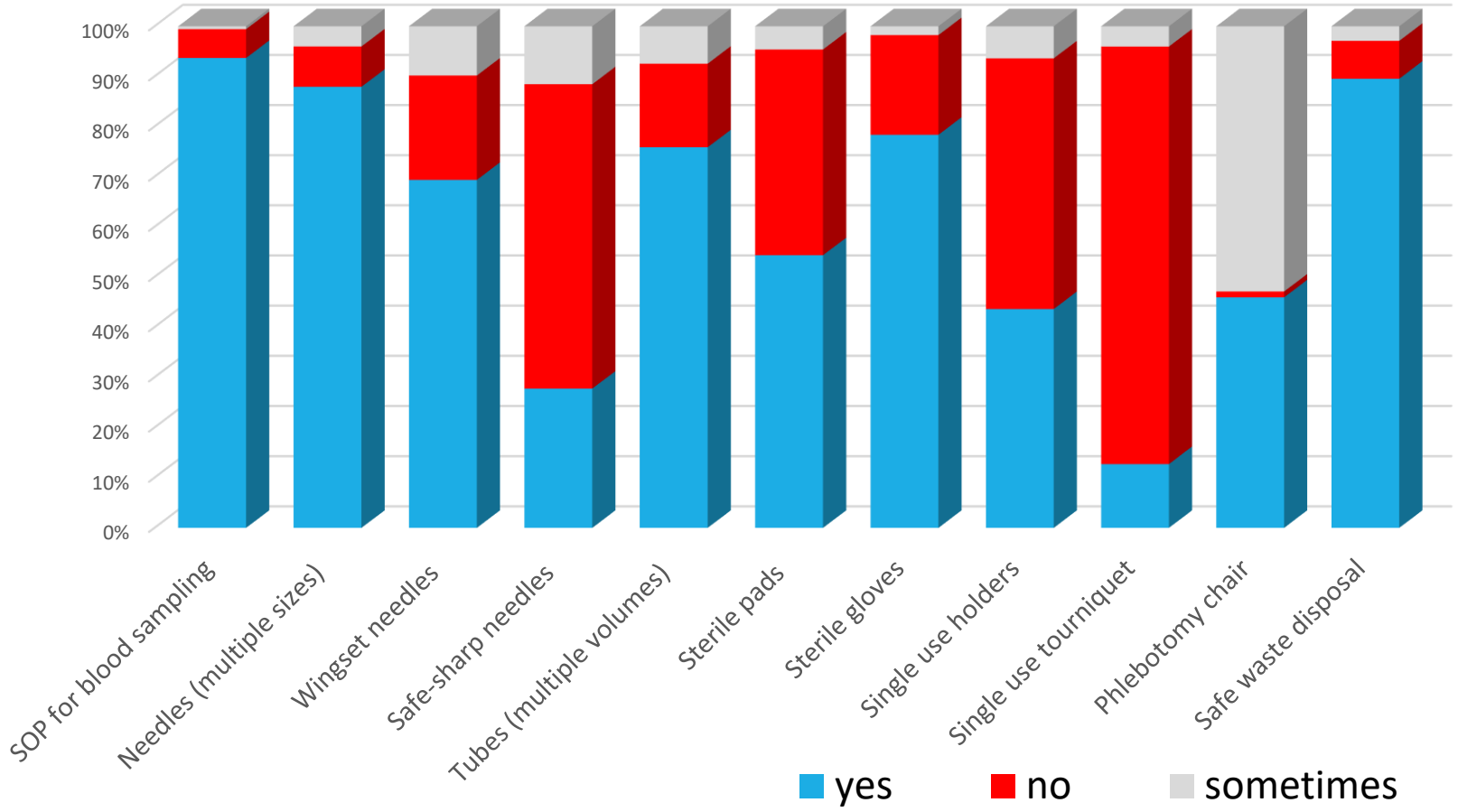
- 1/2015 - consumables, materials and equipment
- 2/2015 - patient identification
- 3/2015 – venous blood sampling
- 1/2016 – sample transport and delivery



Nikolac N, Krleza JL, Simundic AM. Preanalytical external quality assessment of the Croatian Society of Medical Biochemistry and Laboratory Medicine and CROQALM: finding undetected weak spots. Biochem Med. 2017;27(1):131-43.

Preanalytical EQA (1/2015)

