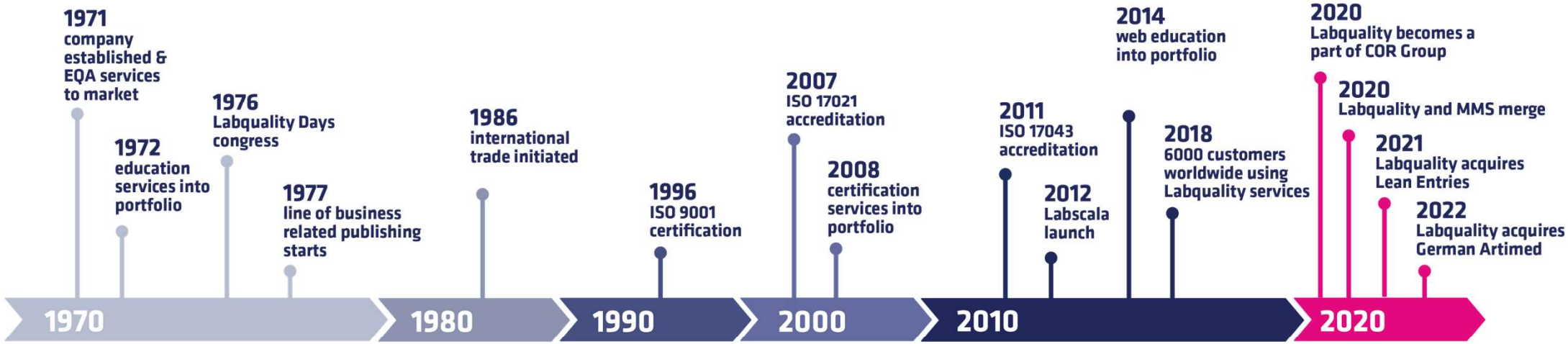
LABQUALITY

Experiences in EQA for phlebotomy and urine sampling

Jonna Pelanti
R&D Director
Ms. Sci. (tech), Clinical Biochemist, EuSpLM

The Global Forerunner in Healthcare Quality and Trusted Partner Providing Quality Services



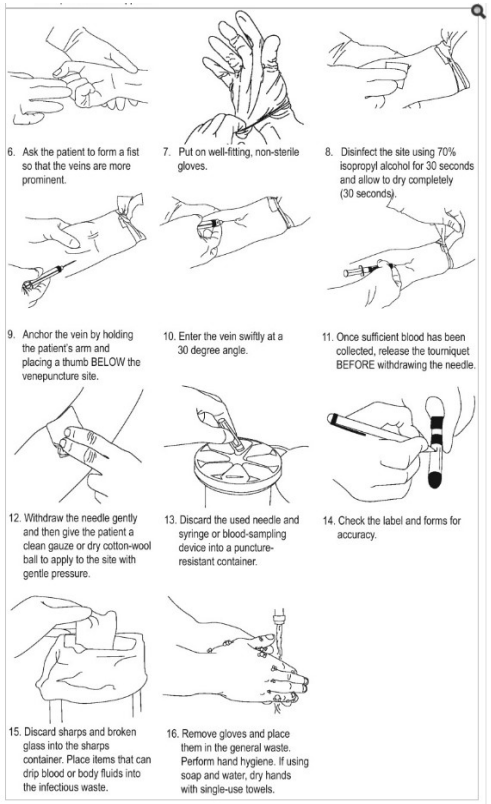
Forerunner in Quality for 50+ Years

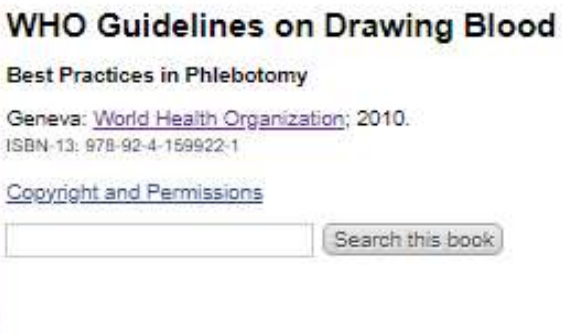
LABQUALITY MY PERSPECTIVE

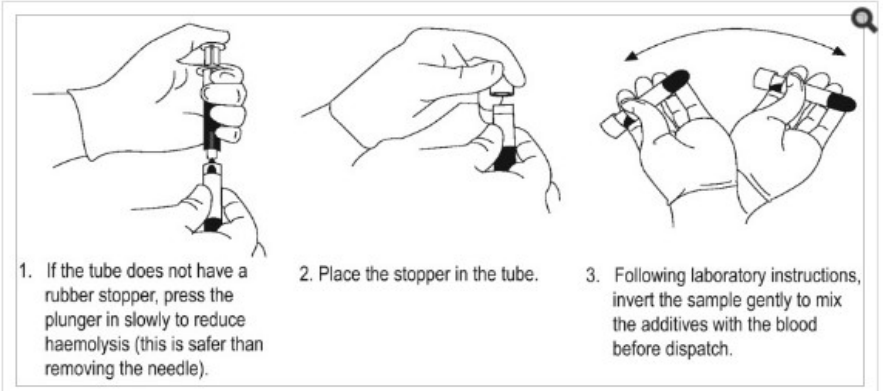
R&D Director at Labquality
Member of the The Nordic preanalytical scientific working group
Member of the Finnish preanalytical group

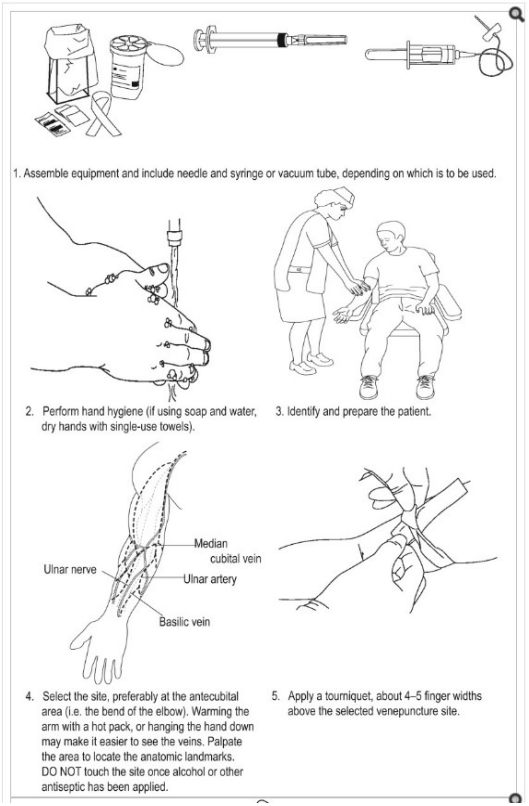
LABQUALITY

WHO Guidelines on Drawing Blood: Best Practices in Phlebotomy.









[WHO Guidelines on Drawing Blood - NCBI Bookshelf (nih.gov)]

DE GRUYTER Clin Chem Lab Med 2018; 56(12): 2015–2038

EFLM Paper

EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

COLABIOCLI

Ana-Maria Simundic*, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Edmée C. van Dongen-Lases, Pinar Eker, Tanja Erdeljanovic, Kjell Grankvist, Joao Tiago Guimaraes, Roger Hoke, Mercedes Ibarz, Helene Ivanov, Svetlana Kovalevskaya, Gunn B.B. Kristensen, Gabriel Lima-Oliveira, Giuseppe Lippi, Alexander von Meyer, Mads Nybo, Barbara De la Salle, Christa Seipelt, Zorica Sumarac and Pieter Vermeersch, on behalf of the Working Group for Preanalytical Phase (WG-PRE), of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI)

Joint EFLM-COLABIOCLI Recommendation for venous blood sampling

v 1.1, June 2018

https://doi.org/10.1515/cclm-2018-0602
Received June 9, 2018; accepted June 10, 2018; previously published online July 13, 2018

***Corresponding author: Ana-Maria Simundic,** Department of Medical Laboratory Diagnostics, Clinical Hospital "Sveti Duh", Zagreb, Croatia, E-mail: am.simundic@gmail.com, amsimundic@kbsd.hr
Karin Bölenius: Department of Nursing, Umeå University, Umeå, Sweden
Janne Cadamuro: Department of Laboratory Medicine, Paracelsus Medical University, Salzburg, Austria
Stephen Church: BD Life Sciences – Preanalytical Systems, Reading, UK
Michael P. Cornes: Department of Clinical Biochemistry, Worcester Acute Hospitals NHS Trust, Worcester, UK
Edmée C. van Dongen-Lases: Department of Clinical Chemistry, Academic Medical Center, Amsterdam, The Netherlands
Pinar Eker: Ümraniye Research and Training Hospital, Istanbul, Turkey
Tanja Erdeljanovic: Clinic for Otorhinolaryngology and Maxillofacial Surgery, Clinical Center of Serbia, Belgrade, Serbia
Kjell Grankvist: Department of Medical Biosciences, Clinical Chemistry, Umeå University, Umeå, Sweden
Joao Tiago Guimaraes: Department of Clinical Pathology, São João Hospital Center, Department of Biomedicine, Faculty of Medicine, Porto, Portugal; and EPI Unit, Institute of Public Health, University of Porto, Porto, Portugal
Roger Hoke: National Association of Phlebotomists, London, UK
Mercedes Ibarz: Department of Clinical Laboratory, University Hospital Arnau de Vilanova, Lleida, Spain. http://orcid.org/0000-0003-0590-946X
Helene Ivanov: Greiner Bio-One GmbH, Kremsmuenster, Austria
Svetlana Kovalevskaya: Clinical Laboratory Diagnostic and Pathomorphology Department, Autonomous non-profit organization of additional professional education "Institute of Laboratory Medicine", Moscow, Russia
Gunn B.B. Kristensen: Norwegian quality improvement of laboratory examinations, Bergen, Norway
Gabriel Lima-Oliveira: Section of Clinical Biochemistry, University of Verona, Verona, Italy; and Latin American Working Group for Preanalytical Phase (WG-PRE-LATAM) of the Latin America Confederation of Clinical Biochemistry (COLABIOCLI), Verona, Italy
Giuseppe Lippi: Section of Clinical Chemistry, University of Verona, Verona, Italy. http://orcid.org/0000-0001-9523-9054
Alexander von Meyer: Institute of Laboratory Medicine, Kliniken Nordoberpfalz AG and Klinikum St. Marien, Weiden and Amberg, Germany
Mads Nybo: Clinical Biochemistry and Pharmacology, Odense University Hospital, Odense, Denmark
Barbara De la Salle: West Hertfordshire Hospitals NHS Trust, Operating UK NEQAS for Haematology and Transfusion, Watford, UK
Christa Seipelt: Sarstedt GmbH & Co.KG, Nümbrecht, Germany
Zorica Sumarac: Center for Medical Biochemistry, Clinical Center of Serbia, Belgrade, Serbia
Pieter Vermeersch: Department of Laboratory Medicine, University of Leuven, Leuven, Belgium

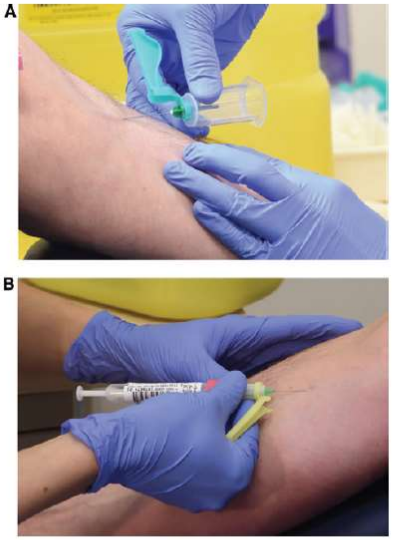


Figure 3: Needle should be inserted into the vessel at an approximately 5–30 degree angle, depending on the vein's depth.
(A) Inserting the needle for the users of pre-evacuated tubes and (B) inserting the needle for the users of blood collection systems using the aspiration technique.

Step 10. Drawing blood into the first tube (1A)

10.1 Draw the blood by a) inserting the tube in the holder so that the cap is perforated and the blood is drawn (vacuum technique) or b) withdrawing the plunger slowly (aspiration technique). Follow the EFLM recommended order of draw [74]. As blood collection techniques may differ with respect to the manufacturer, specific recommendations of the manufacturer should always be followed, along with the recommendations in this document, during blood collection.

