

Quality Assurance of the pre-analytical phase

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Why pre-analytical EQA?
Types of pre-analytical EQA?
Benefits and challenges?
Some examples

Why pre-analytical EQA?

Preamanalytical phase

- is the most common source of errors
- huge variations in practices and policies
 - between continents
 - between countries
 - between labs
 - between individuals





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The quality and scope of information provided by medical laboratories to patients before laboratory testing: Survey of the Working Group for Patient Preparation of the Croatian Society of Medical Biochemistry and Laboratory Medicine



Nora Nikolac ^{a,*}, Ana-Maria Simundic ^a, Sanja Kackov ^b, Tihana Serdar ^c, Adrijana Dorotic ^d, Ksenija Fumic ^e, Jelena Gudasic-Vrdoljak ^f, Kornelija Klenkar ^g, Jadranka Sambunjak ^h, Valentina Vidranski ⁱ

CONCLUSIONS: Laboratory professionals in Croatia have a positive attitude towards the importance of patient preparation for laboratory testing. However, the information for laboratory testing is not standardized and frequently lacks guidance for tests related to TDM, coagulation and endocrinology. This study highlights the need for standardized, updated and evidence-based recommendations for patient preparation in order to minimize the risk for patients.

Original papers

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

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TABLE 1. The questionnaire used in the survey about how patients are informed of proper preparation for phlebotomy (N = 150).

Question	N (%)
4.2. When did you consume meal last time?	
- the last meal consumed 12 hours before	90 (60)
- the last meal consumed 10 hours before	32 (21)
- the last meal consumed 18 hours before	2 (1)
- coffee or tea in the morning	17 (12)
- the last meal prior to phlebotomy	9 (6)
4.4. When did you consume liquid last time (water, juice, coffee, etc.)?	
- without fluid in the morning	69 (46)
- with water in the morning	57 (38)
- coffee or tea in the morning	21 (14)
- juice in the morning	2 (1)
- milk in the morning	1 (1)

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)

- There is a large heterogeneity in Europe!
- Only a few countries have guidelines (7/28)
- phlebotomy is performed by medical and nonmedical personnel
- different level of education and life long training

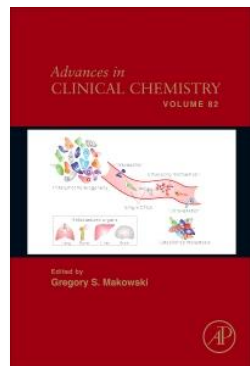
Ana-Maria Simundic*, Stephen Church, Michael P. Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Nora Nikolac, Edmee van Dongen-Lases, Pinar Eker, Svjetlana Kovalevskaya, Gunn B.B. Kristensen, Ludek Sprongl and Zorica Sumarac

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)

Conclusions: The level of compliance of phlebotomy procedures with the CLSI H3-A6 guidelines in 12 European countries was found to be unacceptably low. The most critical steps in need of immediate attention in the investigated countries are patient identification and tube labelling.

The quality of the extra-analytical phase of laboratory practice in some developing European countries and Mexico – a multicentric study

Question	n	Never, %	Rarely, %	Often, %	Always, %	Overall score
Questions on criteria of sample acceptance						
I centrifuge already <u>coagulated samples</u> shorter than required	404	66	17	10	7	3.42
I do not accept the sample for analysis unless the tube containing anticoagulant is <u>filled up to the mark</u>	386	13	19	9	59	3.13
If the potassium concentration in a <u>slightly haemolytic serum</u> is normal, I will not request new blood sampling	263	25	20	34	21	2.50
<u>I centrifuge blood samples</u> for serum for at least 10 min at 3500 rpm	368	20	6	11	63	3.17
I run the complete blood count from a <u>slightly coagulated sample</u> , carefully observing that the coagulum will not be aspirated	377	66	7	2	25	3.13
If the samples for the potassium measurement are even slightly haemolytic, I will request new sampling	359	8	23	16	53	3.14



Blood Glucose Determination: Effect of Tube Additives

Giuseppe Lippi^{*,1,2}, Mads Nybo^{†,2}, Janne Cadamuro^{‡,2},
Joao T. Guimaraes^{§,¶,||,2}, Edmée van Dongen-Lases^{#,2},
Ana-Maria Simundic^{*,2}