Consumables, materials and equipment



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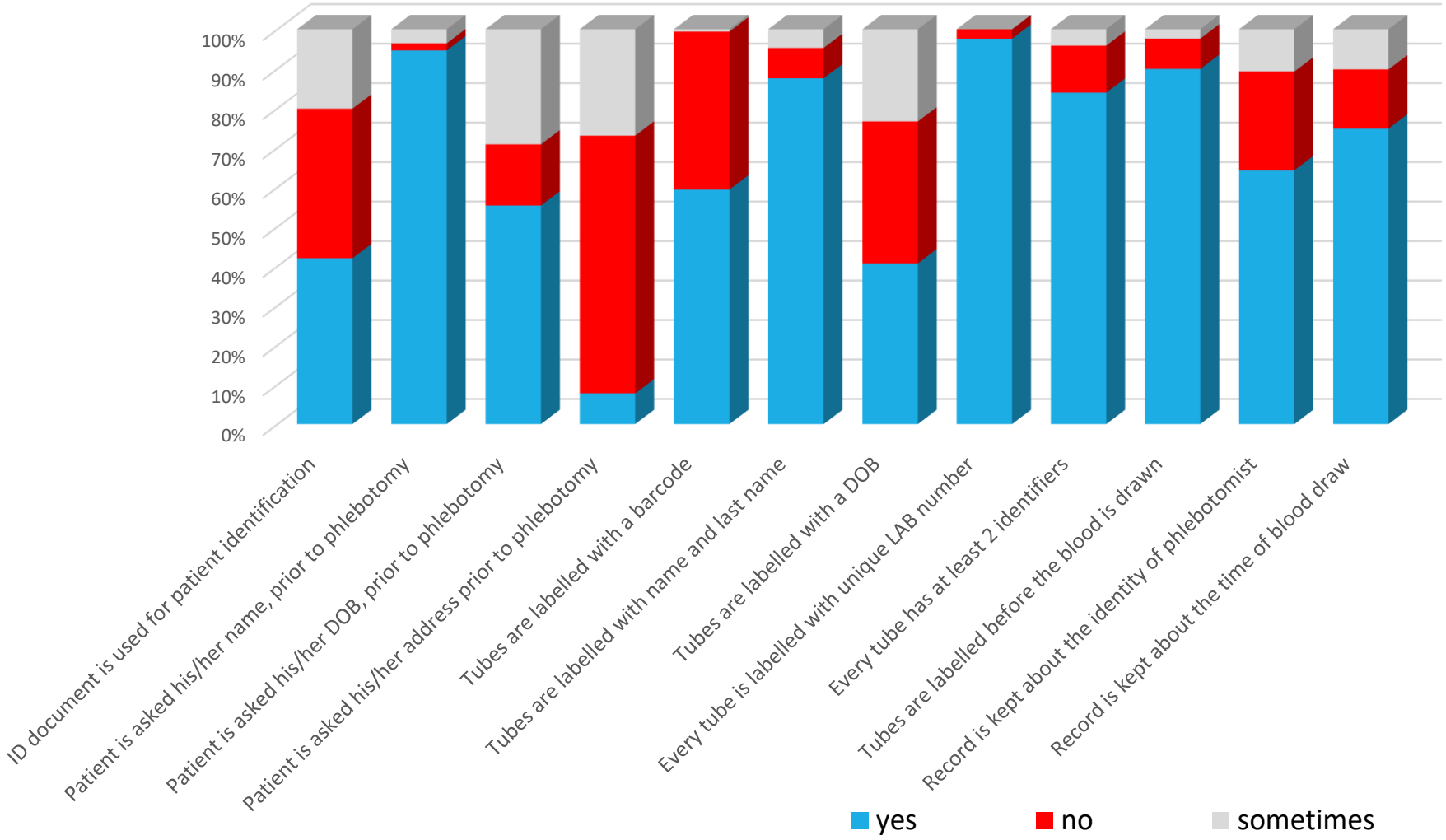
Preanalytical EQA (2/2015)