The recommended order of draw is as follows:

1. Blood culture tube
2. Citrate tube
3. Plain tube or tube with clot activator
4. Heparin tube
5. EDTA tube
6. Glycolysis inhibitor tube
7. Other tubes

10.2 When coagulation tube is collected as the first or the only tube

- and a straight needle is used for blood collection, no discard tube is needed [75, 76]
- and a winged blood collection set (butterfly devices) is used, a discard tube must be collected to prevent underfilling of the tube with subsequent bias in test results [8]

10.3 Ensure that tubes are fully filled (e.g. up to the indi-

- CROATIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- ESTONIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- FRENCH translation1 of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- FRENCH translation2 of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- ITALIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- MACEDONIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- PORTUGUESE translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- RUSSIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- SERBIAN translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- SPANISH translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling
- TURKISH translation of the Joint EFLM-COLABIOCLI Recommendation for venous blood sampling

7th Edition

GP41

Collection of Diagnostic Venous Blood Specimens

SFS Tekninen spesifikaatio

ISO/TS 20658:2019:fi

1 (76)

Suomenkielisen käännöksen päivämäärä 2019-10-04 | Date of translation into Finnish 2019-10-04

Lääketieteelliset laboratoriot. Näytteiden keräystä, kuljetusta, vastaanottamista ja käsittelyä koskevat vaatimukset

Medical laboratories – Requirements for collection, transport, receipt, and handling of samples

Julkaisu sisältää myös englanninkielisen tekstin suomenkielisen käännöksen. | The document also contains a Finnish translation of the English text.

- For laboratories and organizations who do sampling or process samples
- Specific instruction for e.g. the order of draw, patient preparation and sample integrity

Standardista vastaava toimialayhteisö: Yhteinen Toimialaliitto | Standards writing body responsible for the standard: General Industry Federation

Suomen Standardisoimisliitto SFS ry
Malminkatu 34, PL 130, 00101 Helsinki
p. 09 149 9331, www.sfs.fi, sales@sfs.fi

Finnish Standards Association SFS
P.O. Box 130, FI-00101 Helsinki, (Malminkatu 34)
Tel. +358 9 149 9331, www.sfs.fi, sales@sfs.fi

Clinical guideline

- from evidence to outcomes

Hotus
Nursing Research Foundation

Patient guidance for laboratory tests

Clinical guidelines are based on best available evidence concerning effective, feasible, appropriate and/or meaningful interventions in patient's or client's care

LABQUALITY WWW.VIERITESTISUOSITUS.FI – POCT RECOMMENDATION

Vieritestisuositus

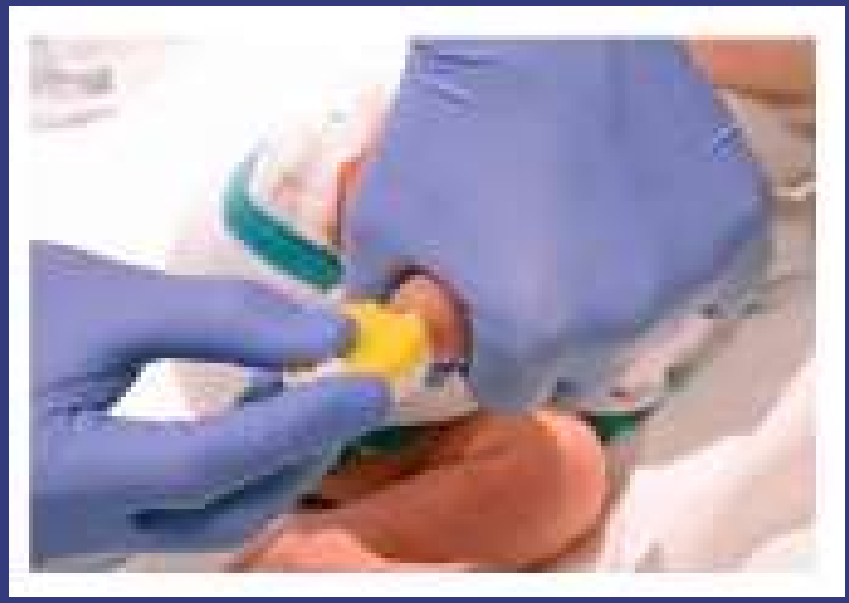
Vieritestisuositus on tarkoitettu vieritestauksesta vastaaville laboratorioalan ammattilaisille sekä vieritestejä suorittavien terveydenhuollon työntekijöiden käyttöön. Suositusta voi soveltaa myös potilaan tekemään omatestaukseen. Tämä suositus ei ole viranomaissuositus vaan suomalaisen asiantuntijatyöryhmän näkemys parhaista käytännöistä.

Uusin versio vieritestisuosituksesta on julkaistu marraskuussa 2021.

Vieritestisuositustyöryhmä

Mia Sneck, pj. sairaalakemisti, yksikön vastaava, HUS Diagnostiikkakeskus **Salla Kiiskinen**, sairaalamikrobiologi, THL **Kristina Hotakainen**, LT Dos, laboratoriosektorin johtaja, Mehiläinen Oy **Kirsi Krum**, bioanalyytikko, TtM, projektipäällikkö, Nordlab	**Annakaisa Herrala**, FT, Dos. sairaalakemisti, HUS Diagnostiikkakeskus, HUSLAB vieritestaus **Eeva-Liisa Paattiniemi**, sairaalakemisti, vyp, HUS Diagnostiikkakeskus, HUSLAB **Päivi Burakoff**, bioanalyytikko, YAMK, koulutuspäällikkö, Labquality **Heidi Berghäll**, sairaalakemisti, tuotekehityspäällikkö, Labquality

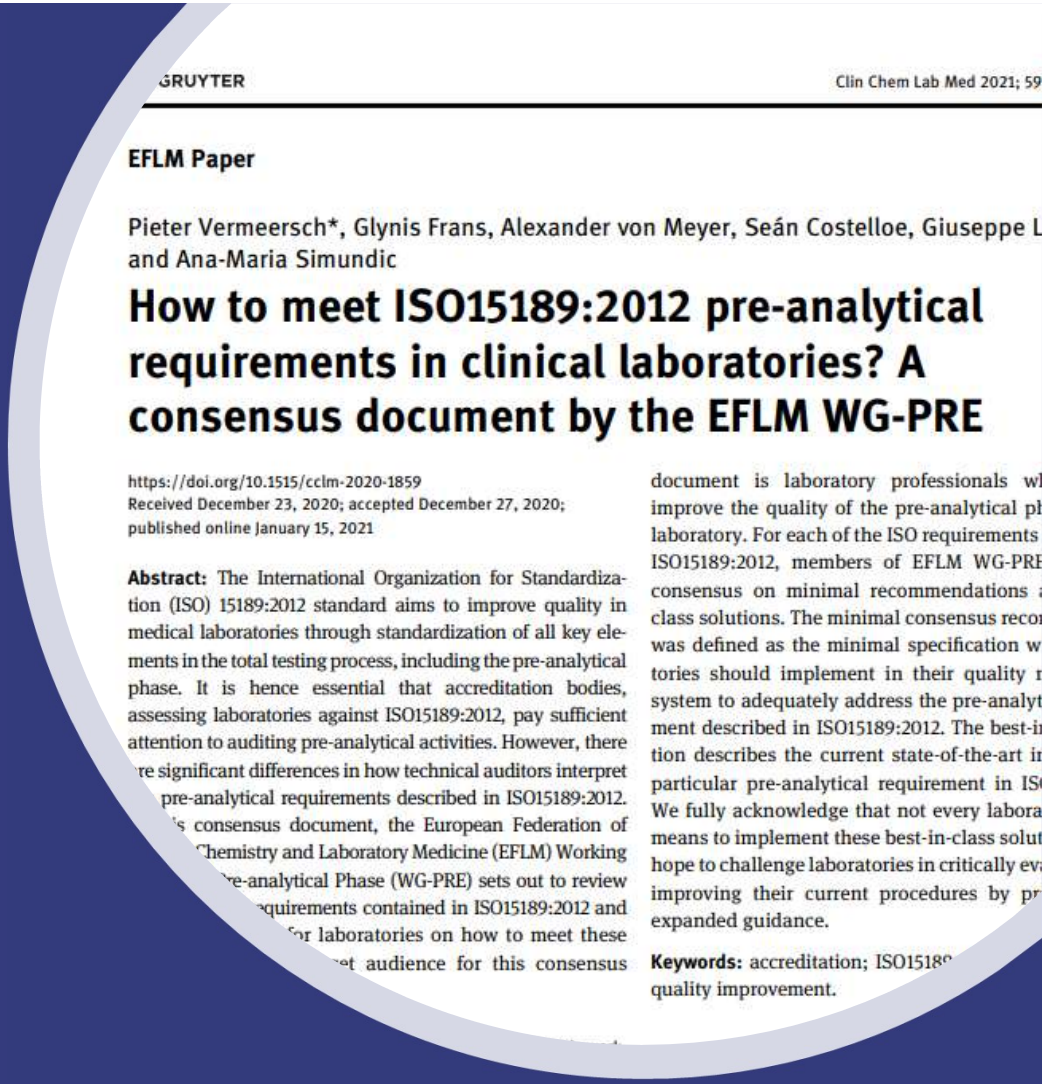
Lisäksi verikaasuasiantuntija toimi Annukka Mäki, sairaalakemisti, HUS Diagnostiikkakeskus, HUSLAB vieritestaus



POCT recommendation

ISO 15189:2012 requires that the laboratories

- Primary sample collection and handling (5.4.4)
  - The laboratory shall have documented procedures for the proper collection and handling of primary samples. The documented procedures shall be available to those responsible for primary sample collection whether or not the collectors are laboratory staff (5.4.4.1)
  - Instructions for pre-collection activities (5.4.4.2)
  - Instructions for collection activities (5.4.4.3)



GRUYTER Clin Chem Lab Med 2021; 59

EFLM Paper

Pieter Vermeersch*, Glynis Frans, Alexander von Meyer, Seán Costelloe, Giuseppe L and Ana-Maria Simundic

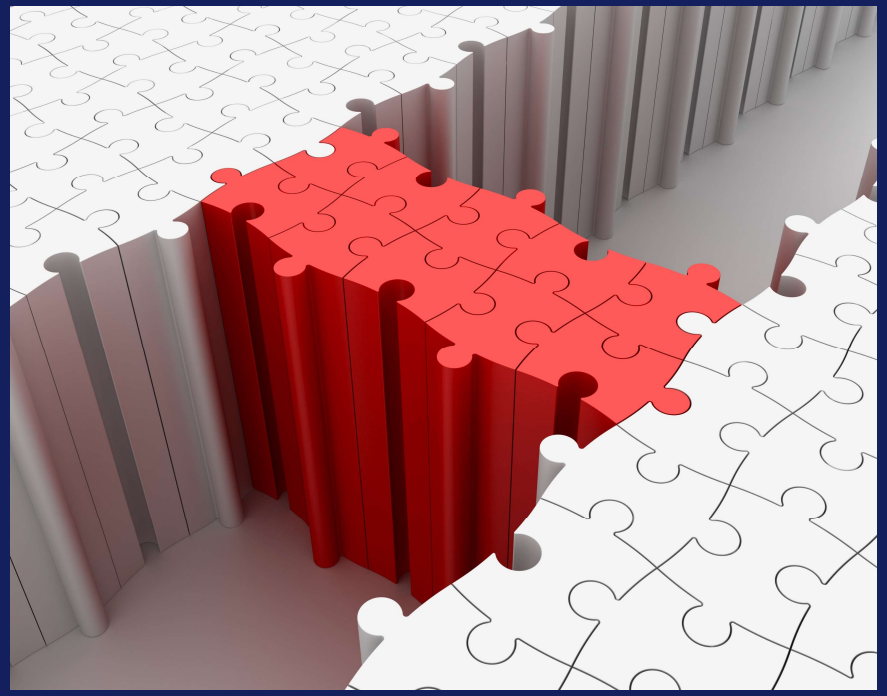
How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE

https://doi.org/10.1515/cclm-2020-1859
Received December 23, 2020; accepted December 27, 2020; published online January 15, 2021

Abstract: The International Organization for Standardization (ISO) 15189:2012 standard aims to improve quality in medical laboratories through standardization of all key elements in the total testing process, including the pre-analytical phase. It is hence essential that accreditation bodies, assessing laboratories against ISO15189:2012, pay sufficient attention to auditing pre-analytical activities. However, there re significant differences in how technical auditors interpret pre-analytical requirements described in ISO15189:2012. s consensus document, the European Federation of Chemistry and Laboratory Medicine (EFLM) Working re-analytical Phase (WG-PRE) sets out to review equirements contained in ISO15189:2012 and or laboratories on how to meet these et audience for this consensus document is laboratory professionals wh improve the quality of the pre-analytical ph laboratory. For each of the ISO requirements ISO15189:2012, members of EFLM WG-PRE consensus on minimal recommendations a class solutions. The minimal consensus reco was defined as the minimal specification w tories should implement in their quality m system to adequately address the pre-analyt ment described in ISO15189:2012. The best-i tion describes the current state-of-the-art in particular pre-analytical requirement in IS We fully acknowledge that not every labora means to implement these best-in-class solut hope to challenge laboratories in critically eva improving their current procedures by pr expanded guidance.