Advances in
Clinical Chemistry

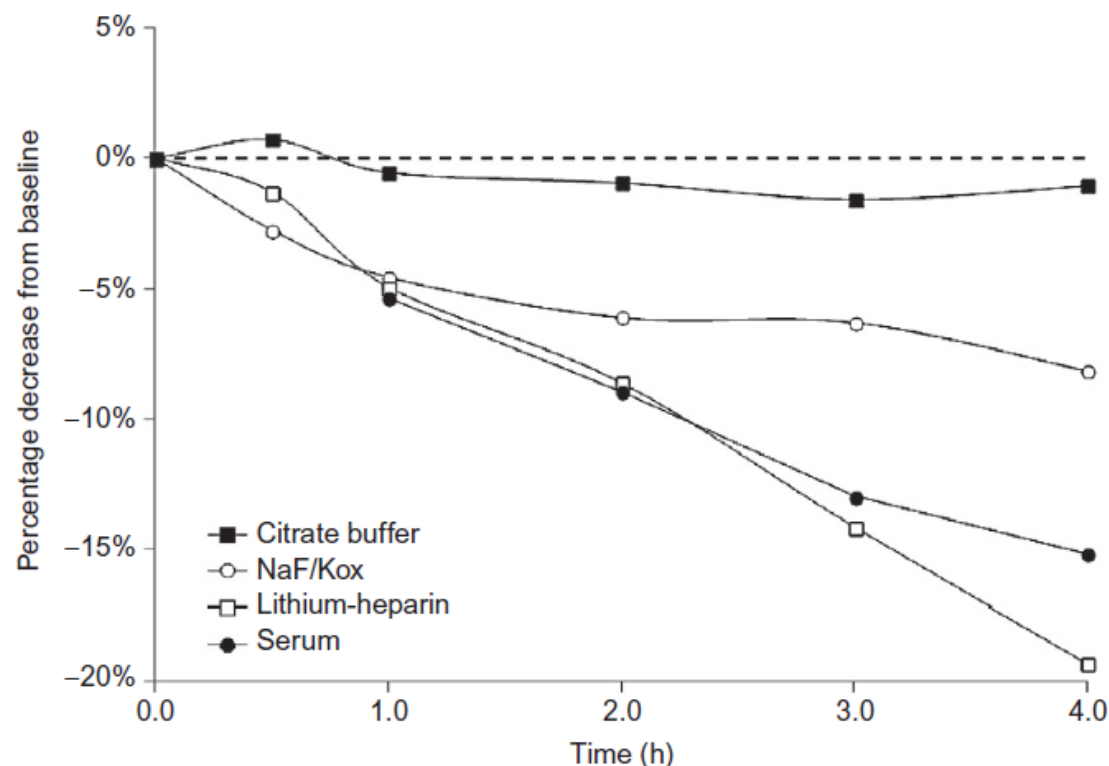


Fig. 3 Variation of glucose concentration in samples stored uncentrifuged for 0.5–4 h at room temperature. *KOx*, potassium oxalate; *NaF*, sodium fluoride.

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



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

Giuseppe Lippi^{1,2}, Ana-Maria Simundic^{1,3}, Leocadio Rodrigues-Manas⁴, Patrick Bossuyt⁵, Giuseppe Banfi⁶

Patients should receive the same level of care across Europe!

Standardization of preanalytical practices is essential!

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.

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.

Review

Mario Plebani*

Harmonization in laboratory medicine: the complete picture

- harmonization in laboratory medicine is **mandatory**
- standardization and harmonization projects should deal with **all steps of the total testing process**: pre-, analytical and post-analytical phase
- initiatives aiming to improve harmonization of laboratory test results have an **ethical dimension**,
- main purpose is to provide reliable information that, in turn, should assure optimal **care for patients** in a global world

External quality assessment (EQA)

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

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.

Types of pre-analytical EQA?

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

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

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 <i>via</i> web-based multiple choice questionnaire	Clinical chemistry: Hemolysis, stability of samples (2011)	1 x year	Norwegian Clinical Chemistry EQA program (NKK) Not published
	Hemostasis testing: Phlebotomy, sample handling and sample acceptance (2012)		
	Glucose: Sample handling and sample treatment (2013)		
Registration of procedures <i>via</i> 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 <i>via</i> 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 <i>via</i> multiple choice questionnaire	Urine chemistry, clinical chemistry	4 x year	* WEQAS
Registration of procedures <i>via</i> web-based multiple choice questionnaire	Hematology, sample handling	1 x year	* INSTAND

PREANALYTICAL EXTERNAL QUALITY ASSESSMENT SURVEY



The Preanalytical 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 Preamanalytical 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 Šimundić³, Vesna Šupak Smolčić¹, Nora Nikolac³, Lorena Honović⁴

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

Type I Preamanalytical EQA in Croatia – *the origins*



Izvorni znanstveni članak

Original scientific article

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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.

2014 - First preanalytical EQA

In 2014 - 1 pilot round per year:

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

From 2015 - 3 rounds per year:

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



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



Prenanalytical 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)
<input checked="" type="radio"/> 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)

RESULTS ANALYSIS AND INTERPRETATION



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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Oznaka dokumenta	Izdanje 01	List 2 / 5
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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

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Oznaka dokumenta	Izdanje 01	List 2 / 5
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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.

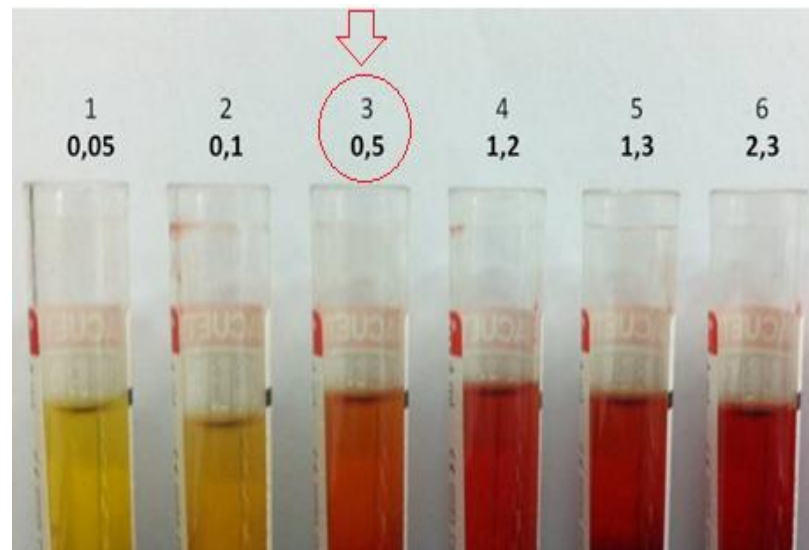
U trećem slučaju poželjni odgovor c) odabralo je 134/159 = 85,53% laboratorija. Kalij je jedan od parametara čija je koncentracija promijenjena čak i pri najmanjoj hemolizi uzorka. S obzirom da stupanj hemolize nije u linearnom odnosu s promjenom koncentracije kalija, nemoguće je iz koncentracije slobodnog 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.

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

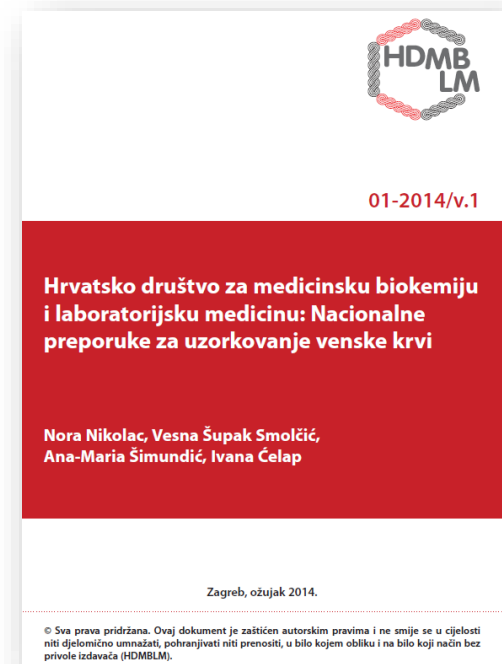
Please select response which best describes the policy procedure with a sample in your laboratory:

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)

Preanalytical EQA (2015)

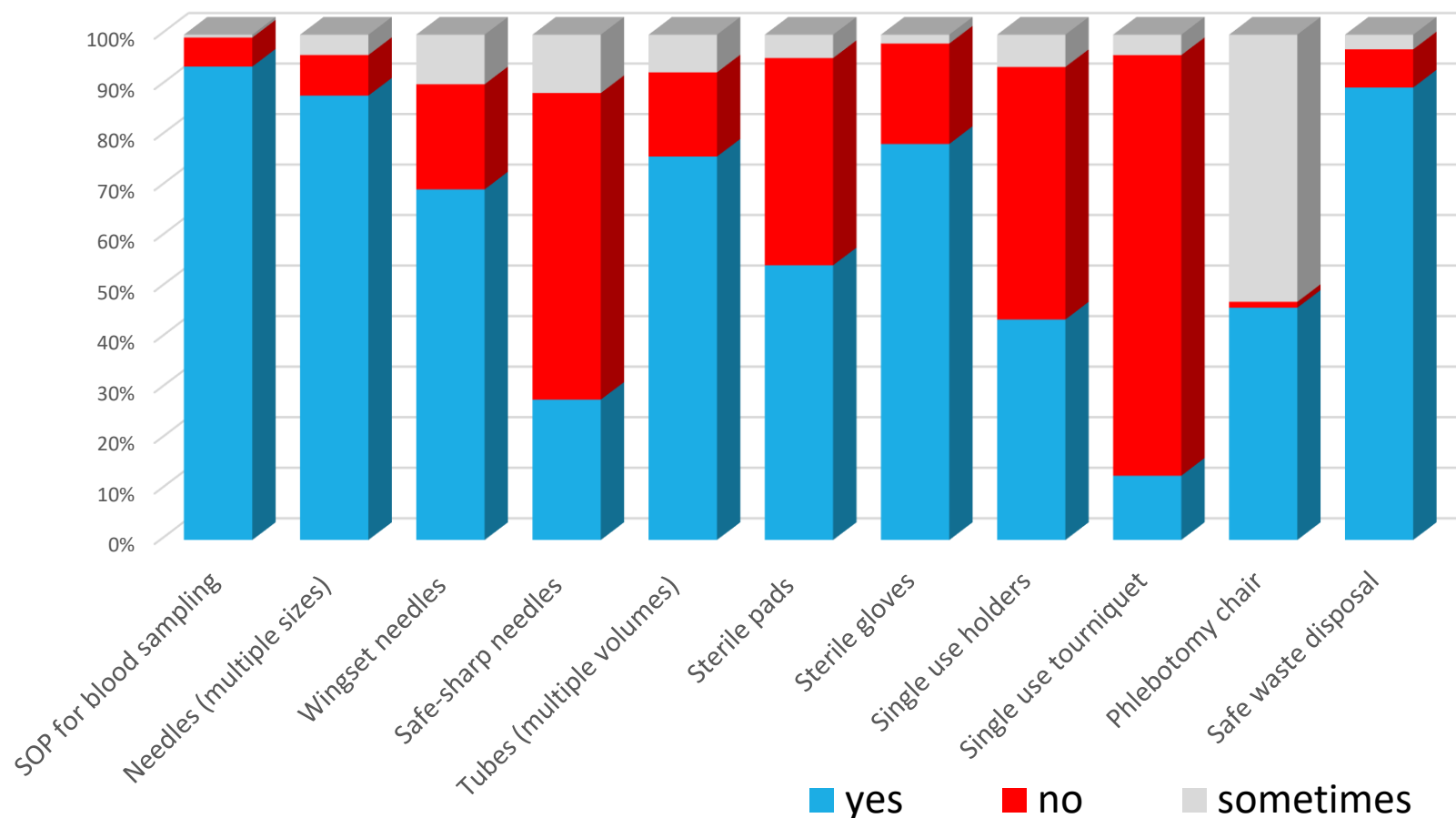
Compliance with National recommendation for venous blood sampling (published 2014):

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



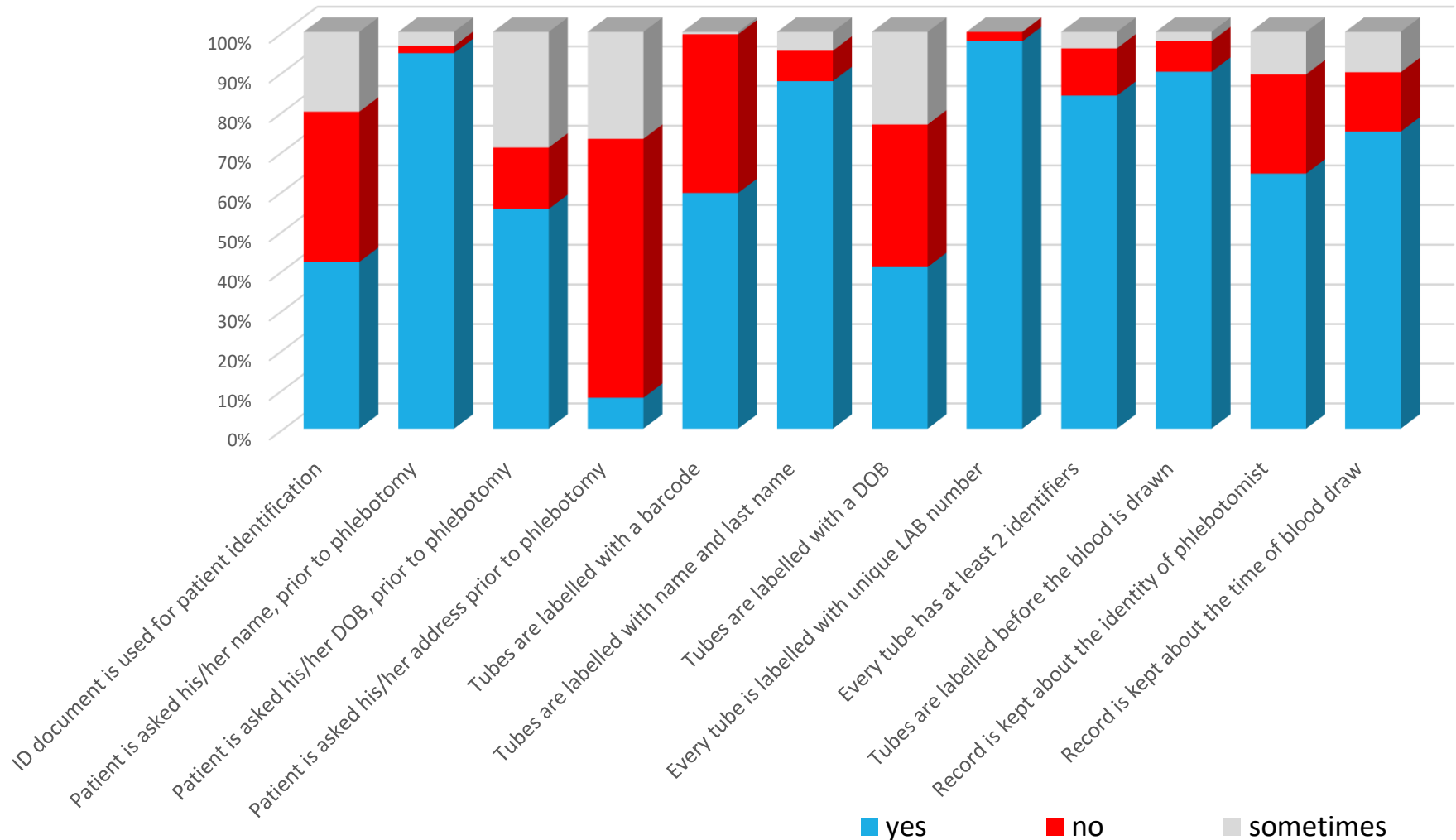
Preanalytical EQA (1/2015)