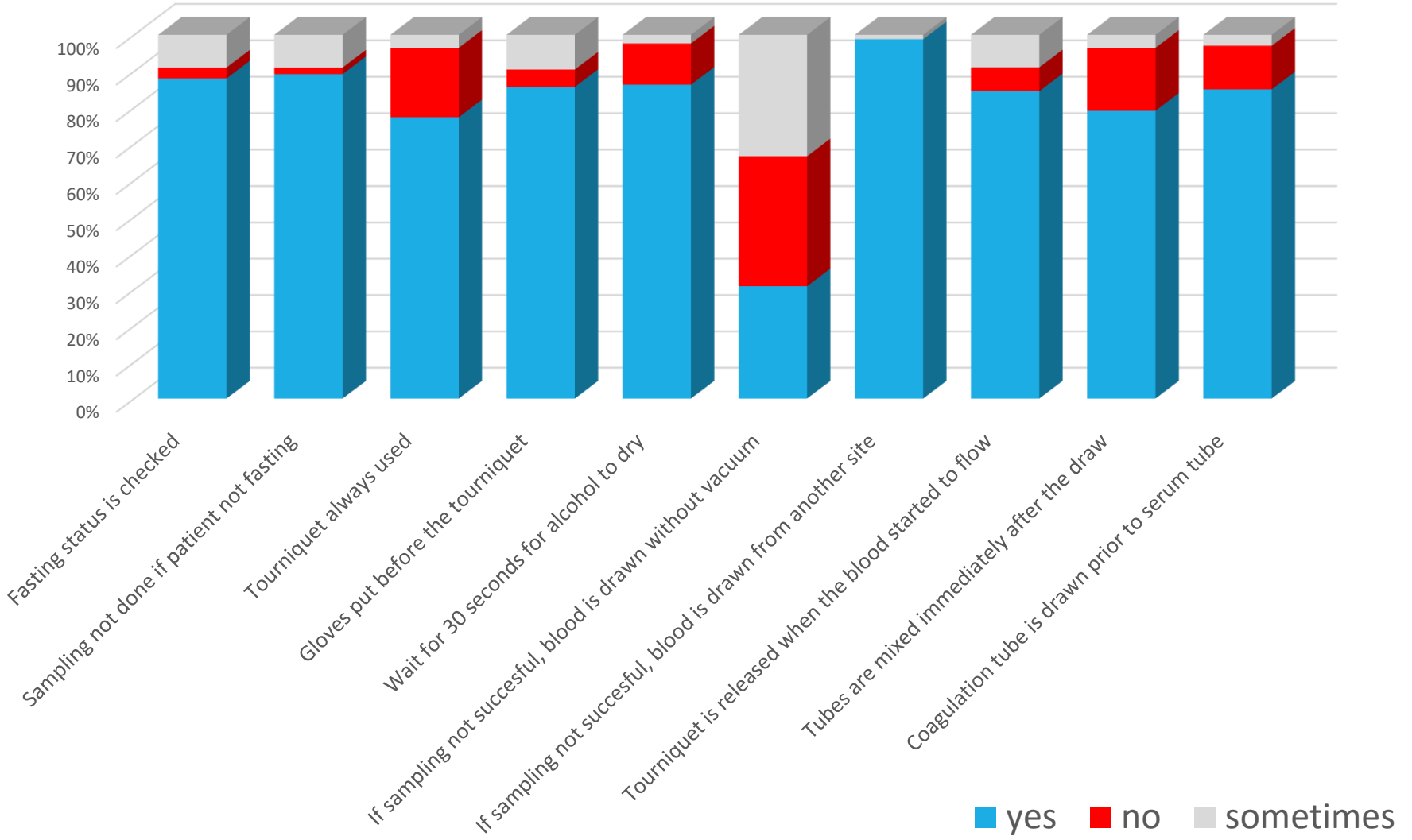
Patient identification



Nikolac N, Krleza JL, Simundic AM. Preanalytical external quality assessment of the Croatian Society of Medical Biochemistry and Laboratory Medicine and CROQALM: finding undetected weak spots. Biochem Med. 2017;27(1):131-43.

Preanalytical EQA (3/2015)

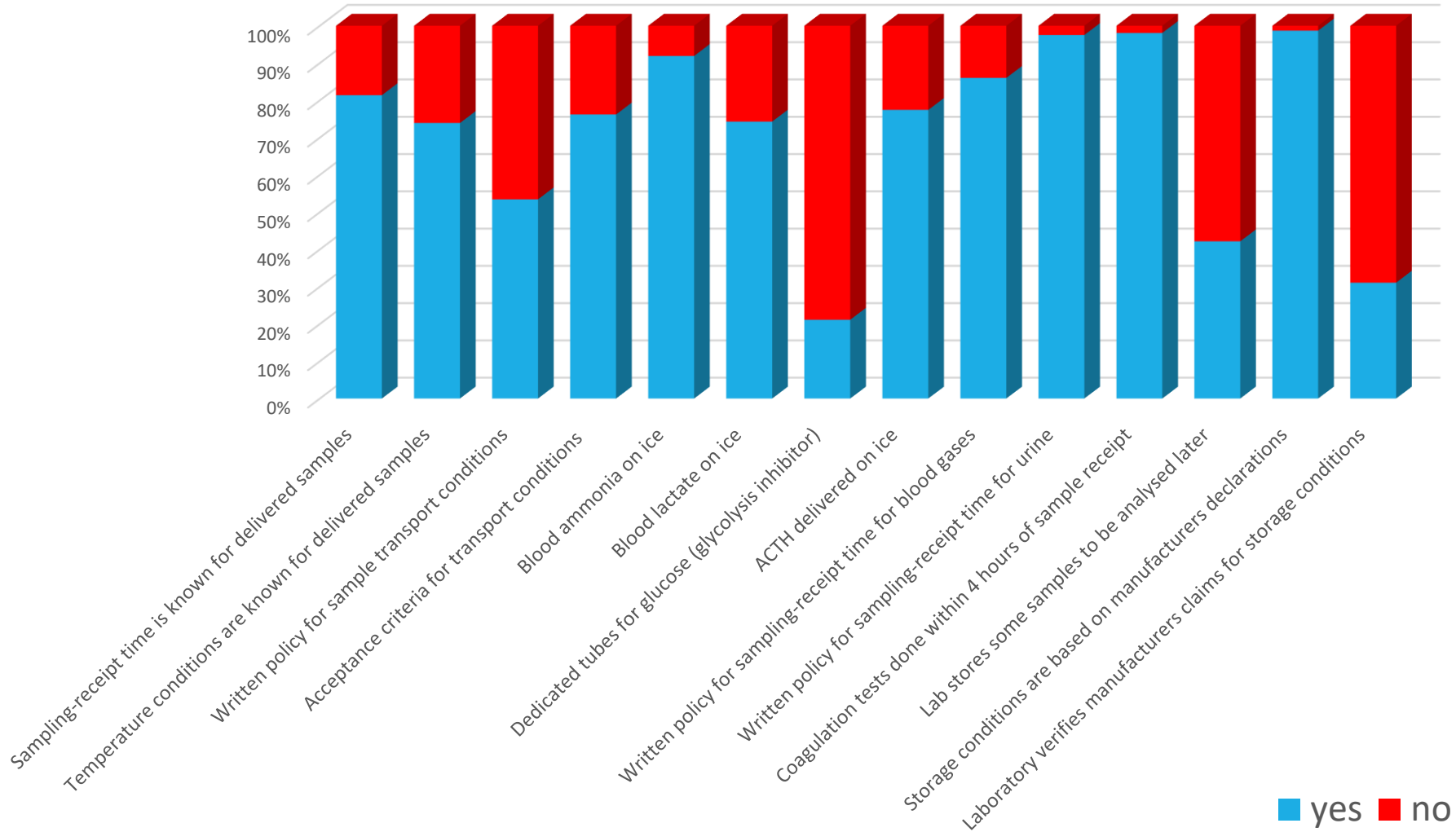
Blood sampling



Nikolac N, Krleza JL, Simundic AM. Preanalytical external quality assessment of the Croatian Society of Medical Biochemistry and Laboratory Medicine and CROQALM: finding undetected weak spots. Biochem Med. 2017;27(1):131-43.