Keywords: accreditation; ISO15189 quality improvement.

LABQUALITY CHALLENGES



- Laboratories are not always the ones taking the samples,
- In Finland counties or cities or joint municipal authorities take a lot of the samples
- These facilities are not necessarily accredited or certified and some of them have only the recommendations of the laboratories.

LABQUALITY SFS-EN ISO 22870:2016

Standardi

SFS-EN ISO 22870:2016

Yhteinen Toimialaliitto
General Industry Federation

Vahvistettu
2016-12-09

SFS/ICS 03.120.10; 11.100.01

Korvaa standardin SFS-EN ISO 22870:2006

Replaces the standard SFS-EN ISO 22870:2006

Ristiriitatapauksissa pätee englanninkielinen teksti.	*In case of interpretation disputes the English text applies.*
Suomenkielisen käännöksen päivämäärä 2018-04-06	*Date of translation into Finnish 2018-04-06*

Vieritestaus. Laatu-ja pätevyysvaatimukset

Point-of-care testing (POCT). Requirements for quality and competence (ISO 22870:2016)

Tämä standardi sisältää eurooppalaisen standardin EN ISO 22870:2016 "Point-of-care testing (POCT). Requirements for quality and competence (ISO 22870:2016)" englanninkielisen tekstin.

This standard consists of the English text of the European Standard EN ISO 22870:2016 "Point-of-care testing (POCT). Requirements for quality and competence (ISO 22870:2016)".

Standardi sisältää myös englanninkielisen tekstin suomenkielisen käännöksen.

The Standard also contains a Finnish translation of the English text.

Eurooppalainen standardi EN ISO 22870:2016 on vahvistettu suomalaiseksi kansalliseksi standardiksi.

The European Standard EN ISO 22870:2016 has the status of a Finnish national standard.

Does not take the sampling itself into account that much.

It relies on the instructions set in ISO 15189:2012.

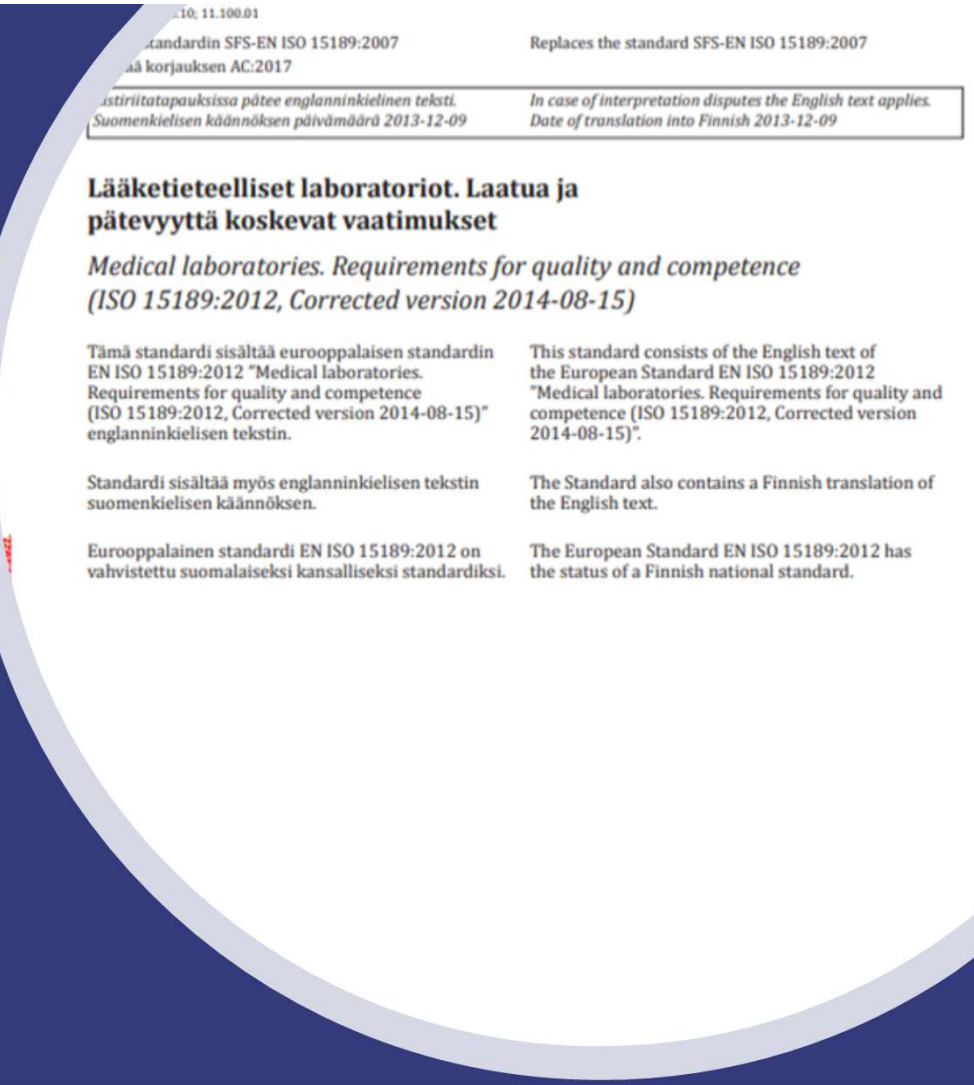
ISO 15189:2012
Preanalytical phase

shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence.

4:11

4:14

The laboratory shall establish quality indicators to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes (4.14.7)



...10; 11.100.01

...standardin SFS-EN ISO 15189:2007 ...aä korjauksen AC:2017

Replaces the standard SFS-EN ISO 15189:2007

...istiriitatapauksissa pätee englanninkielinen teksti. Suomenkielisen käännöksen päivämäärä 2013-12-09

In case of interpretation disputes the English text applies. Date of translation into Finnish 2013-12-09

Lääketieteelliset laboratoriot. Laatua ja pätevyyttä koskevat vaatimukset

Medical laboratories. Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)

Tämä standardi sisältää eurooppalaisen standardin EN ISO 15189:2012 "Medical laboratories. Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)" englanninkielisen tekstin.

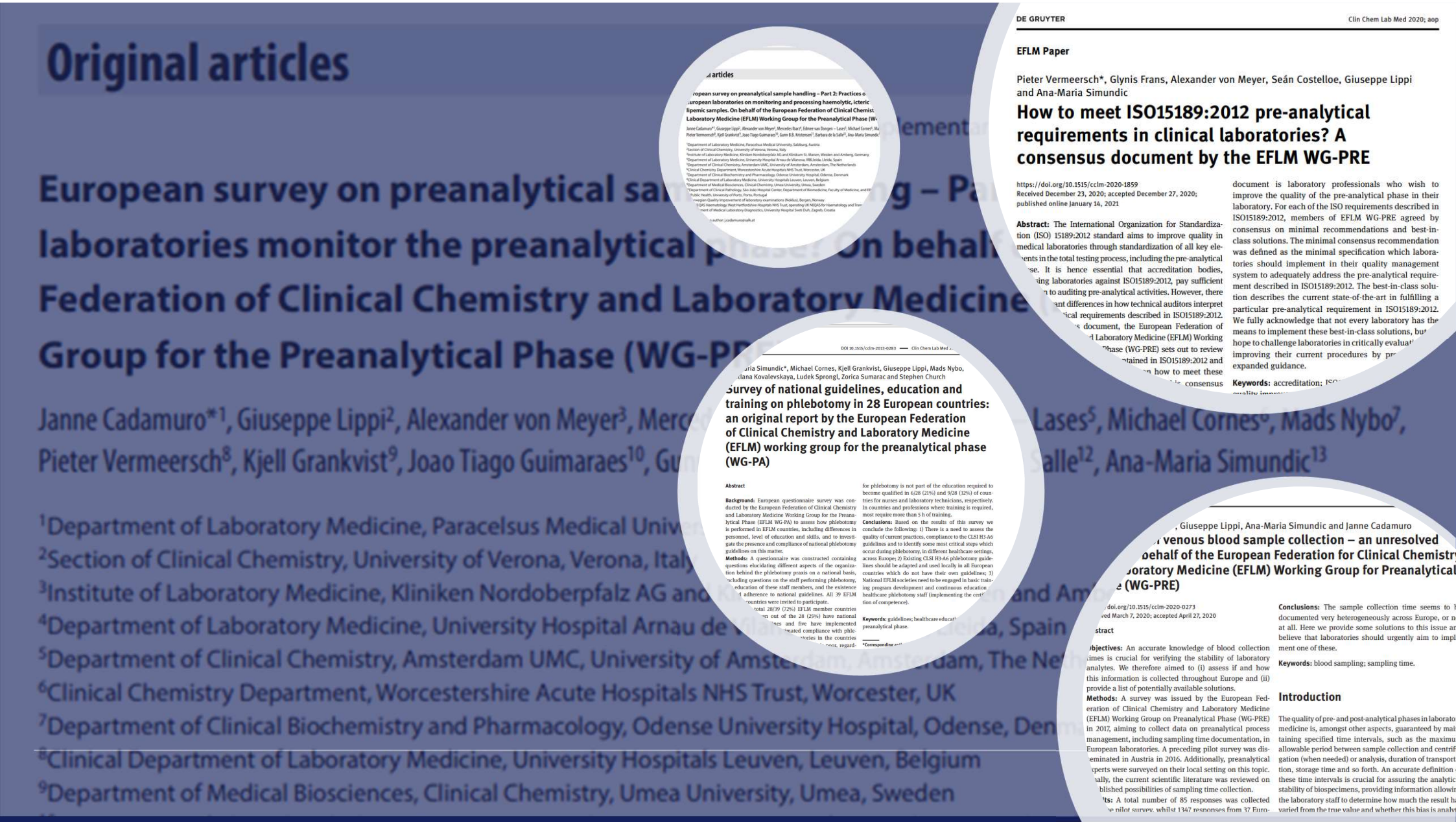
This standard consists of the English text of the European Standard EN ISO 15189:2012 "Medical laboratories. Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)".

Standardi sisältää myös englanninkielisen tekstin suomenkielisen käännöksen.

The Standard also contains a Finnish translation of the English text.

Eurooppalainen standardi EN ISO 15189:2012 on vahvistettu suomalaiseksi kansalliseksi standardiksi.

The European Standard EN ISO 15189:2012 has the status of a Finnish national standard.



DE GRUYTER Clin Chem Lab Med 2020; aop

EFLM Paper

Pieter Vermeersch*, Glynis Frans, Alexander von Meyer, Seán Costelloe, Giuseppe Lippi and Ana-Maria Simundic

How to meet ISO15189:2012 pre-analytical requirements in clinical laboratories? A consensus document by the EFLM WG-PRE

https://doi.org/10.1515/cclm-2020-1859
Received December 23, 2020; accepted December 27, 2020; published online January 14, 2021

Abstract: The International Organization for Standardization (ISO) 15189:2012 standard aims to improve quality in medical laboratories through standardization of all key elements in the total testing process, including the pre-analytical phase. It is hence essential that accreditation bodies, assessing laboratories against ISO15189:2012, pay sufficient attention to auditing pre-analytical activities. However, there are significant differences in how technical auditors interpret the technical requirements described in ISO15189:2012. In this document, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for the Preanalytical Phase (WG-PRE) sets out to review the requirements contained in ISO15189:2012 and provide guidance on how to meet these requirements. The consensus document is laboratory professionals who wish to improve the quality of the pre-analytical phase in their laboratory. For each of the ISO requirements described in ISO15189:2012, members of EFLM WG-PRE agreed by consensus on minimal recommendations and best-in-class solutions. The minimal consensus recommendation was defined as the minimal specification which laboratories should implement in their quality management system to adequately address the pre-analytical requirement described in ISO15189:2012. The best-in-class solution describes the current state-of-the-art in fulfilling a particular pre-analytical requirement in ISO15189:2012. We fully acknowledge that not every laboratory has the means to implement these best-in-class solutions, but hope to challenge laboratories in critically evaluating and improving their current procedures by providing expanded guidance.