Consumables, materials and equipment



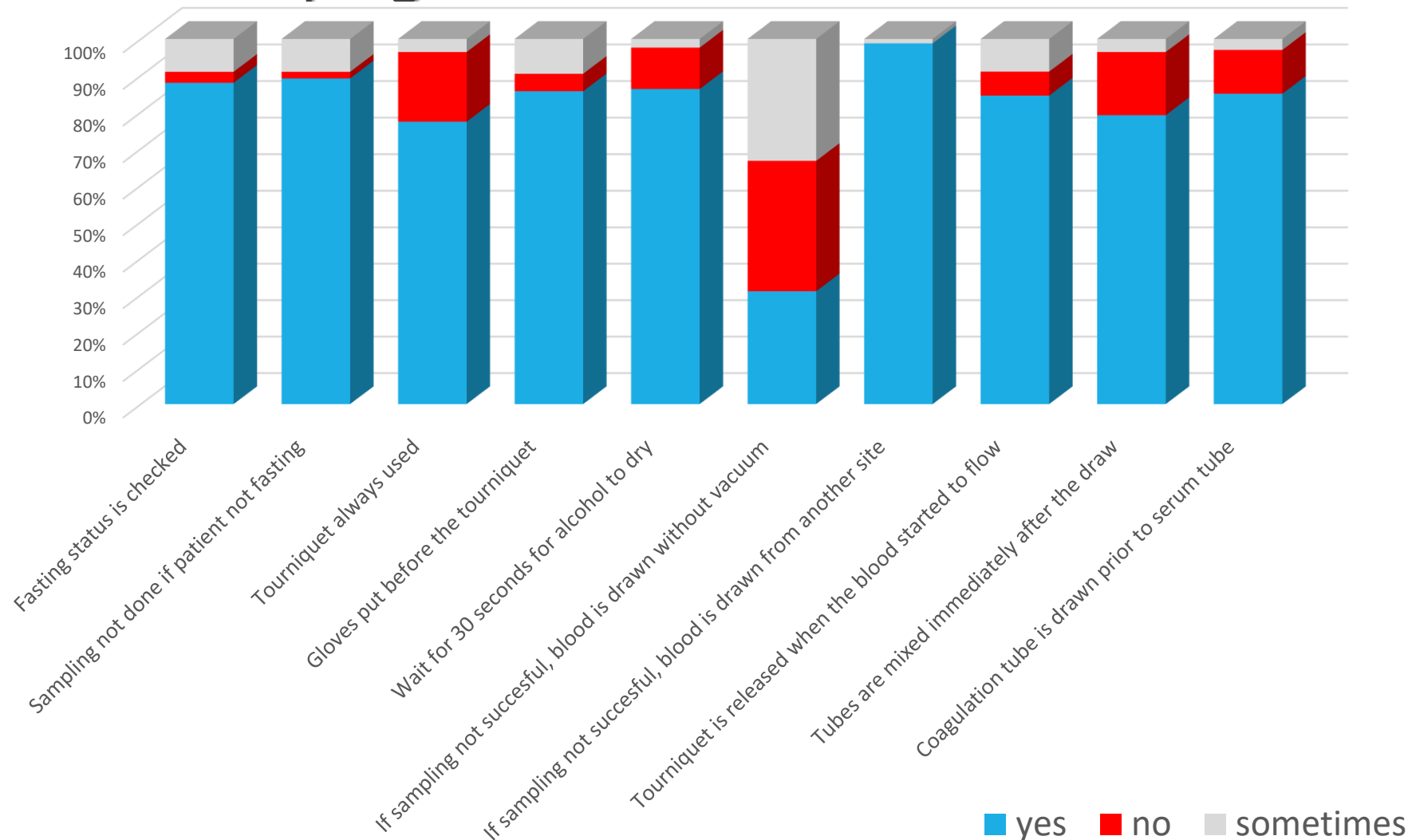
Preanalytical EQA (2/2015)