Preanalytical EQA (1/2016)

Sample transport and storage



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Type II preanalytical EQA

- circulation of samples with some kind of error
  - lipemic, hemolyzed, icteric sample
  - drug interference
  - EDTA contamination
  - wrong additive (heparin instead of clot activator)
- could be accompanied with a case history

Type II preanalytical EQA

Type II. Circulation of samples simulating errors			
Circulate samples for extraction of RNA/DNA	Sample preparation for DNA and RNA testing	1 x year	SPIDIA-DNA, 2012 SPIDIA-RNA, 2011 European Commission (EC) (33, 34)
Circulate samples	Sample indicies – lipemic, icteric, hemolysis index	4 x year	* WEQAS

- Nordic hemolysis project
- Croatian society (CROQALM)

Kristensen GB, Aakre KM, Kristoffersen AH, Sandberg S. How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochem Med (Zagreb). 2014;24(1):114-22.

Nordic Hemolysis project 2014

Effects of hemoglobin on some common serum analysis

- 143 laboratories participated (response rate was 97%):
  - 32 from Denmark,
  - 25 from Finland,
  - 4 from Iceland,
  - 53 from Norway
  - 29 from Sweden.
- Four samples with different degrees of hemolysis were distributed to the laboratories (0, 100, 200 and 400 mg Hb/dL).

Nordic Hemolysis project 2014

Effects of hemoglobin on some common serum analysis

- The laboratories were asked to provide their H-index (Hb concentration) value and measure 15 different clinical chemistry components in duplicate:
  - Alkaline phosphatase (ALP), bilirubin (total), calcium, creatine kinase (CK), chloride (Cl), cobalamin, folate, free thyroxine (FT4), gamma glutamyltransferase (GGT), glucose, lactate dehydrogenase (LDH), potassium, sodium, thyroid-stimulating hormone (TSH) and uric acid.
- Labs were also asked to answer some questions concerning how hemolyzed samples were handled in the laboratory.

Results

Participating laboratories differ in actions taken upon the analytical results for most of the components (reject, reject with comment, report or report with comment).

P160

Weqas GLOBAL PROVIDER OF QUALITY IN DIAGNOSTIC MEDICINE

A PRE-ANALYTICAL EQA SCHEME FOR SAMPLE INTEGRITY: A WEQAS STUDY TO MONITOR THE EFFECTIVENESS OF SERUM INDICES

Thomas MA, Davies G, Jones S, Davison L, Phillips J
WEQAS, Cardiff and Vale University Health Board, Unit 6, Parc Ty Glas, Llanishen, Cardiff, UK, CF14 5DU

Corresponding author: Annette.thomas2@wales.nhs.uk

Background: Whilst most EQA schemes focus on the data counting of the number of rejected samples, WEQAS has developed a programme to evaluate the laboratory's ability to detect unsuitable samples and assess their testing protocols for the analytes affected.

Materials and methods: Samples were distributed every 3 months with varying degrees of lipemia, hemolysis and icterus over a 4 year period. Two matched pools were distributed, one containing the interferent and the other containing normal physiological levels. Participants were asked to provide their serum indices value and to report results as they would a patient sample. The data for the two matched samples was also compared with a reference method wherever possible to ascertain the degree of analytical interference.

Results: For the icterus sample, 220 laboratories returned results, 57 provided serum indices and 41 provided additional comments indicating as to whether they would have reported the result on a patient sample. Of these, the majority stated that they would not report total protein, creatinine or GGT.

For the lipemic sample, 111 laboratories provided serum indices and 61 participants provided additional comments. Of these, the majority stated that they would not report ALT and AST with 8 laboratories adding further lipid investigations.

For the hemolyzed sample, 144 laboratories returned results, 109 participants provided additional comments that they would not report Potassium, ALT, AST CK, LDH and ALP. Fifteen stated that they would not have provided any results.

Conclusions There appears to be little harmonization of reporting for serum indices even within users of the same instrument. It is important that laboratories are aware of potential interferences in their assays, are aware of which analytes could be affected, have the ability to detect the potential interferences and have systems in place to ensure the accuracy of results when these interferences are present.

Poster abstract @ 3rd EFLM-BD Conference on Preanalytical Phase, March 20–21, 2015, Porto, Portugal

SPIDIA

- funded by the European Commission, 4 year project
- project aim:
  - to develop quality guidelines and tools for in vitro molecular diagnostics
  - to standardize the preanalytical process (transport and handling)
- the implementation of EQA for the collection, transport and processing of blood samples for RNA and DNA-based analyses is an essential part of this project

SPIDIA

- Labs receive blood samples and are asked to do:
  - DNA or RNA extraction
  - provide details about the reagents and protocols used for the extraction

- Extracted DNA and RNA samples are evaluated for purity, yield, integrity, stability, and the presence of interfering substances inhibiting molecular assays.
- All participants received a report comparing the performance of the DNA and RNA they submitted to that of the other participants