Keywords: accreditation; ISO

DOI 10.1515/cclm-2013-0283 — Clin Chem Lab Med

Simundic*, Michael Cornes, Kjell Grankvist, Giuseppe Lippi, Mads Nybo, Ljiljana 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)

Abstract

Background: European questionnaire survey was conducted by the European Federation of Clinical Chemistry and Laboratory Medicine Working Group for the Preanalytical Phase (EFLM WG-PA) to assess how phlebotomy is performed in EFLM countries, including differences in personnel, level of education and skills, and to investigate the presence and compliance of national phlebotomy guidelines on this matter.

Methods: A questionnaire was constructed containing questions elucidating different aspects of the organization behind the phlebotomy praxis on a national basis, including questions on the staff performing phlebotomy, education of these staff members, and the existence and adherence to national guidelines. All 39 EFLM countries were invited to participate.

A total 28/39 (72%) EFLM member countries [illegible] out of the 28 (25%) have national guidelines and five have implemented [illegible] compliance with phlebotomy guidelines in the countries [illegible] poor, regarding for phlebotomy is not part of the education required to become qualified in 6/28 (21%) and 9/28 (32%) of countries for nurses and laboratory technicians, respectively. In countries and professions where training is required, most require more than 5 h of training.

Conclusions: 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 healthcare phlebotomy staff (implementing the certification of competence).

Keywords: guidelines; healthcare educat preanalytical phase.

*Corresponding

, Giuseppe Lippi, Ana-Maria Simundic and Janne Cadamuro

venous blood sample collection – an unresolved behalf of the European Federation for Clinical Chemistry oratory Medicine (EFLM) Working Group for Preanalytical e (WG-PRE)

doi.org/10.1515/cclm-2020-0273
ved March 7, 2020; accepted April 27, 2020

stract

bjectives: An accurate knowledge of blood collection imes is crucial for verifying the stability of laboratory analytes. We therefore aimed to (i) assess if and how this information is collected throughout Europe and (ii) provide a list of potentially available solutions.

Methods: A survey was issued by the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) Working Group on Preanalytical Phase (WG-PRE) in 2017, aiming to collect data on preanalytical process management, including sampling time documentation, in European laboratories. A preceding pilot survey was disseminated in Austria in 2016. Additionally, preanalytical experts were surveyed on their local setting on this topic. Finally, the current scientific literature was reviewed on published possibilities of sampling time collection.

ts: A total number of 85 responses was collected [illegible] pilot survey, whilst 1347 responses from 37 Euro-

Conclusions: The sample collection time seems to b documented very heterogeneously across Europe, or n at all. Here we provide some solutions to this issue ar believe that laboratories should urgently aim to impl ment one of these.

Keywords: blood sampling; sampling time.

Introduction

The quality of pre- and post-analytical phases in laborato medicine is, amongst other aspects, guaranteed by mai taining specified time intervals, such as the maximu allowable period between sample collection and centrif gation (when needed) or analysis, duration of transport tion, storage time and so forth. An accurate definition these time intervals is crucial for assuring the analytic stability of biospecimens, providing information allowin the laboratory staff to determine how much the result ha varied from the true value and whether this bias is analyt

THE ECLM- EUROPEAN URINALYSIS GUIDELINES 2000

The document to be updated

ECLM. European Urinalysis Guidelines.

(Kouri T, Fogazzi G, Gant V, Hallander H, Hofmann W, Guder W, editors).

Scand J Clin Lab Invest 2000; 60 (Suppl 231): 1-96.

Courtesy of Dr. Timo Kouri

TFG: Urinalysis
TERMS OF REFERENCE

Background: The updating NEEDS of the European Urinalysis Guidelines 2000

- New automation in particle counting and bacteriology
- New biomarkers (kidney disease) and infective agents (bacteria)
- New tools of specimen collection, techniques, possible preservation?
- Quality of processes, including performance specifications

Courtesy of Dr. Timo Kouri

N.B. Texts still in draft mode!

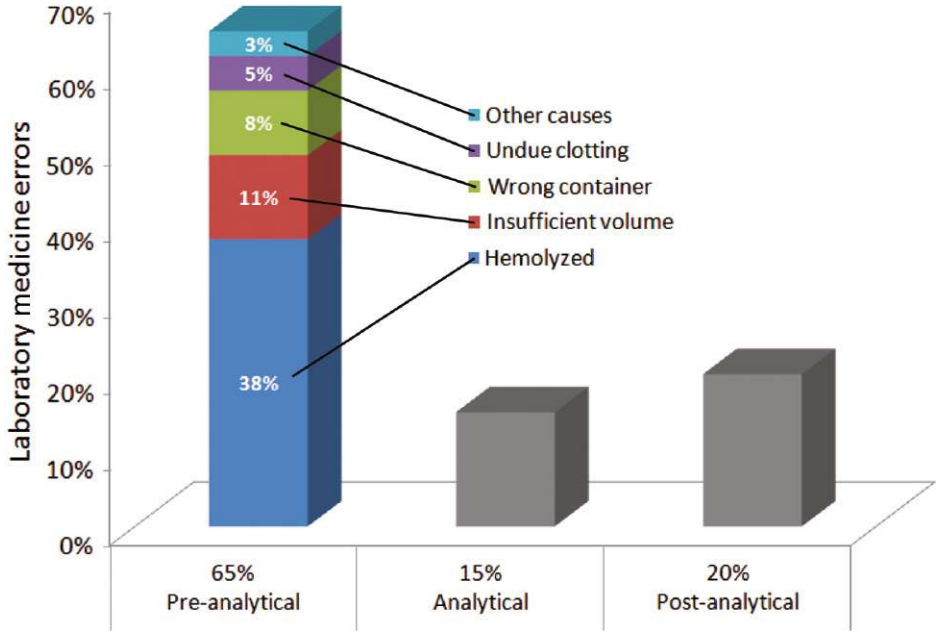
Terms of reference:

- To revise the previous publication by evidence-based knowledge
- To promote standardised and high-quality procedures in clinical urinalysis
- To support development of new urinalysis technologies

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Sampling occurs in the preanalytical phase

The extra-analytical phases have the highest rates in errors



Lippi et al. Diagnosis 2018

LABQUALITY

There are a lot of guidelines

Most of the errors happen in the preanalytical phase

LABQUALITY ARE THE GUIDELINES FOLLOWED?

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)

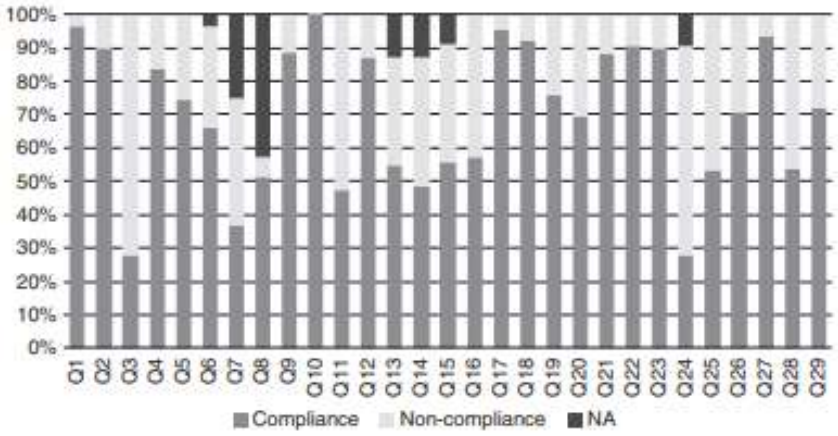
DOI 10.1515/cclm-2014-1053
Received October 27, 2014; accepted October 28, 2014

Abstract

Background: An observational study was conducted in 12 European countries by the European Federation of Clinical Chemistry and Laboratory Medicine Working Group for the Preanalytical Phase (EFLM WG-PRE) to assess the level of compliance with the CLSI H3-A6 guidelines.

Methods: A structured checklist including 29 items was created to assess the compliance of European phlebotomy procedures with the CLSI H3-A6 guideline. A risk occurrence chart of individual phlebotomy steps was created from the observed error frequency and severity of harm of each guideline key issue. The severity of errors occurring during phlebotomy was graded using the risk occurrence chart.

Results: Twelve European countries participated with a median of 33 (18–36) audits per country, and a total of 336 audits. The median error rate for the total phlebotomy procedure was 26.9 % (10.6–43.8), indicating a low overall



Our study shows that the overall level of compliance of phlebotomy procedures with CLSI H3-A6 guideline in 12 European countries is unacceptably low, especially regarding patient identification and tube labelling. These issues call for immediate attention and improvement.

Simundic et al., Clin Chem Lab Med, 2014

Continuous quality control of the blood sampling procedure using a structured observation scheme

Tine Lindberg Seemann[1], Mads Nybo*[1]

[1]Department of Clinical Biochemistry and Pharmacology, Odense University Hospital, Odense, Denmark

* Corresponding author: mads.nybo@rsyd.dk

Abstract

Introduction: An observational study was conducted using a structured observation scheme to assess compliance with the local phlebotomy guideline, to identify necessary focus items, and to investigate whether adherence to the phlebotomy guideline improved.

Materials and methods: The questionnaire from the EFLM Working Group for the Preanalytical Phase was adapted to local procedures. A pilot study of three months duration was conducted. Based on this, corrective actions were implemented and a follow-up study was conducted. All phlebotomists at the Department of Clinical Biochemistry and Pharmacology were observed. Three blood collections by each phlebotomist were observed at each session conducted at the phlebotomy ward and the hospital wards, respectively. Error frequencies were calculated for the phlebotomy ward and the hospital wards and for the two study phases.

Results: A total of 126 blood drawings by 39 phlebotomists were observed in the pilot study, while 84 blood drawings by 34 phlebotomists were

Conclusion: Continuous quality control of the phlebotomy procedure revealed a number of items not conducted in compliance with the local phlebotomy guideline. It supported significant improvements in the adherence to the recommended phlebotomy procedures and facilitated documentation of the phlebotomy quality.

Key words: observation; phlebotomy; preanalytical phase; quality control

Received: September 19, 2015 *Accepted: August 08, 2016*

Assessed the compliance with the local phlebotomy guideline to investigate whether adherence to the phlebotomy guideline improved with the help of quality control

Lindberg Seemann & Nybo, Biochemia Medica 2016

Bölenius et al. BMC Health Services Research 2013, 13:463
http://www.biomedcentral.com/1472-6963/13/463

BMC Health Services Research

RESEARCH ARTICLE Open Access

Impact of a large-scale educational intervention program on venous blood specimen collection practices

Karin Bölenius[1*], Marie Lindkvist[2,3], Christine Brulin[1], Kjell Grankvist[4], Karin Nilsson[1] and Johan Söderberg[4]

Abstract

Background: Phlebotomy performed with poor adherence to venous blood specimen collection (VBSC) guidelines jeopardizes patient safety and may lead to patient suffering and adverse events. A first questionnaire study demonstrated low compliance to VBSC guidelines, motivating an educational intervention of all phlebotomists within a county council. The aim was to evaluate the impact of a large-scale educational intervention program (EIP) on primary health care phlebotomists' adherence to VBSC guidelines. We hypothesised that the EIP would improve phlebotomists' VBSC practical performance.

Conclusions: The present study demonstrated several significant improvements on phlebotomists' adherence to VBSC practices. Still, guideline adherence improvement to several crucial phlebotomy practices is needed. We

twice. The EIP included three parts: guideline studies, an oral presentation, and an examination. Non-parametric statistics were used for comparison within and between the groups.

Results: Evaluating the EIP, we found significant improvements in the intervention group compared to the control group on self-reported questionnaire responses regarding information search (ES = 0.23-0.33, $p < 0.001$-0.003), and patient rest prior to phlebotomy (ES = 0.27, $p = 0.004$). Test request management, patient identity control, release of venous stasis, and test tube labelling had significantly improved in the intervention group but did not significantly differ from the control group (ES = 0.22- 0.49, $p = < 0.001$- 0.006). The control group showed no significant improvements at all (ES = 0–0.39, $p = 0.016$-0.961).