Patient identification



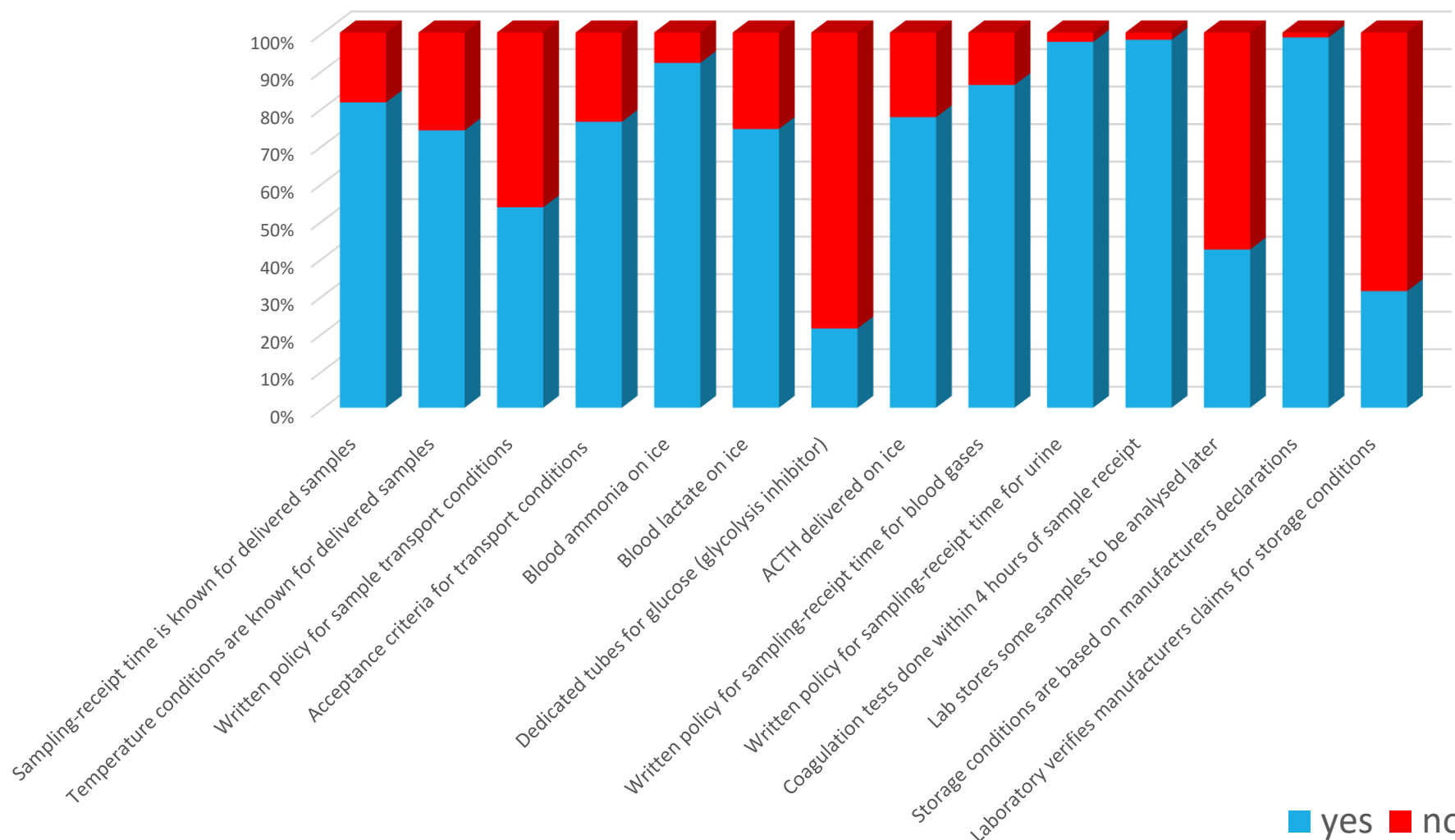
Preanalytical EQA (3/2015)

Blood sampling



Preanalytical EQA (1/2016)

Sample transport and storage



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 indices – lipemic, icteric, hemolysis index	4 x year	* WEQAS

- Nordic hemolysis project
- Croatian society (CROQALM)

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.

Nordic Hemolysis project 2014

Effects of hemoglobin on some common serum analysis

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).

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

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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.



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

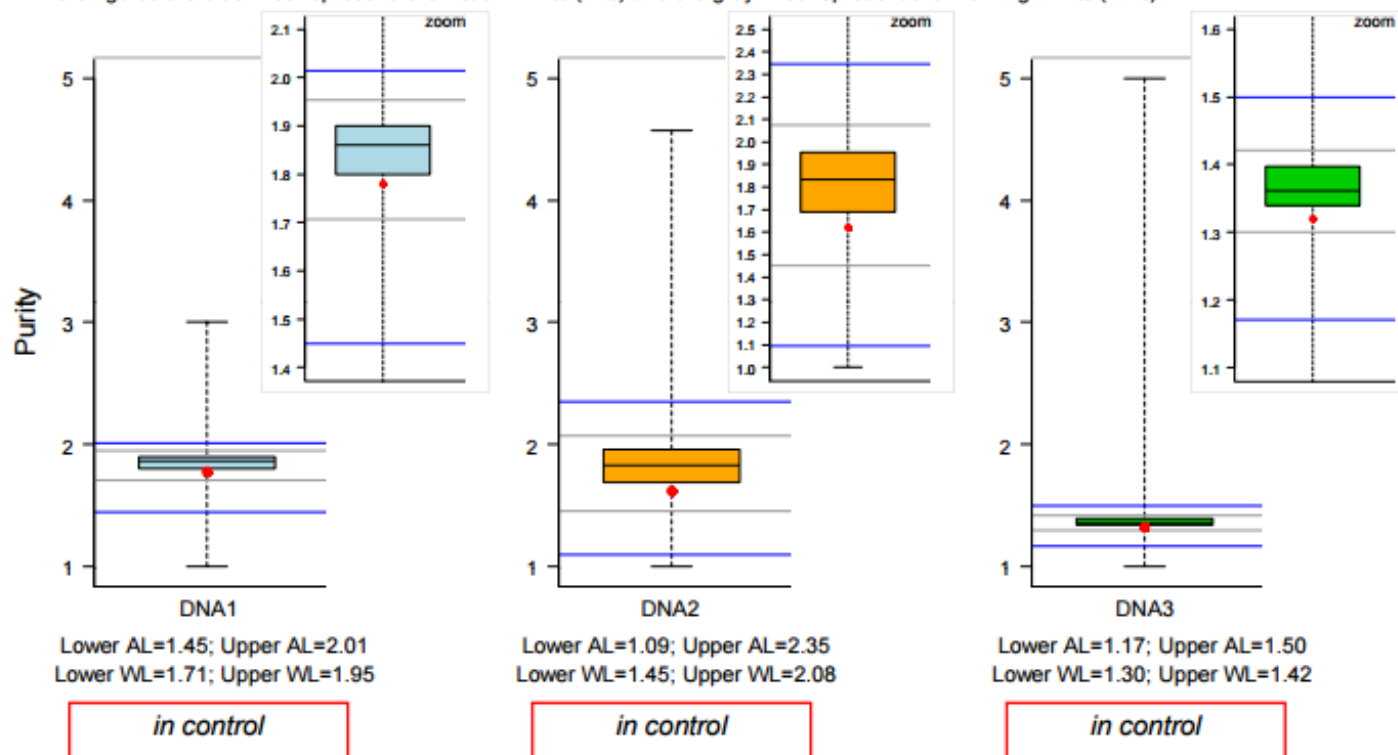
A. Purity and Concentration of DNA1, DNA2 and DNA3 (pre-extracted DNAs)