Lab ID: LXXX

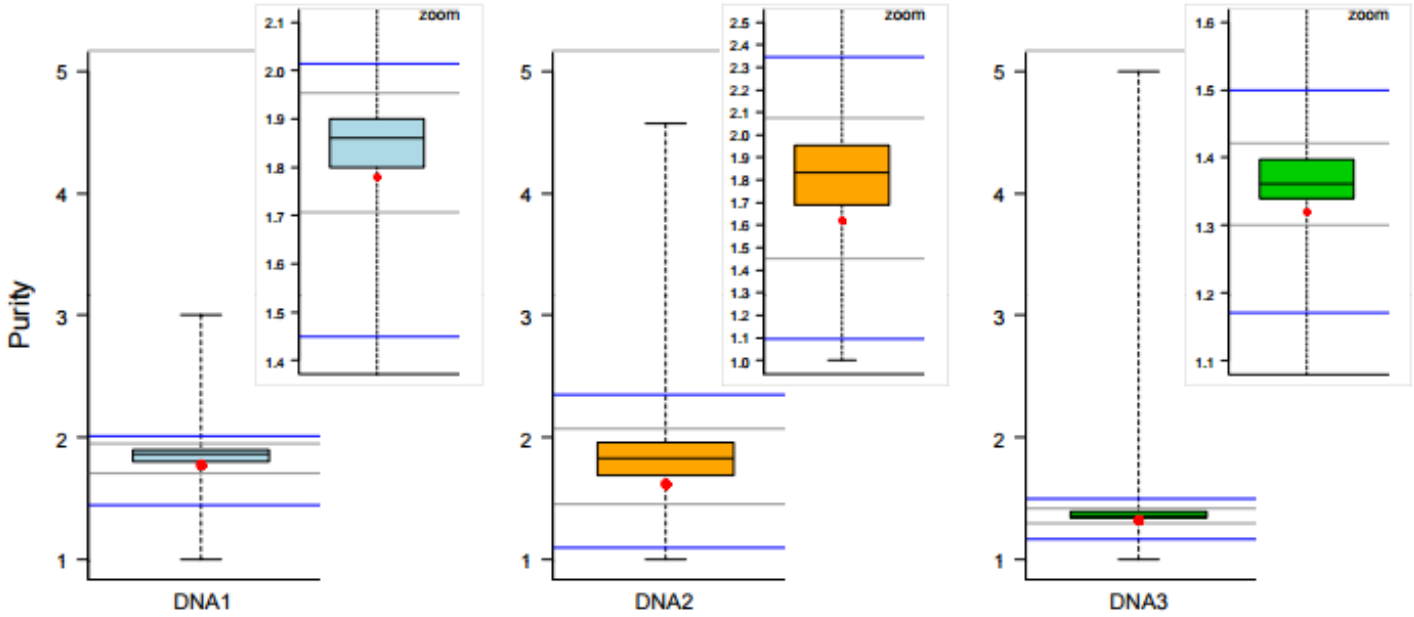
A. Purity and Concentration of DNA1, DNA2 and DNA3 (pre-extracted DNAs)

A.1 Spectrophotometric data provided by your lab

	260nm	280nm	320nm	Purity	Concentration (ng/µl)	Dilution factor
DNA1	1.397	0.783	.	1.78	69.8	1
DNA2	0.389	0.240	.	1.62	19.4	1
DNA3	1.817	1.373	.	1.32	90.8	1

A.2 Your lab (●) versus overall distribution (N=172) – Purity

In the figures the blue lines represent the Action Limits (ALs) and the gray lines represent the Warning Limits (WLs).



Lower AL=1.45; Upper AL=2.01
Lower WL=1.71; Upper WL=1.95

in control

Lower AL=1.09; Upper AL=2.35
Lower WL=1.45; Upper WL=2.08

in control

Lower AL=1.17; Upper AL=1.50
Lower WL=1.30; Upper WL=1.42

in control

Preanalytical EQA (2017-2018)

How do labs treat lipemic samples?

- 1/2017 - chemistry
- 2/2017 - hematology
- 3/2017 – coagulation

Sample spiked with Intralipid

How do labs treat icteric samples?

- 1/2018 – chemistry
- 2/2018 – coagulation
- 3/2018 - hematology

Sample spiked with bilirubin

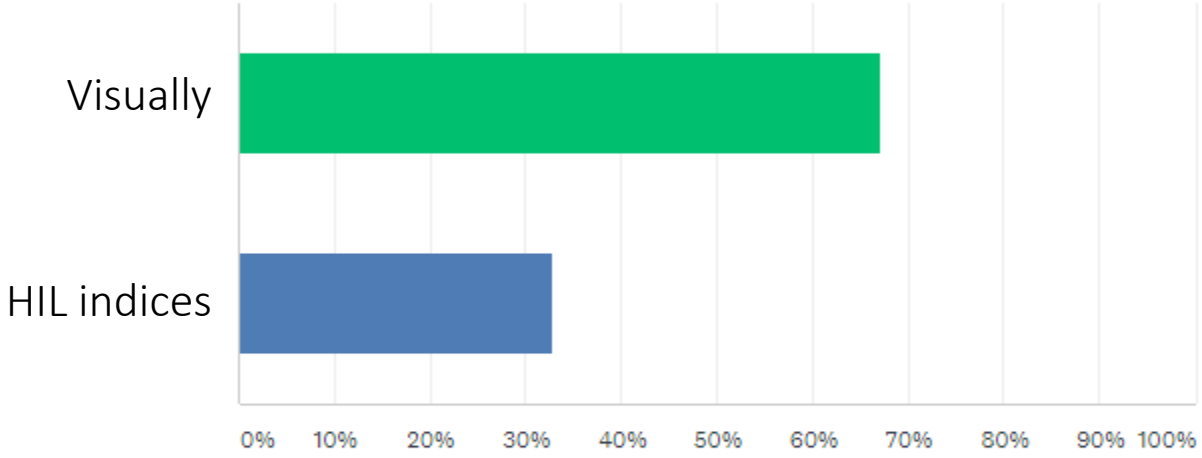
(data not published)

CROQALM Modul 10 2018/01

Q1

How do you detect degree of icterus in chemistry samples?