Conclusions: The present study demonstrated several significant improvements on phlebotomists' adherence to VBSC practices. Still, guideline adherence improvement to several crucial phlebotomy practices is needed. We cannot conclude that the improvements are solely due to the EIP and suggest future efforts to improve VBSC. The program should provide time for reflections and discussions. Furthermore, a modular structure would allow directed educational intervention based on the specific VBSC guideline flaws existing at a specific unit. Such an approach is probably more effective at improving and sustaining adherence to VBSC guidelines than an EIP containing general pre-analytical practices.

Keywords: Adherence to guidelines, Education, Implementation, Intervention, Phlebotomy, Pre-analytical errors, Primary healthcare, Venous blood specimen collection

Bölenius et al.,BMC Health Services Reseach 2013

LABQUALITY

Available online at www.sciencedirect.com
ScienceDirect
Clinica Chimica Acta 391 (2008) 91–97
www.elsevier.com/locate/clinchim

Preanalytical venous blood sampling practices demand improvement — A survey of test-request management, test-tube labelling and information search procedures ☆

Olof Wallin [a,*], Johan Söderberg [a], Bethany Van Guelpen [b], Hans Stenlund [c], Kjell Grankvist [a], Christine Brulin [d]

[a] Department of Medical Biosciences, Clinical Chemistry, Umeå University, Umeå, Sweden
[b] Department of Medical Biosciences, Pathology, Umeå University, Umeå, Sweden
[c] Department of Public Health and Clinical Medicine, Epidemiology, Umeå University, Umeå, Sweden
[d] Department of Nursing, Umeå University, Umeå, Sweden

Received 6 February 2008; accepted 18 February 2008
Available online 21 February 2008

Abstract

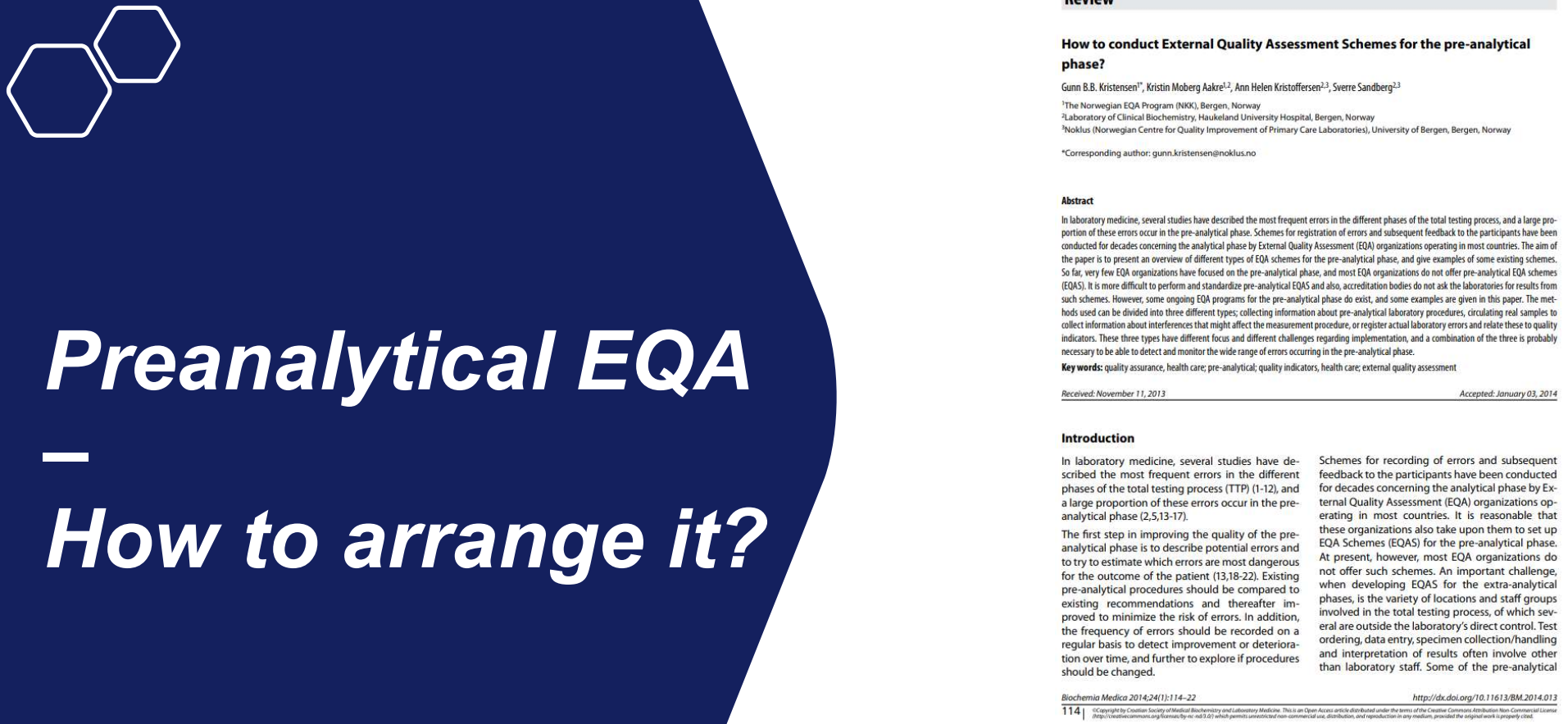
Background: Most errors in laboratory medicine are preanalytical in nature. In the present study, we aimed to survey preanalytical steps in venous blood sampling, prior to actual sample collection. These steps included test-request management and test-tube labelling, as well as information search procedures.

Conclusions: Our results indicate a substantial risk of preanalytical error in test-request management, test-tube labelling, and information search practices, particularly in the wards. Our findings thus underscore the importance of quality control in venous blood sampling, in order to increase patient safety in modern health care.

© 2008 Elsevier B.V. All rights reserved.

Wallin et al., Clinica Chimica Acta, 2009

Preanalytical EQA – How to arrange it?



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

Abstract

In laboratory medicine, several studies have described the most frequent errors in the different phases of the total testing process, and a large proportion of these errors occur in the pre-analytical phase. Schemes for registration of errors and subsequent feedback to the participants have been conducted for decades concerning the analytical phase by External Quality Assessment (EQA) organizations operating in most countries. The aim of the paper is to present an overview of different types of EQA schemes for the pre-analytical phase, and give examples of some existing schemes. So far, very few EQA organizations have focused on the pre-analytical phase, and most EQA organizations do not offer pre-analytical EQA schemes (EQAS). It is more difficult to perform and standardize pre-analytical EQAS and also, accreditation bodies do not ask the laboratories for results from such schemes. However, some ongoing EQA programs for the pre-analytical phase do exist, and some examples are given in this paper. The methods used can be divided into three different types; collecting information about pre-analytical laboratory procedures, circulating real samples to collect information about interferences that might affect the measurement procedure, or register actual laboratory errors and relate these to quality indicators. These three types have different focus and different challenges regarding implementation, and a combination of the three is probably necessary to be able to detect and monitor the wide range of errors occurring in the pre-analytical phase.

Key words: quality assurance, health care; pre-analytical; quality indicators, health care; external quality assessment

Received: November 11, 2013 *Accepted: January 03, 2014*

Introduction

In laboratory medicine, several studies have described the most frequent errors in the different phases of the total testing process (TTP) (1-12), and a large proportion of these errors occur in the pre-analytical phase (2,5,13-17).

The first step in improving the quality of the pre-analytical phase is to describe potential errors and to try to estimate which errors are most dangerous for the outcome of the patient (13,18-22). Existing pre-analytical procedures should be compared to existing recommendations and thereafter improved to minimize the risk of errors. In addition, the frequency of errors should be recorded on a regular basis to detect improvement or deterioration over time, and further to explore if procedures should be changed.

Schemes for recording of errors and subsequent feedback to the participants have been conducted for decades concerning the analytical phase by External Quality Assessment (EQA) organizations operating in most countries. It is reasonable that these organizations also take upon them to set up EQA Schemes (EQAS) for the pre-analytical phase. At present, however, most EQA organizations do not offer such schemes. An important challenge, when developing EQAS for the extra-analytical phases, is the variety of locations and staff groups involved in the total testing process, of which several are outside the laboratory's direct control. Test ordering, data entry, specimen collection/handling and interpretation of results often involve other than laboratory staff. Some of the pre-analytical

Kristensen et al.,Biochemia Medica, 2014

Procedures

- Collecting information about preanalytical laboratory procedures

Samples

- Circulating real samples to collect information on the interferences having an affect on the results

Quality Indicators

- Asking the laboratories to provide actual laboratory errors and relate these to quality indicators

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

Abstract

In laboratory medicine, several studies have described the most frequent errors in the different phases of the total testing process, and a large proportion of these errors occur in the pre-analytical phase. Schemes for registration of errors and subsequent feedback to the participants have been conducted for decades concerning the analytical phase by External Quality Assessment (EQA) organizations operating in most countries. The aim of the paper is to present an overview of different types of EQA schemes for the pre-analytical phase, and give examples of some existing schemes. So far, very few EQA organizations have focused on the pre-analytical phase, and most EQA organizations do not offer pre-analytical EQA schemes (EQAS). It is more difficult to perform and standardize pre-analytical EQAS and also, accreditation bodies do not ask the laboratories for results from such schemes. However, some ongoing EQA programs for the pre-analytical phase do exist, and some examples are given in this paper. The methods used can be divided into three different types; collecting information about pre-analytical laboratory procedures, circulating real samples to collect information about interferences that might affect the measurement procedure, or register actual laboratory errors and relate these to quality indicators. These three types have different focus and different challenges regarding implementation, and a combination of the three is probably necessary to be able to detect and monitor the wide range of errors occurring in the pre-analytical phase.

Key words: quality assurance, health care; pre-analytical; quality indicators, health care; external quality assessment

Received: November 11, 2013 *Accepted: January 03, 2014*

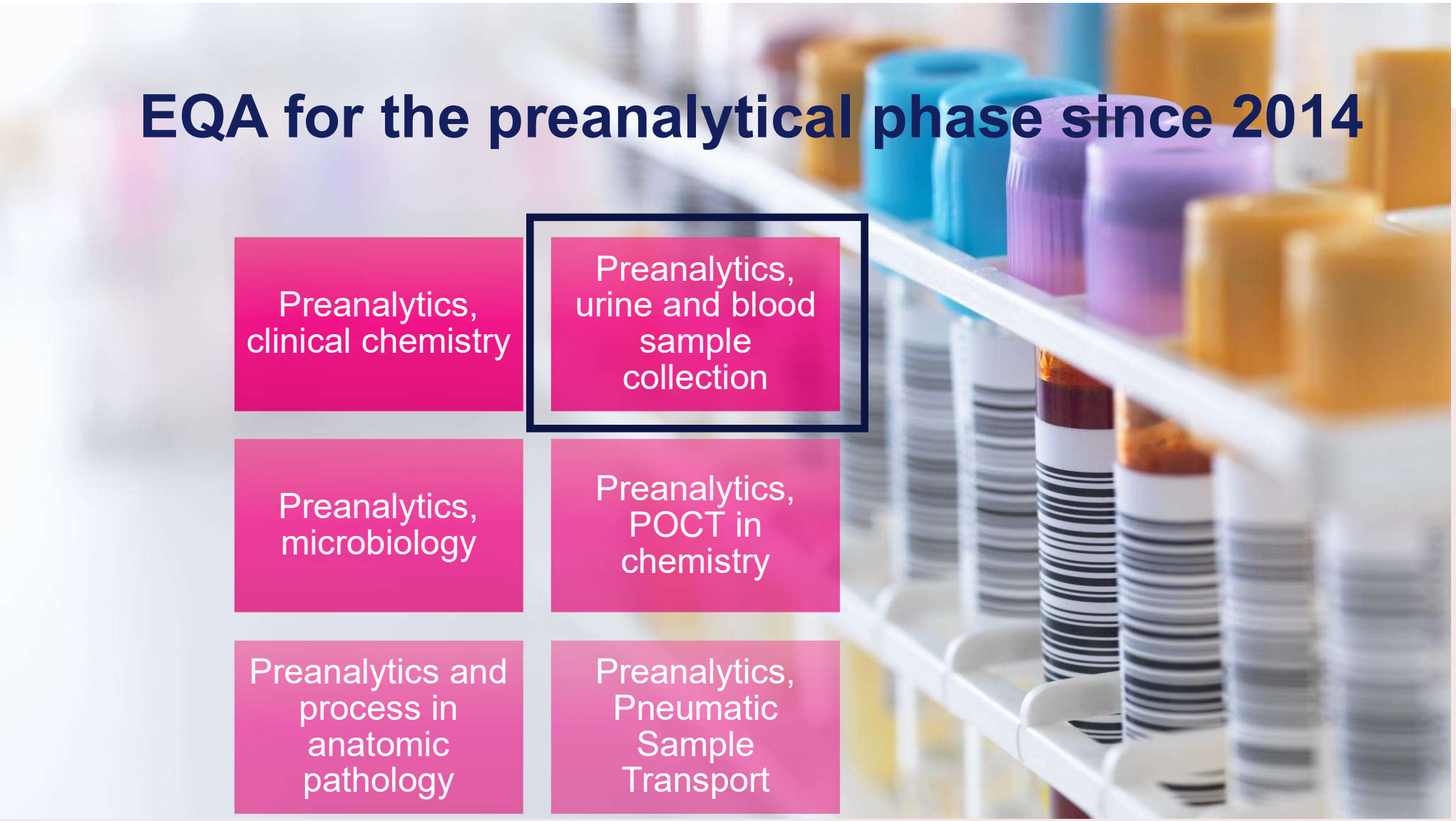
Introduction

In laboratory medicine, several studies have described the most frequent errors in the different phases of the total testing process (TTP) (1-12), and a large proportion of these errors occur in the pre-analytical phase (2,5,13-17).

