

INNOVATION IN EDUCATION CLINICAL TRIALS SYMPOSIUM

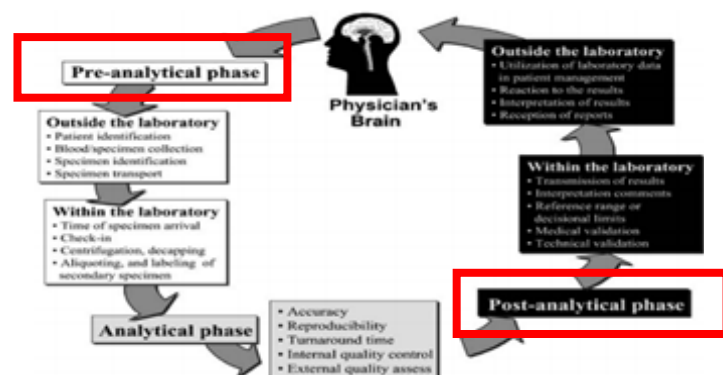
OCTOBER 11, 2019 - BUCHAREST, ROMANIA
INTERCONTINENTAL HOTEL, RONDA HALL

Pre- and Postanalytical Cause of Laboratory Errors

Gian Luca Salvagno, MD, PhD

Assoc. Prof. of Clinical Biochemistry - Department of Neurological, Biomedical and Movement Sciences, University of Verona, Italy

Phase	CAP Laboratory General Checklist	ISO 15189:2007
Pre-analytical	All steps in the process prior to the analytic phase of testing, starting with the physician's order. Examples include accuracy of transmission of physicians' orders, specimen transport and preparation, requisition accuracy, quality of phlebotomy services, specimen acceptability rates, etc.	Steps starting, in chronological order, from the clinicians request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the lab and ending when the analytical examination procedure begins.
Post - analytical	All steps in the overall laboratory process between completion of the analytic phase of testing and results receipt by the requesting physician. Examples are accuracy of data transmission across electronic interfaces, reflex testing, turnaround time from test completion to chart posting (paper and/or electronic), and interpretability of reports.	Processes following the examination including systematic review, formatting and interpretation, authorization for release, reporting and transmission of results and storage of samples of the examinations.



Review article Clinical Chemistry

Ann Lab Med 2012;32:5-16
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ANNALS OF LABORATORY MEDICINE

Managing the Pre- and Post-analytical Phases of the Total Testing Process

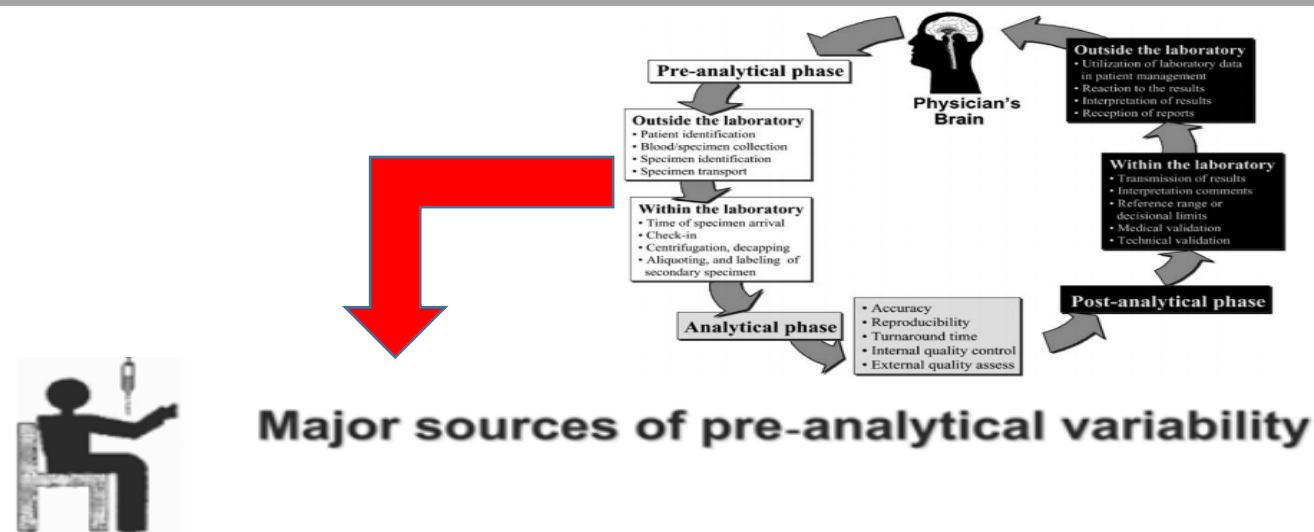
Robert Hawkins, M.D.