Answered: 161 Skipped: 1



ANSWER CHOICES	RESPONSES	
Vizualno	67.08%	108
Mjerenje na automatskom analizatoru	32.92%	53
TOTAL		161

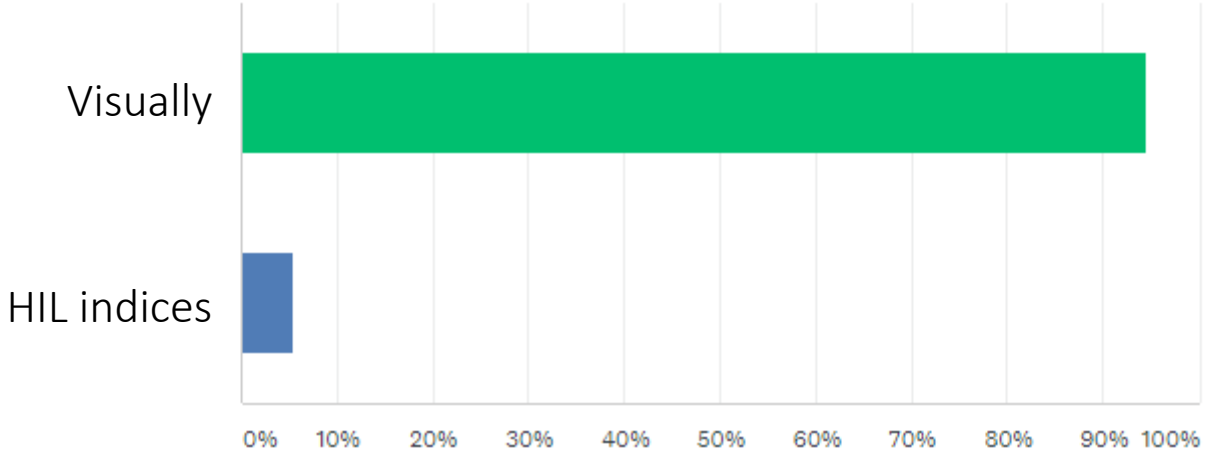
(data not published)

CROQALM Modul 10 2018/02

Q1

How do you detect degree of icterus in coagulation samples?

Answered: 148 Skipped: 1



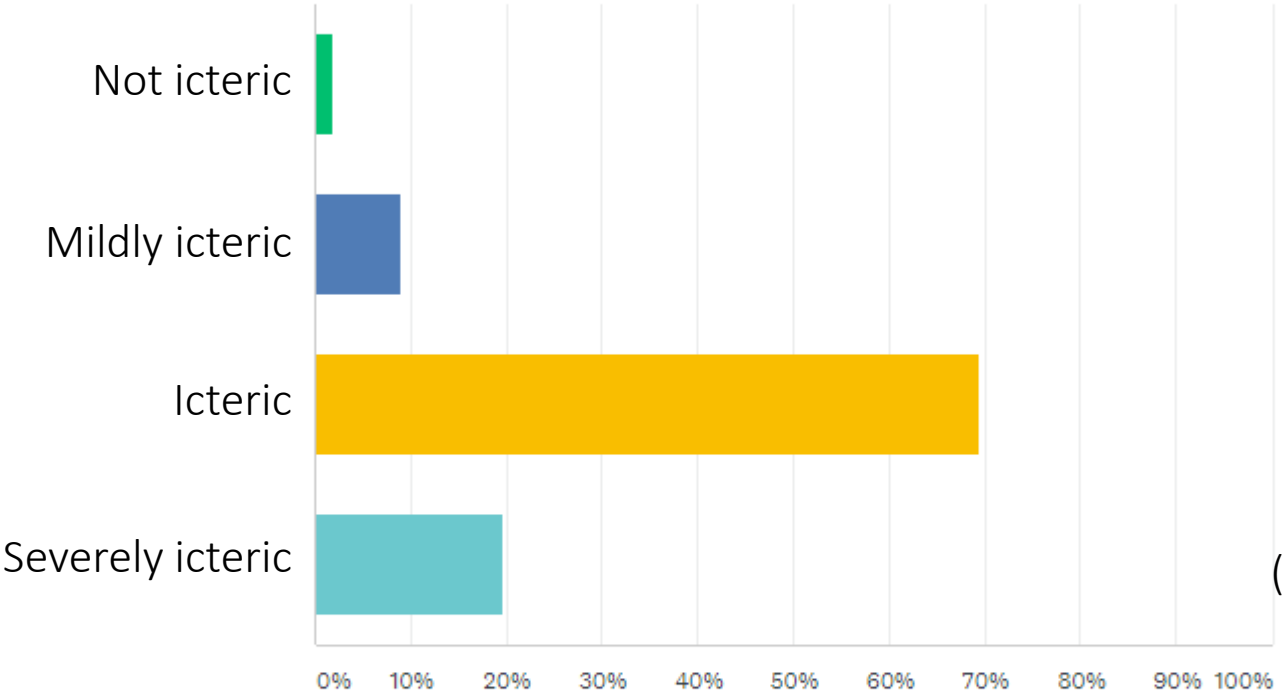
(data not published)

CROQALM Modul 10 2018/01

Q2

Estimate the degree of icterus in the (chemistry) sample.