The first step in improving the quality of the pre-analytical phase is to describe potential errors and to try to estimate which errors are most dangerous for the outcome of the patient (13,18-22). Existing pre-analytical procedures should be compared to existing recommendations and thereafter improved to minimize the risk of errors. In addition, the frequency of errors should be recorded on a regular basis to detect improvement or deterioration over time, and further to explore if procedures should be changed.

Schemes for recording of errors and subsequent feedback to the participants have been conducted for decades concerning the analytical phase by External Quality Assessment (EQA) organizations operating in most countries. It is reasonable that these organizations also take upon them to set up EQA Schemes (EQAS) for the pre-analytical phase. At present, however, most EQA organizations do not offer such schemes. An important challenge, when developing EQAS for the extra-analytical phases, is the variety of locations and staff groups involved in the total testing process, of which several are outside the laboratory's direct control. Test ordering, data entry, specimen collection/handling and interpretation of results often involve other than laboratory staff. Some of the pre-analytical

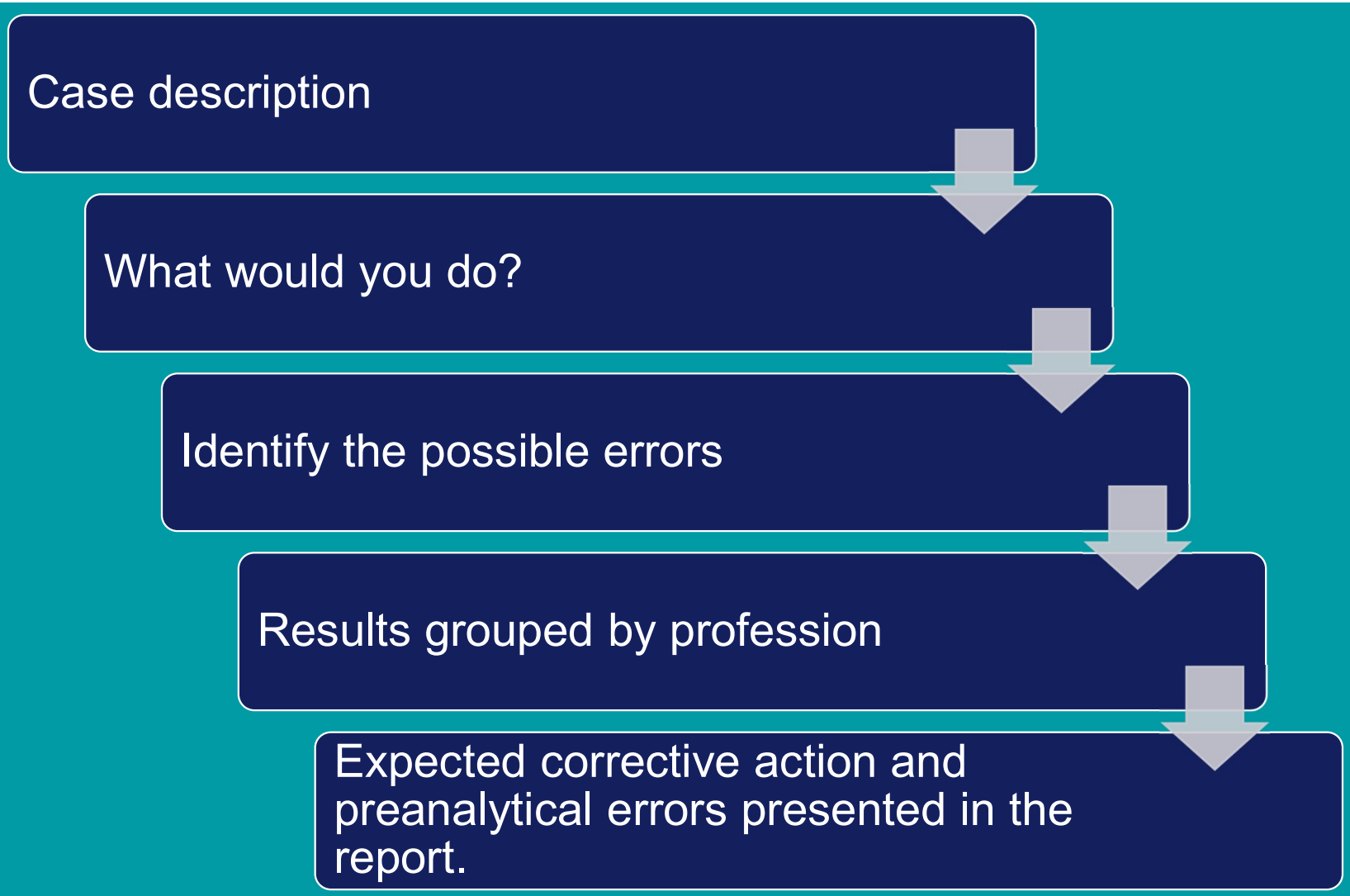
EQA for the preanalytical phase since 2014



Preanalytics, clinical chemistry	Preanalytics, urine and blood sample collection
Preanalytics, microbiology	Preanalytics, POCT in chemistry
Preanalytics and process in anatomic pathology	Preanalytics, Pneumatic Sample Transport

LABQUALITY

TYPE 1: COLLECTING INFORMATION



Integrated EQA

Preanalytical cases (written cases, images videos) related to the scope of the scheme to be evaluated

Traditional specimens to be analyzed

Postanalytical cases related to scope of the scheme to be evaluated

> 40 schemes with EQA[3]

2399: Preanalytics, urine and blood sample collection, March, 1-2020 - Sample set 1 (Case 3)

Help

<<Previous step>>Preanalytics, urine and blood sample collection>>Next step

SAMPLE SETS

First | Previous | 1 | Next | Last

Case 1 | Case 2 | Case 3

Results 1

The following examinations are taken from a baby by brick in the heel: blood gas analysis, K, Na, Krea, CRP, INR and PVK. After the puncture, the nurse wipes off the first drop and then fills the blood gas capillary. Then the nurse fills the INR microtube, then the heparin microtube and finally the EDTA microtube. The sample flows well throughout the sampling and all samples are obtained with the same injection.

Is the sampling order correct?

Case example:
Preanalytics, urine and blood sample collection

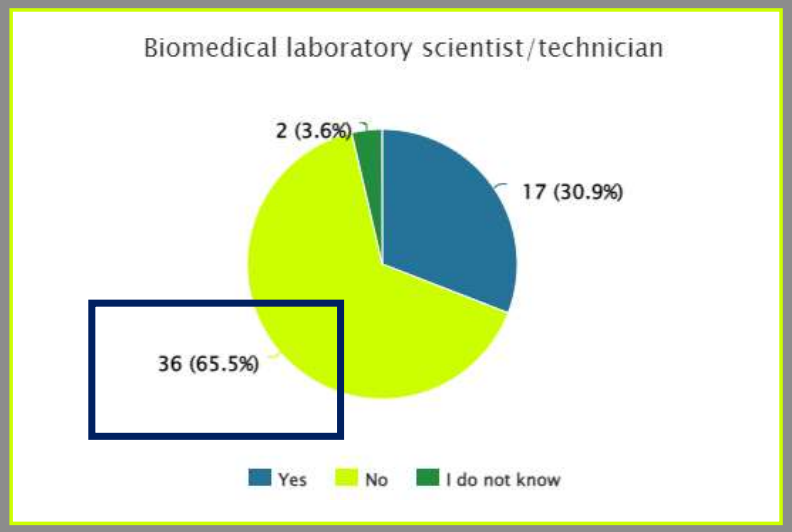
Scheme experts
Clinical chemist, PhD, Elina Porkkala-Saratahо
POCT nurse Teija Vainiomäki

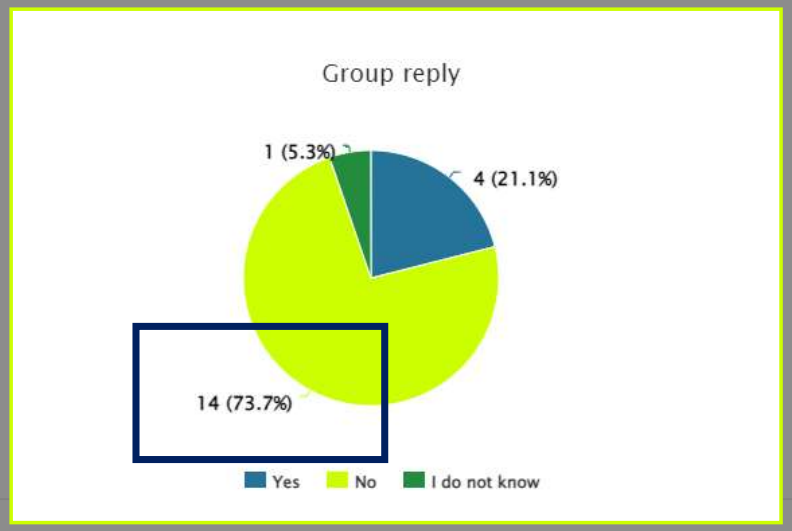
The following examinations are taken from a baby by a prick in the heel:
blood gas analysis, K, Na, Crea, CRP, INR and basic blood count
After the puncture, the nurse wipes off the first drop and then fills the blood gas capillary. Then the nurse fills the INR microtube, then the heparin microtube and finally the EDTA microtube. The sample flows well throughout the sampling and all samples are obtained with the same injection.

Is the sampling order correct?

Expert comments

- The order of skin injection sampling differs from the order of venous blood sampling.
- Because the injection activates the clotting system, blood clotting tests are usually taken from the first drop.
- The anticoagulant-containing tubes are then taken, and finally the serum tubes, as the samples coagulate easily and the cells disintegrate.
- However, to minimize gas leakage, the capillary sample is taken immediately first or, in the case described, immediately after the INR sample.