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).



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

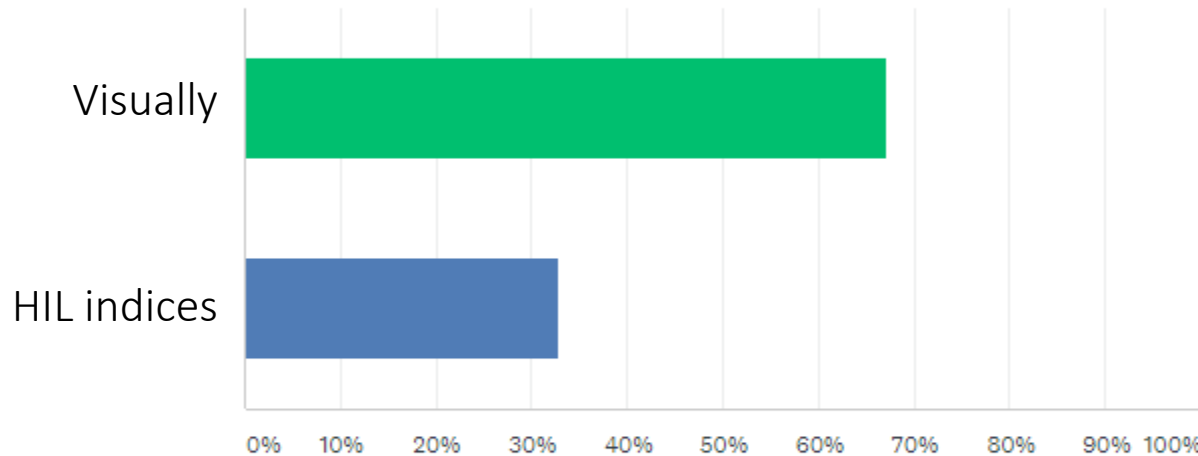


Sample spiked with bilirubin

Q1

How do you detect degree of icterus in chemistry samples?

Answered: 161 Skipped: 1

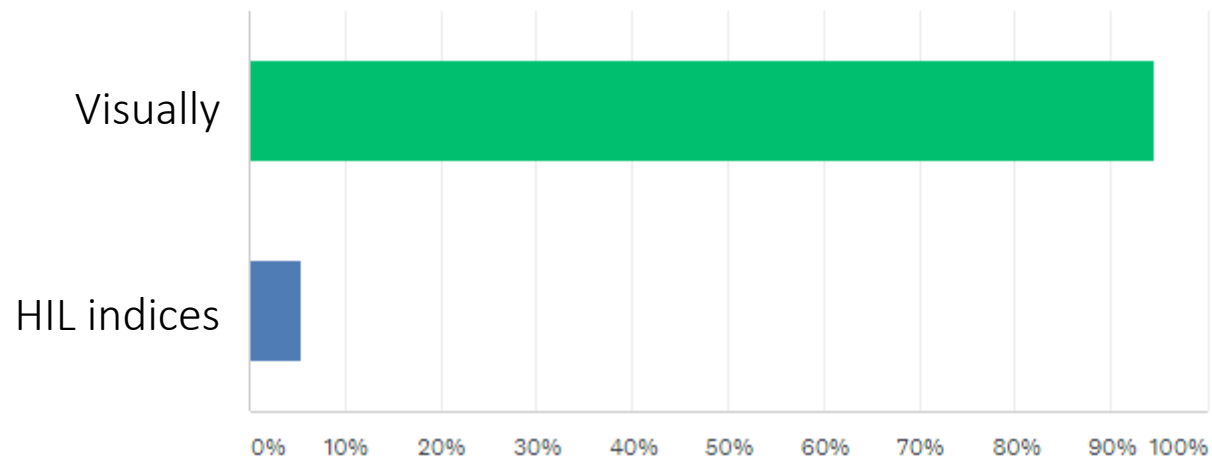


ANSWER CHOICES	RESPONSES	
Vizualno	67.08%	108
Mjerenje na automatskom analizatoru	32.92%	53
TOTAL		161

Q1

How do you detect degree of icterus in coagulation samples?