Answered: 157 Skipped: 5



(data not published)

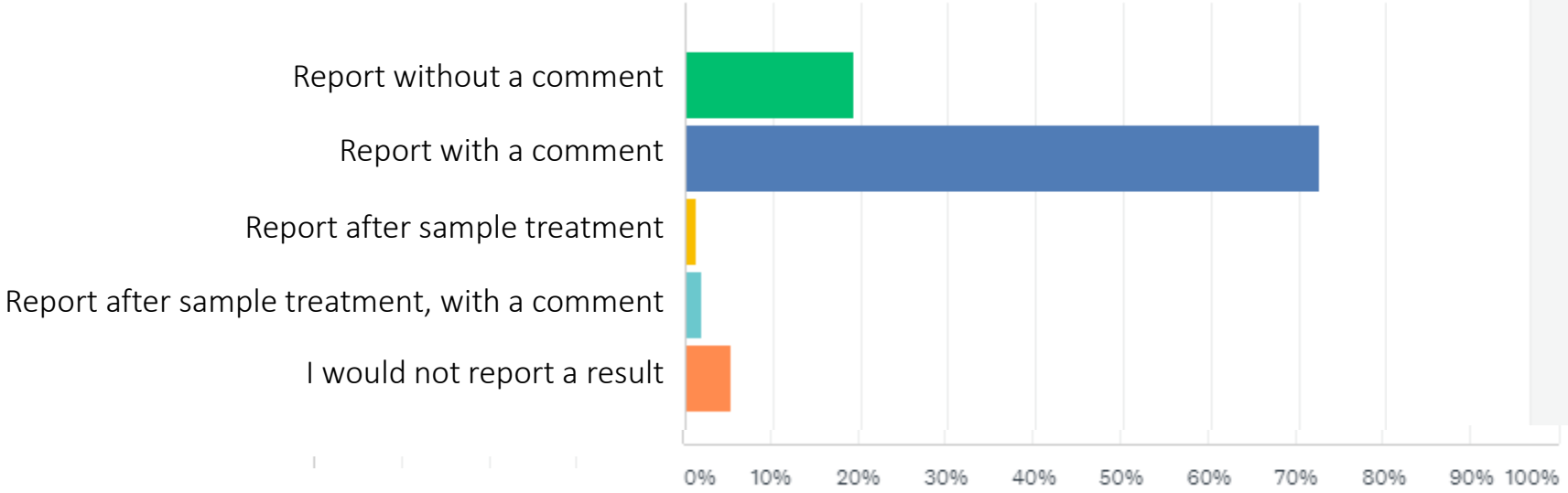
ANSWER CHOICES	RESPONSES	
uzorak nije ikteričan	1.91%	3
uzorak lagano ikteričan	8.92%	14
uzorak ikteričan	69.43%	109
uzorak izrazito ikteričan	19.75%	31

CROQALM Modul 10 2018/01

Q8

Given the estimated degree of icterus, please state what would you do with the request for creatinine in the sample.

Answered: 157 Skipped: 5



	IZDAJEM BEZ NAPOMENE	IZDAJEM UZ NAPOMENU O IKTERIJI	IZDAJEM NAKON UKLANJANJA INTERFERENCIJE BEZ NAPOMENE	IZDAJEM NAKON UKLANJANJA INTERFERENCIJE UZ NAPOMENU O IKTERIJI	NE IZDAJEM REZULTAT	TOTAL
Kreatinin	19.23% 30	72.44% 113	1.28% 2	1.92% 3	5.13% 8	156

(data not published)

Challenges in Type II EQA

- same as analytical EQA (sample stability, commutability, homogeneity, etc.)
- requires dedicated and competent personnel and some resources (equipment, samples, facilities)
- requires expertise (how to produce unsuitable samples??)
- difficult to mimic real life preanalytical problems on a large scale
- only a very limited number of preanalytical problems can be explored (not to be used on a regular basis)
- response bias (participants know they are receiving *„preanalytical samples”*)

Type III preanalytical EQA

- registration of errros/adverse events
  - labs report their data regularly over time
  - standardized system of reporting

Type III preanalytical EQA

Type III. Registration of errors/adverse events

Q-Track (since 1998, 1 x year, ongoing) programs, registration of error rates	Patient/sample identification, specimen handling/preparation, specimen acceptability, customer satisfaction	4 x year	College of American Pathologists (CAP) (39)
Registration of rejection of samples	Registration of the rejection rate and causes for rejecting the samples during 1 month or 100 rejections	2 x year	Committee for the Quality of the Extra-analytical phase (started within The Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC) in 1998 (41)
Registration of key incidents which represent either the most frequent or most serious incident	Patient identification, incorrect patient preparation, phlebotomy, sample preparation/handling and sample acceptability	4 x year	Key Incident Monitoring and Management Systems Quality Assurance (KIMMS QA) 2009 (43).

- UK experience
- IFCC Working Group on Laboratory errors and patient safety (WG-LEPS)

Kristensen GB, Aakre KM, Kristoffersen AH, Sandberg S. How to conduct External Quality Assessment Schemes for the pre-analytical phase? Biochem Med (Zagreb). 2014;24(1):114-22.