Biomedical laboratory scientist/technician
2 (3.6%)
17 (30.9%)
36 (65.5%)
Yes
No
I do not know


Group reply
1 (5.3%)
4 (21.1%)
14 (73.7%)
Yes
No
I do not know

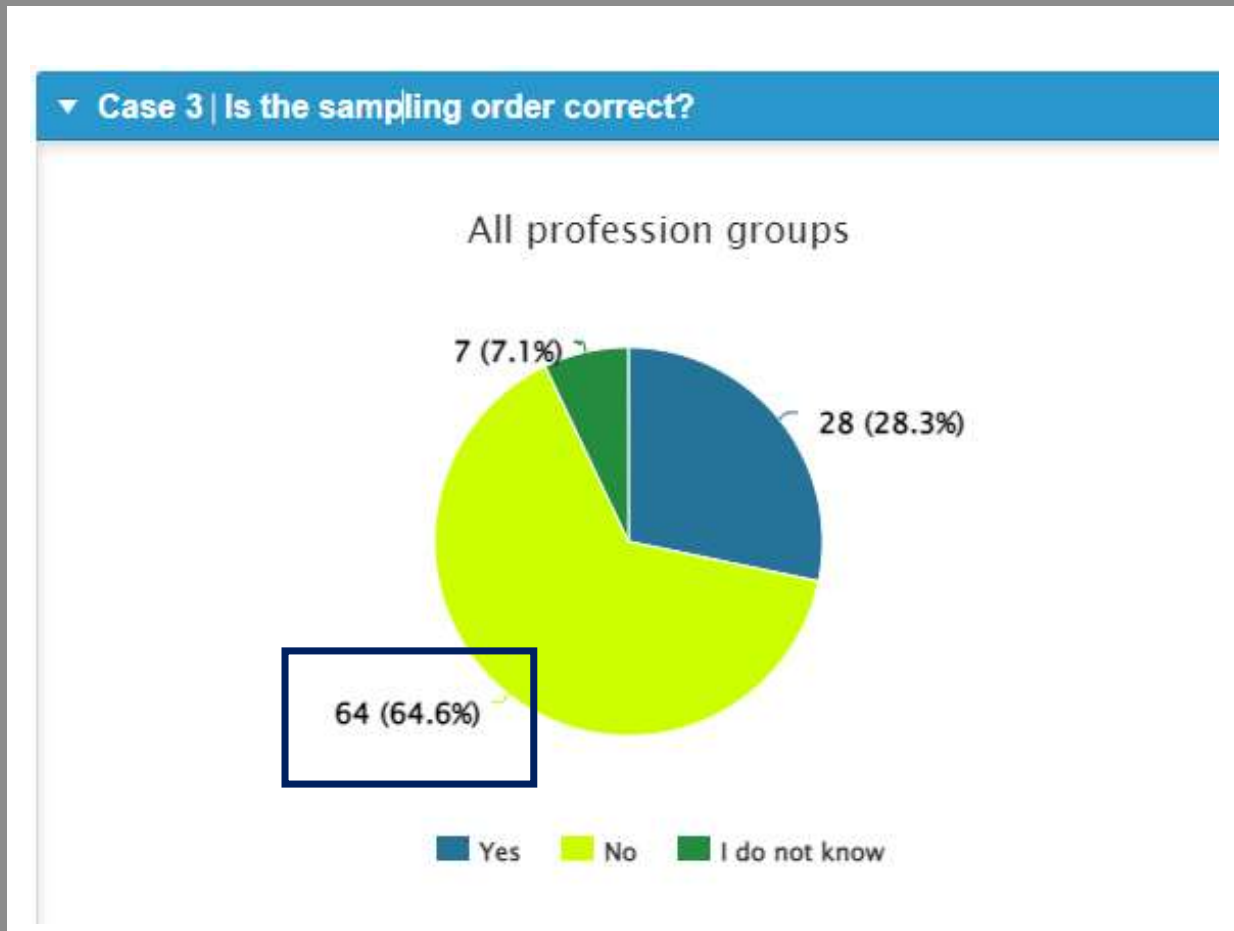

Case 3 | Is the sampling order correct?
All profession groups
7 (7.1%)
28 (28.3%)
64 (64.6%)
Yes
No
I do not know

Figure 2. Correct preanalytical errors found

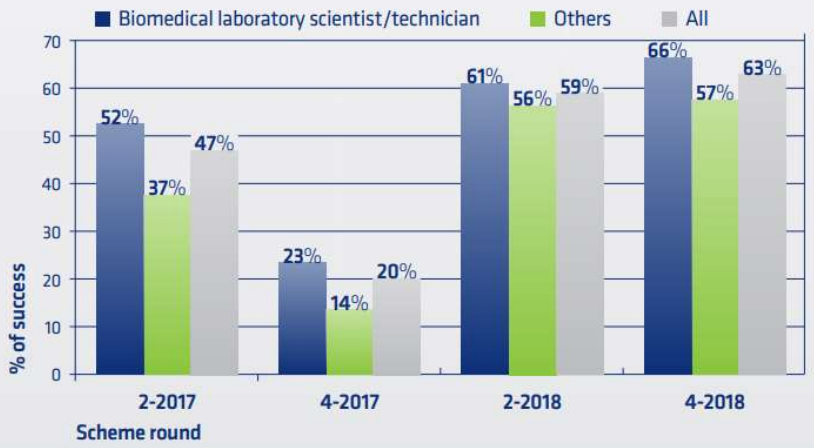
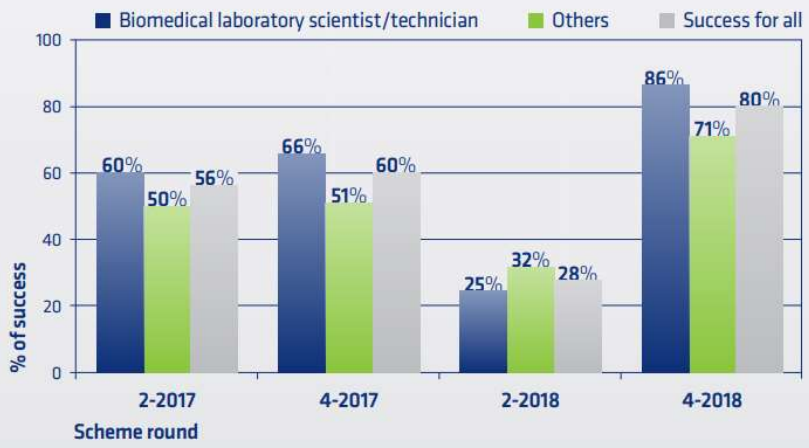


Figure 1. Expected action found by different groups



Integrated preanalytical EQA as part of the blood gas scheme

Pelanti J, Vanhanen A-R, Rauhio A, Berghäll H, poster

- Results from 2017 and 2018
- Success in finding the peranalytical errors is case-dependent
- Routines, education and training in the preanalytical phase vary in different countries

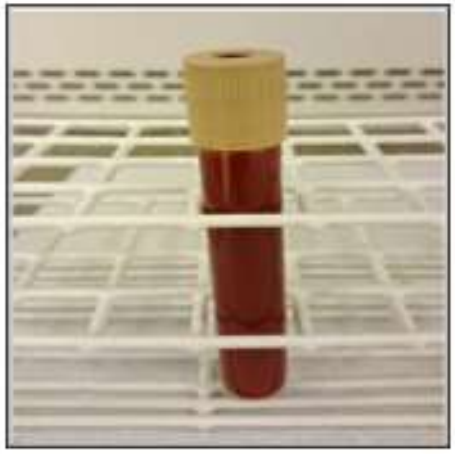
Sample S001 | Preanaytical case

Results

Pre-analytical case : Highly coloured urine sample

Nurse, working for a domestic care services, makes a visit to a customer. The nurse receives a highly coloured urine sample (picture attached) from the customer. Together with the customer they go through the essentials in urine sample collection. Urine should be in the bladder for at least 4 hours. In addition, the nurse makes sure that the sample collection has been performed according to instructions. The nurse identifies the sample with an ID-label including personal information and sample collection time. The nurse puts the sample into a container with a cold pack.

As soon as the nurse arrives to the office, the urine sample is carefully taken out from the container to the table. On the table, the nurse finds a container full of test strips. The nurse makes sure that the strips are dry, straight (i.e. unbent), and that their expiration date is in the future. The nurse picks one strip from the container and lays it on the table. Then, the nurse takes a pipette and drops a small amount of sample on each test pad. Fast reactions are seen on each reaction pad. The nurse writes down the reactions to a form for results. Finally, the results are copied from the form to an electronic information system.



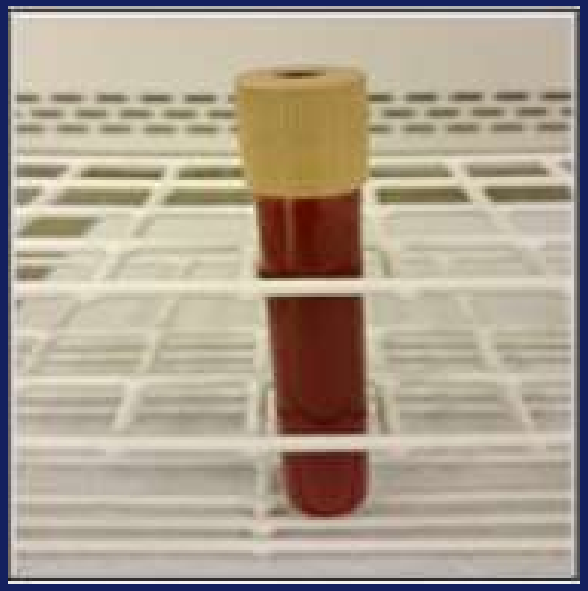
Case example:
Urine strip test, EQA3
Scheme expert
PhD, Production Control Manager Eeva Toivari, Fimlab

LABQUALITY URINE STRIP TEST, EQA3

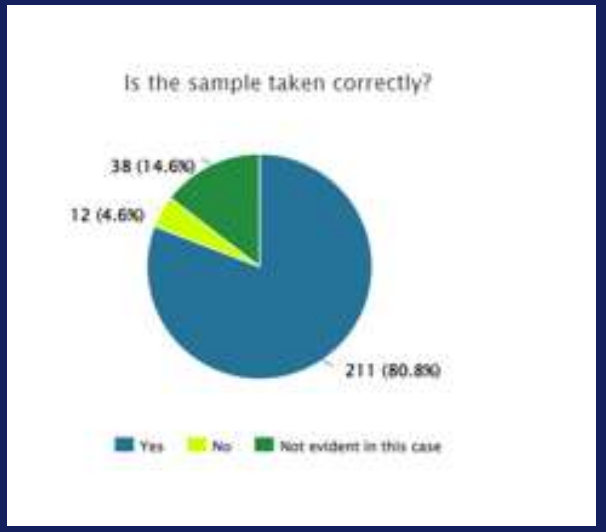
Nurse, working for a domestic care services, makes a visit to a customer. The nurse receives a highly coloured urine sample (picture attached) from the customer. Together with the customer they go through the essentials in urine sample collection. Urine should be in the bladder for at least 4 hours. In addition, the nurse makes sure that the sample collection has been performed according to instructions. The nurse identifies the sample with an ID-label including personal information and sample collection time. The nurse puts the sample into a container with a cold pack.

As soon as the nurse arrives to the office, the urine sample is carefully taken out from the container to the table. On the table, the nurse finds a container full of test strips. The nurse makes sure that the strips are dry, straight (i.e. unbent), and that their expiration date is in the future. The nurse picks one strip from the container and lays it on the table. Then, the nurse takes a pipette and drops a small amount of sample on each test pad. Fast reactions are seen on each reaction pad. The nurse writes down the reactions to a form for results. Finally, the results are copied from the form to an electronic information system.

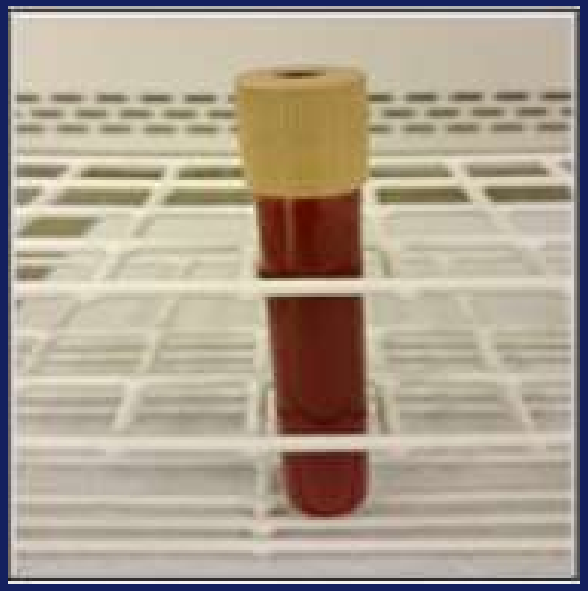
Expert comments



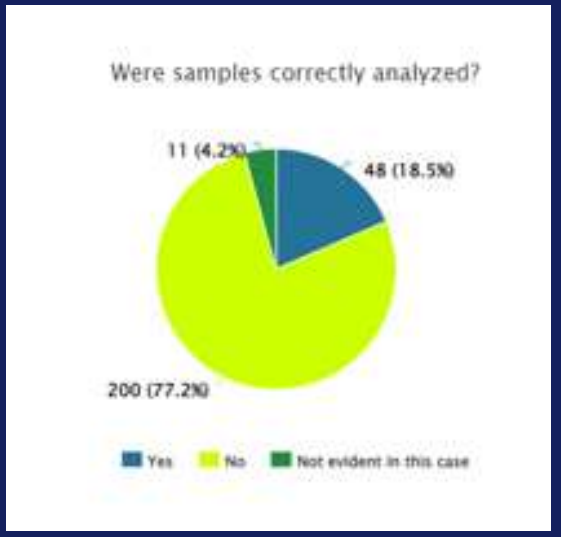
- The sample collection can be considered to have been performed correctly. The nurse went through the essentials in urine sample collection with the customer.