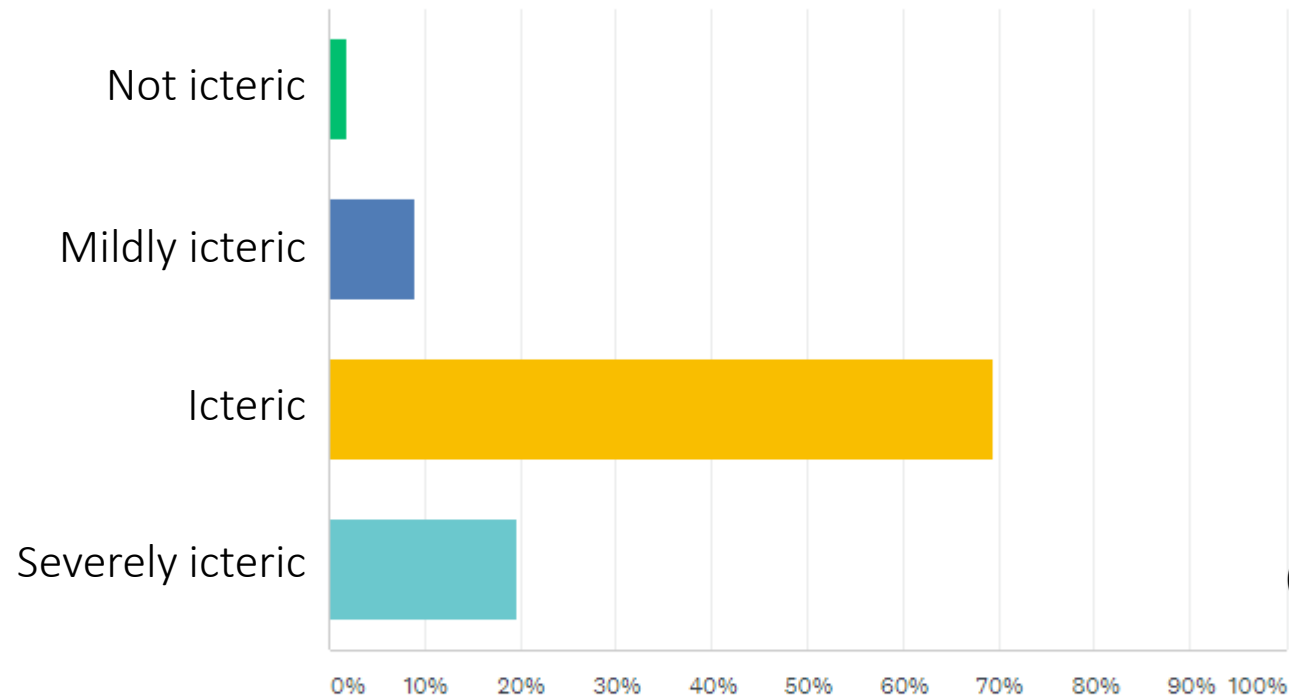
Answered: 148 Skipped: 1



Q2

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

Answered: 157 Skipped: 5



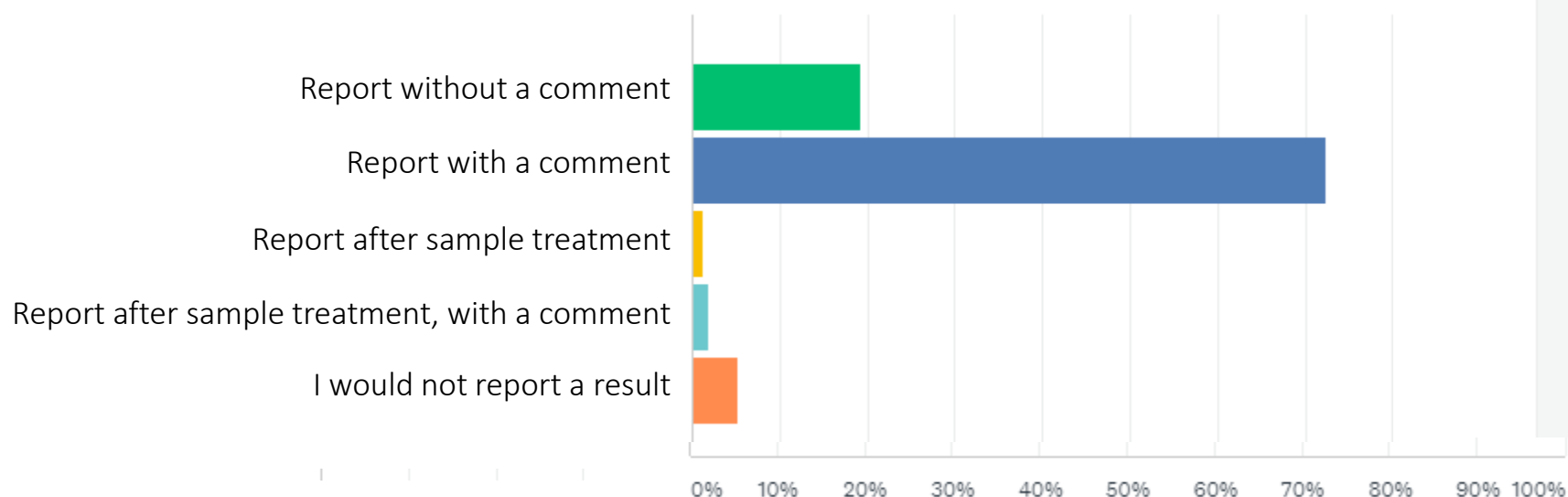
(data not published)

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

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 errors/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)