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Monitoring and reporting of preanalytical errors in laboratory medicine: the UK situation

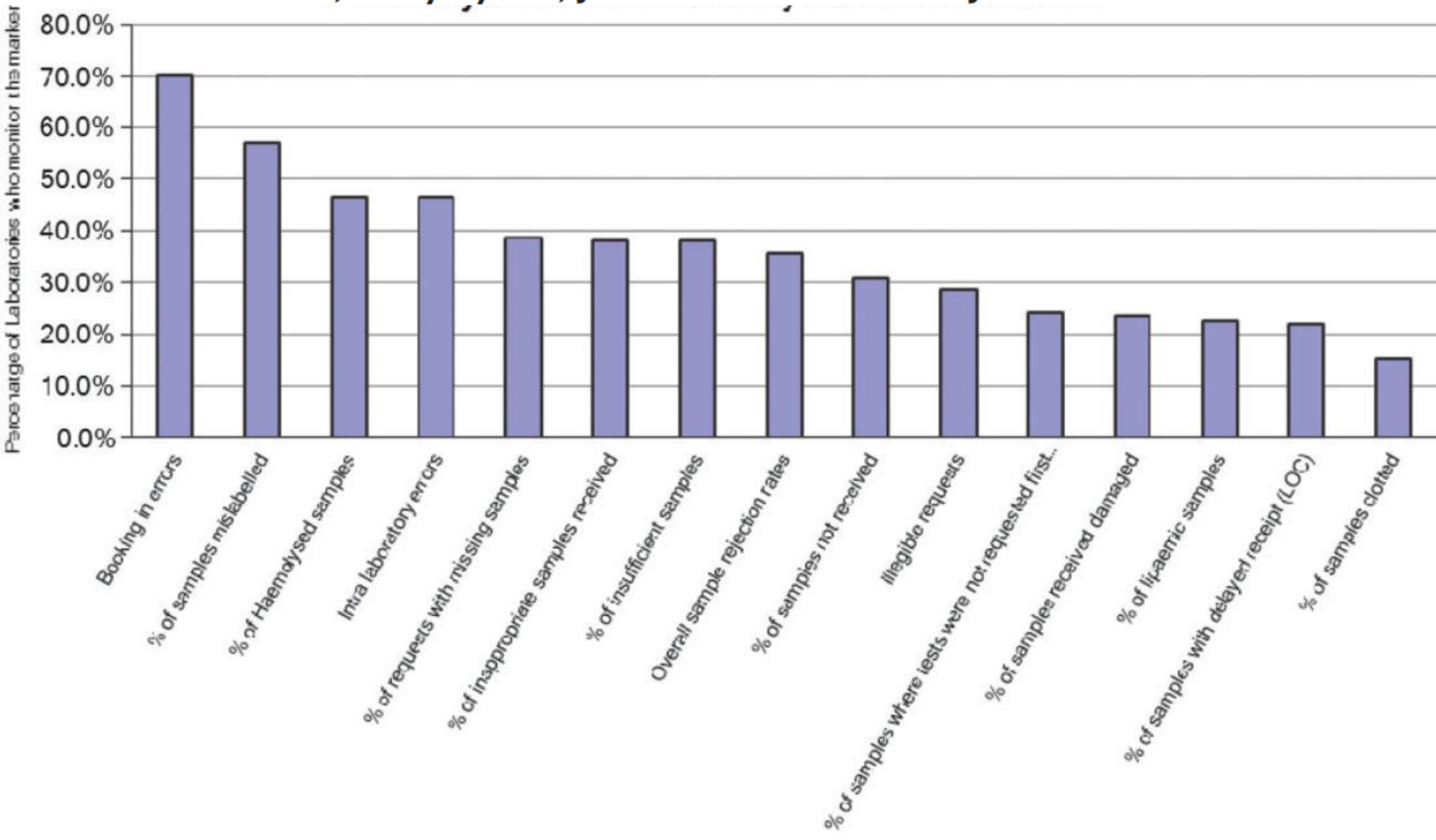
Michael P Cornes[1,2], Jennifer Atherton[2,3], Ghazaleh Pourmahram[2,4], Hazel Borthwick[2,5], Betty Kyle[2,6], Jamie West[2,7] and Seán J Costelloe[2,8]

Responses indicate that:

- 20% of laboratories do not use automated serum indices.
- 34.5% of laboratories do not routinely monitor any preanalytical quality indicators.
- 91.8% of laboratories are interested in the establishment of an EQA scheme to allow interlaboratory comparisons of preanalytical errors.

Monitoring and reporting of preanalytical errors in laboratory medicine: the UK situation

Michael P Cornes[1,2], Jennifer Atherton[2,3], Ghazaleh Pourmahram[2,4], Hazel Borthwick[2,5], Betty Kyle[2,6], Jamie West[2,7] and Seán J Costelloe[2,8]



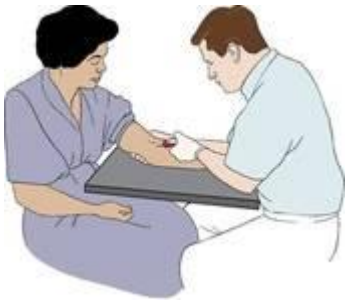
Challenges of Type III EQA

- results between different schemes not comparable due to the:
  - differences in the reporting system
  - different definitions of errors
- requires substantial amount of time and dedicated personnel
- reporting potentially not reflecting the real life (underreporting)

Benefit of Type III EQA

- offers practical and effective method to monitor preanalytical errors over time and compare with other labs
- promotes a continuous improvement to the benefit of the patient

Are preanalytical practices comparable between labs?



We know they are
not comparable!

Conclusions 1/3

- EQA is used to assess the degree of comparability of preanalytical practices
- Various EQA
  - offer different benefits
  - have different challenges
- all types of EQA are useful and complementary
  - should be used together

Conclusions 2/3

- EQA is valuable tool only if there is a system in place for:
  - analysing EQA failures
  - implement corrective and preventive actions
  - monitor changes over time

Conclusions 3/3

- National EQA schemes are advisable as they will more likely target local needs

- Responsibility:
  - National societies
  - Laboratories


Thank you!