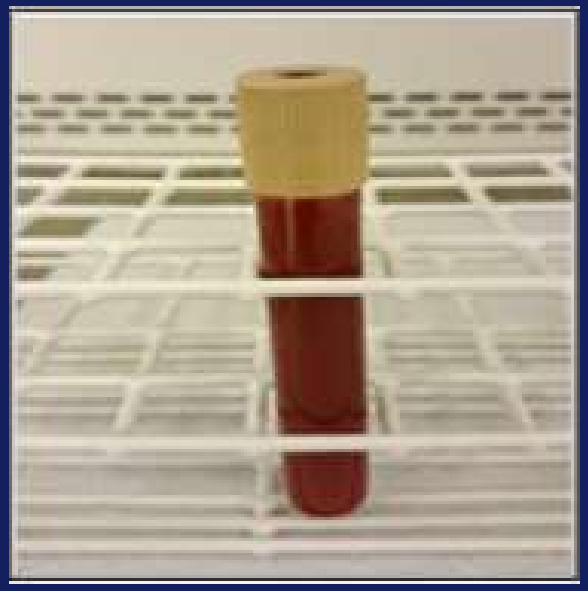
Expert comments



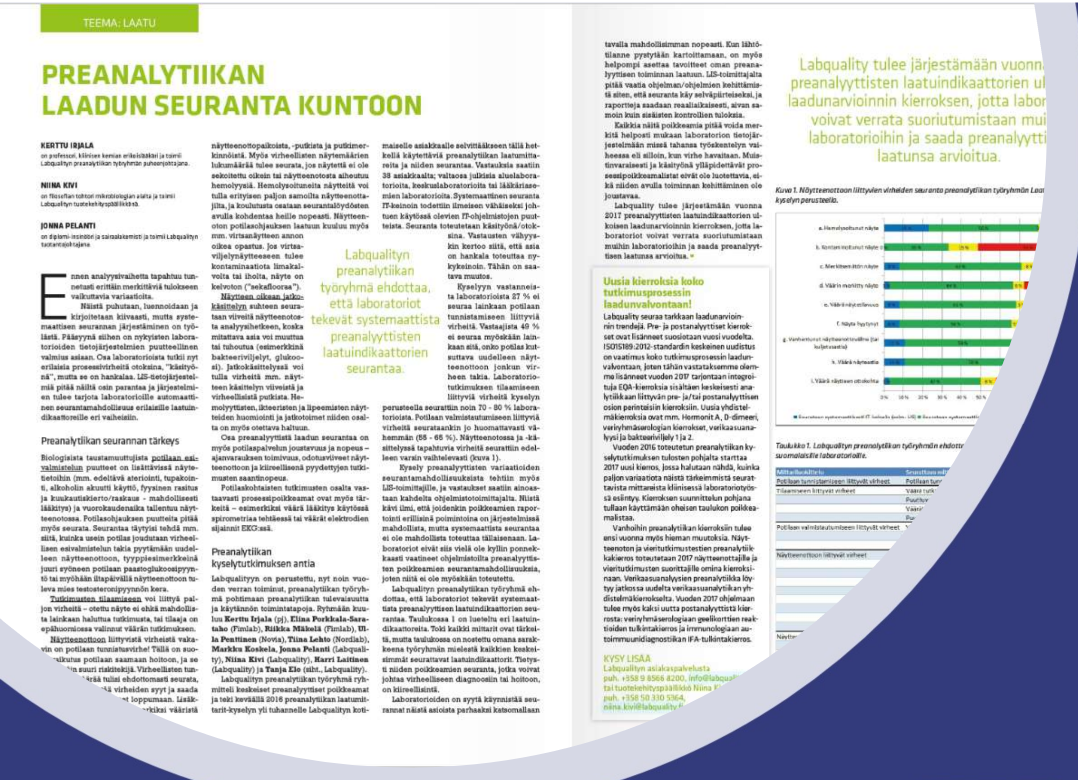
- The sample collection can be considered to have been performed correctly. The nurse went through the essentials in urine sample collection with the customer.
- The sample was not correctly analyzed.



Expert comments



- The sample collection can be considered to have been performed correctly. The nurse went through the essentials in urine sample collection with the customer.
- The sample was not correctly analyzed.
- The sample was incorrectly handled as in the sample not mixed), there was an error in dipping the test strip and incorrect timing for reading the results).
- This caused an elevated risk of patient safety.


TEEMA: LAATU

PREANALYTIIKAN LAADUN SEURANTA KUNTOON

Labqualityn preanalytiikan työryhmä ehdottaa, että laboratoriot tekevät systemaattista preanalyyttisten laatuindikaattorien seurantaa.

Labquality tulee järjestämään vuonna ... preanalyyttisten laatuindikaattorien ... laadunarvioinnin kierroksen, jotta labor... voivat verrata suoriutumistaan mui... laboratorioihin ja saada preanalyytti... laatunsa arvioitua.

Uusia kierroksia koko tutkimusprosessin laadunvalvontaan!

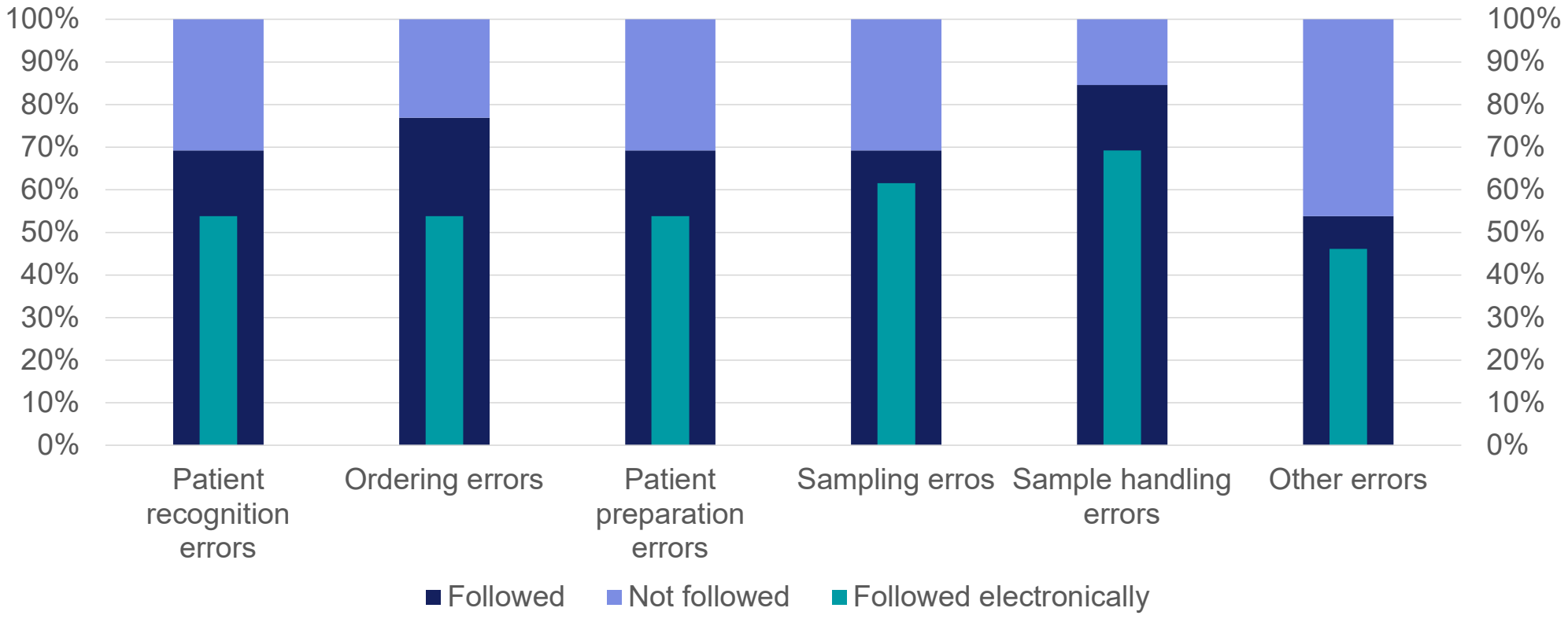

Potilasohjeissa kerrotaan muun muassa, miten ruokailla ja liikkua ennen näytteenottoon menoa.

National preanalytical group, chair professor Kerttu Irjala

- Recommendation for Finnish preanalytical quality indicators published in 2016
- Selected QI's

  Patient misidentification
  Errors in sample collection
  Sample unmarked
  Sample marked wrong
  Wrong sample container
  Contaminated sample
  Delays in STAT –samples
  Patient reinvited to sampling

Questionnaire: which QI's are in use?



Noklus EQA-program for common quality indicators 2021 (2018-2021)

- 5 quality indicators:
  1. Proportion of rejected potassium analyzes due to hemolysis (Preanalytical)
  2. Proportion of EQA results for HbA1c outside Noklus' acceptance limits (Analytical)
  3. Turn Around Time (TAT) of CRP/INR value at 90th percentile (STAT) (Postanalytical)
  4. Incorrect sent laboratory reports (Postanalytical)
  5. Waiting time at the outpatient clinic (Preanalytical)
- September as registration period
- Anonymous reporting
- 48 registered and 45 submitted answers (94%)

Norsk kvalitetsforbedring av laboratorieundersøkelser www.noklus.no

Courtesy of Gunn B.B. Kristensen

What the future holds

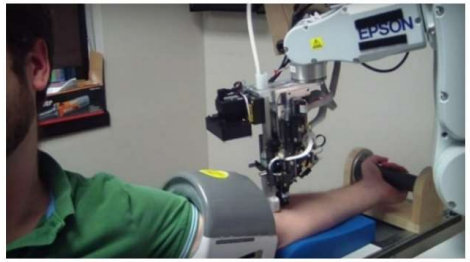
The Product

Vitestro's device combines AI-based, ultrasound-guided 3D reconstruction with robotic needle insertion, ensuring accurate and secure blood collection . The procedure is performed fully automatically, from tourniquet to bandage application.

REQUEST MORE INFORMATION

Meet your new blood-drawing, needle-wielding robot phlebotomist

By John Hewitt on August 19, 2013 at 2:43 pm | Comments



Drawing blood should be a routine procedure. Unfortunately complications can be common either in the elderly, who may have a compromised vasculature, or in children who are literally scared out of their minds. A startup based in Mountain View, California aims to replace your friendly phlebotomist with a robot. If this new device can gain patient confidence and perform well under ideal conditions, perhaps it can also be of service in more demanding conditions as well.

The robot phlebotomist, known as the Veebot, looks like it is a specially modified version of one of Epson's standard manipulator arms. Epson manufactures some of the fastest, and fortunately, most accurate multi-axis arms in the business. The head used on the Veebot appears to be custom adapted to provide the additional elements needed to finesse the ideal stick. Human technicians undoubtedly have more flexibility in adjusting the angle and force applied when trying to penetrate the near side of vein without going clean through it. What the robot has going for it, though, is better tools for identifying the optimal place to jab you in the first place.

- Possibilities, pros and cons of these robots?
- Could the sample be screened for hemolysis right away? And a new sample taken if needed?
- How do robot and human phlebotomists differ? Is one better than the other?
- What about children and the elderly who are not the easiest ones to take samples from. How will the sampling robot work on them? How about patients with anxiety towards phlebotomy?
- How should we arrange the QC and EQA for the sampling robots?

LABQUALITY Experiences in EQA for phlebotomy and urine sampling

Procedures

+ Easy to come up with relevant cases
- Makes it tricky for the experts to adhere to all guidelines
- Not followed necessarily, education needed

Samples

+ Cases work well and can be used for educational purposes.
- If only we could mimic the phlebotomy or the urine sampling procedure

Quality Indicators

+ Easy to repeat if a procedure up and running
- Laborous to gather if no help from LIS
- Are all mistakes reported if not LIS used

LABQUALITY

Quality cannot be improved without being measured

Performance in the preanalytical phase needs to be monitored and measured

We need to be on our toes to develop the best possible ways to challenge our participants also in the preanalytical phase, not just for phlebotomy and urine sampling but for all parts of the preanalytical process.