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

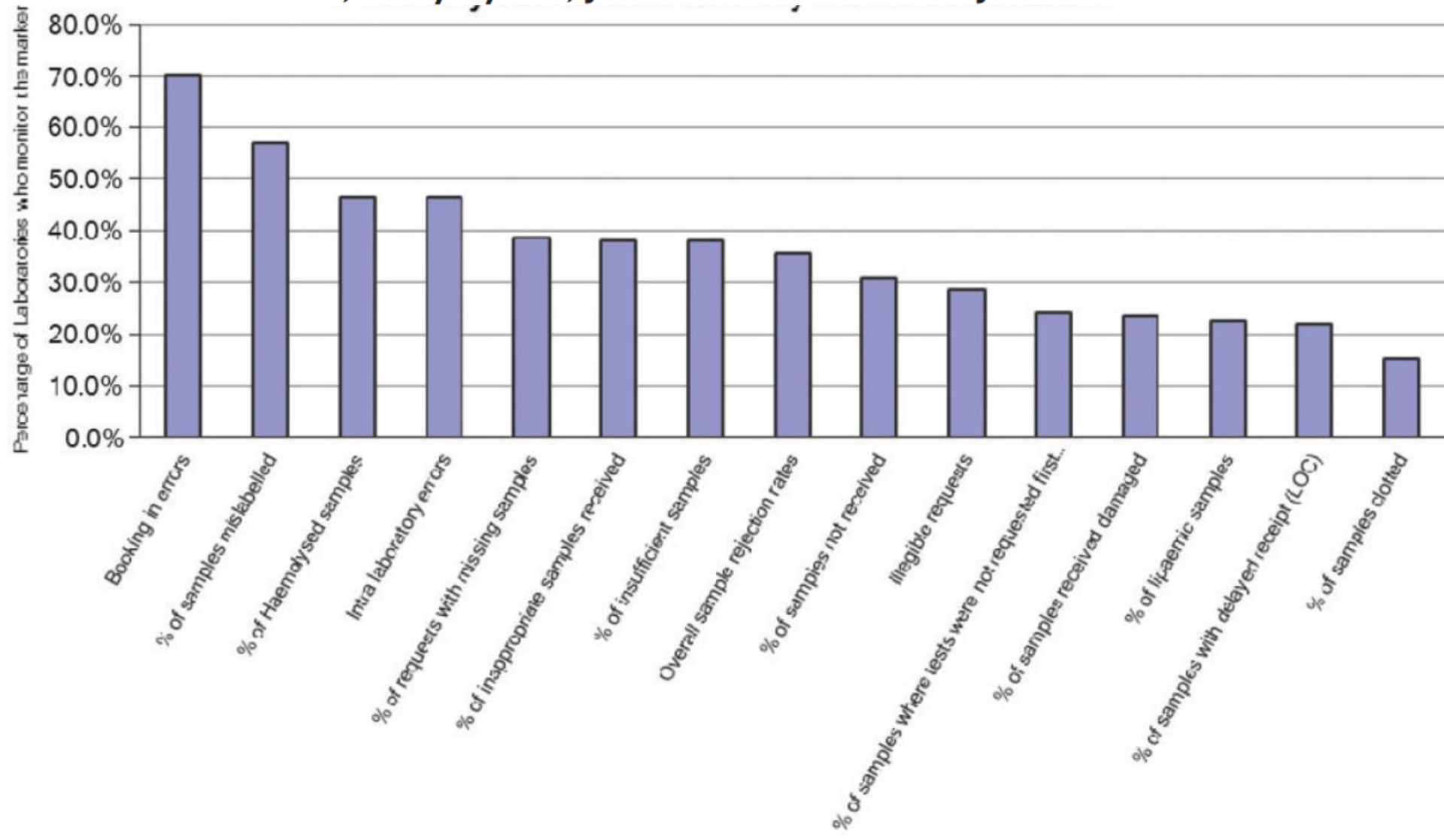
**Michael P Cornes^{1,2}, Jennifer Atherton^{2,3}, Ghazaleh Pourmahram^{2,4},
Hazel Borthwick^{2,5}, Betty Kyle^{2,6}, Jamie West^{2,7} and Seán J Costelloe^{2,8}**

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},
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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

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

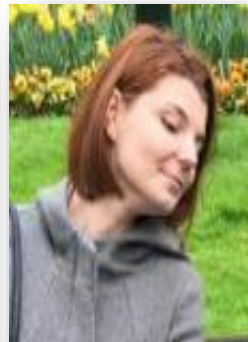
Conclusions 2/3

- 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

Acknowledgments



5th EFLM Conference on Preanalytical Phase

Preanalytical challenges - time for solutions



Zagreb (Croatia), 22-23 March 2019

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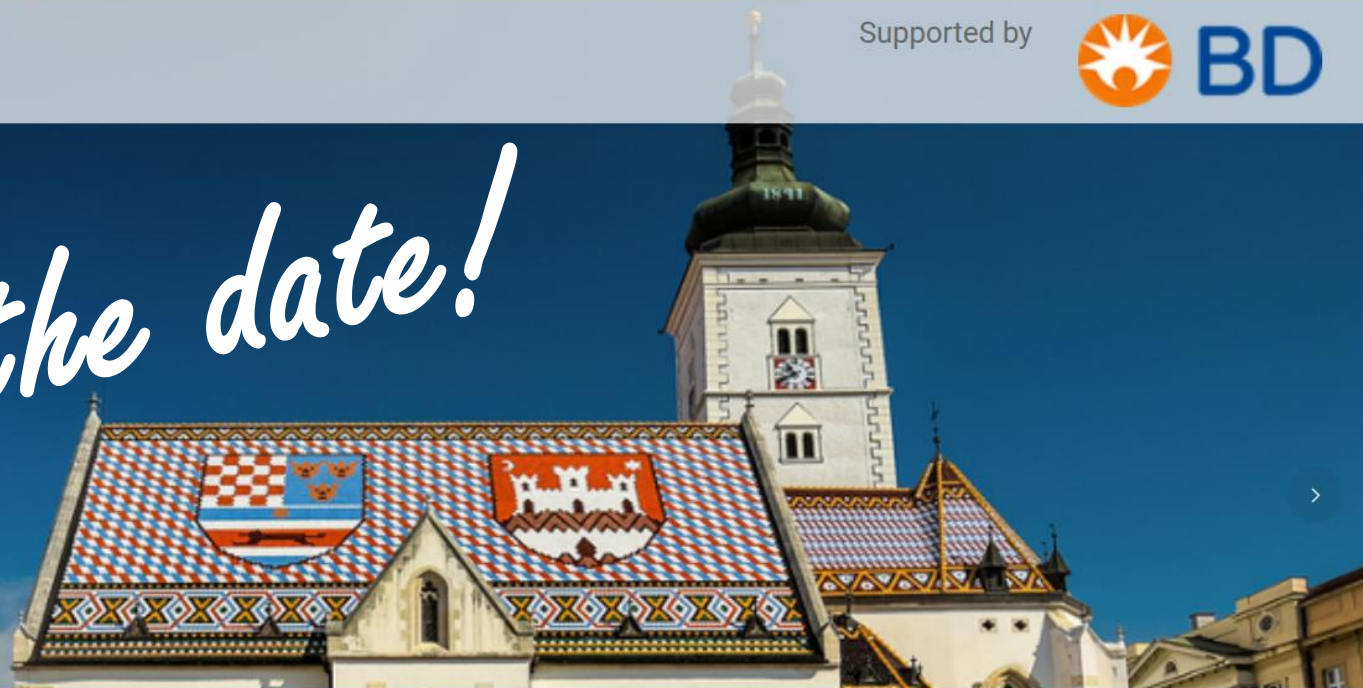
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