Department of Laboratory Medicine, Tan Tock Seng Hospital, Tan Tok Seng, Singapore

Clin Chem Lab Med 2006;44(2):150–160 © 2006 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2006.028

Opinion Paper **Mario Plebani^{1,*}, Ferruccio Ceriotti², Gianni Messeri³, Cosimo Ottomano⁴, Nicola Pansini⁵ and Pierangelo Bonini⁶**

Laboratory network of excellence: enhancing patient safety and service effectiveness



1. Patient preparation

- Biological variability
- Environmental conditions (e.g., climate, pollution)
- Postural changes

3. Sample transportation

- Length and environmental conditions
- Pneumatic tube systems

5. Sample storage

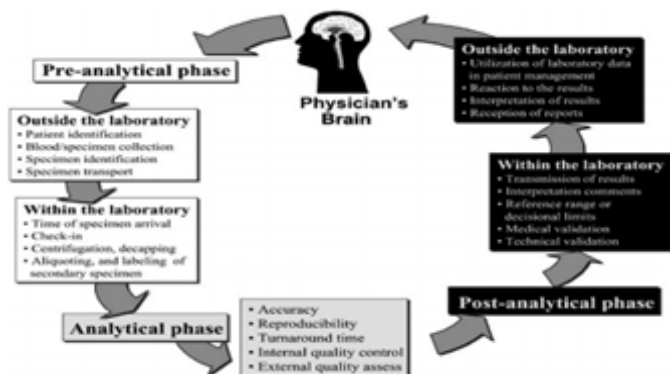
- Length
- Temperature
- Freezing & thawing

2. Sample collection

- Patient identification and sample labeling
- Type of disposal for collecting blood (e.g., straight needle, butterfly, cannula)
- Caliber (gauge) of the needle
- Tourniquet time
- Container (e.g., primary tube)
- Order of draw
- Phlebotomy procedure
- Contamination from
- Tube/s mixing

4. Sample preparation for analysis

- Length, speed and temperature of centrifugation
- Preparing aliquots



The procedures of the post-analytical phase include:

1: Evaluation of test results

1.1. Comparison with reference intervals

1.2. Comparison with previous results

1.2.1. Reference change value

1.2.2. Testing the difference between two consecutive results (delta check)

2: Decision to release test results

2.1. Competences of decision-making laboratory personnel

3: Preparation of the laboratory test report

3.1. Content and layout of the laboratory test report

4: Release of the laboratory test report

5: Reporting of test results

5.1. Reporting of critical results

6: Sample storage and disposal

7: Archiving of laboratory documentation

Post-analytical laboratory work: national recommendations from the Working Group for Post-analytics on behalf of the Croatian Society of Medical Biochemistry and Laboratory Medicine

Jasna Lenicek Krljeza^{*1,2}, Lorena Honovic^{1,3}, Jelena Vlasic Tanaskovic^{1,3}, Sonja Podolar^{1,4}, Vladimira Rimac^{1,5}, Anja Jokic^{1,6}

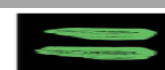
Requirements for the sample transport, handling and delivery to the laboratory:

- **Consolidated laboratory network organization**
- **Accreditation program: commission on laboratory accreditation**
- **Stability of plasma analytes after delayed separation of whole blood: implications for epidemiological studies and clinical trials**
- **World anti-doping program: guidelines for blood sample collection**

The Role of Total Laboratory Automation in a Consolidated Laboratory Network

RICHARD S. SEABERG,¹ ROBERT O. STALLONE,^{1*} and BERNARD E. STATLAND²

Clinical Chemistry 46, No. 5, 2000



WORLD
ANTI-DOPING
AGENCY

World Anti-Doping Program
**GUIDELINES FOR
BLOOD SAMPLE
COLLECTION**

HEM.22625

Phase I

N/A YES NO

Has the laboratory clearly defined sample storage conditions and stability for all hematology and coagulation parameters?

COMMENTARY:

The laboratory should define sample storage conditions and stability for all hematology and coagulation parameters, as time- and temperature-dependent alterations can occur, creating spurious results.

REFERENCES: 1) Boos MS, *et al.* Temperature- and storage-dependent changes in hematologic variable and peripheral blood morphology. *Am J Clin Pathol.* 1998;110:537; 2) Davis KD, *et al.* Use of different thromboplastin reagents causes greater variability in international normalized

METHODOLOGY

Stability of plasma analytes after delayed separation of whole blood: implications for epidemiological studies

Sarah Clark,¹ Linda D Youngman,^{1,2} Alison Palmer,¹ Sarah Parish,¹ Richard Peto¹ and Rory Collins¹

International Journal of Epidemiology 2003;32:125-130

DOI: 10.1093/ije/dyg023

Preanalytical Processing and Biobanking Procedures of Biological Samples for Metabolomics Research: A White Paper, Community Perspective (for "Precision Medicine and Pharmacometabolomics Task Group"—The Metabolomics Society Initiative)

Jennifer A. Kirwan,^{1,2*} Lorraine Brennan,³ David Broadhurst,⁴ Oliver Fiehn,⁵ Marta Cascante,⁶

Clinical Chemistry 64:8 Warwick B. Dunn,⁷ Michael A. Schmidt,^{8,9} and Vidya Velagapudi^{10*}
1158–1182 (2018)

Multicentric study of the effect of pre-analytical variables in the quality of plasma samples stored in biobanks using different complementary proteomic methods



Journal of Proteomics 150 (2017) 109–120

Jesús Mateos^{a,1}, Isabel Carneiro^b, Fernando Corrales^c, Felix Elortza^d, Alberto Paradela^e, Manuel Sánchez del Pino^f, Ibon Iloro^d, Miguel Marcilla^e, María Isabel Mora^c, Luz Valero^f, Sergio Ciordia^e, Verónica Fernández^g, María Antonia Fortuño^h, Isabel García-Sánchezⁱ, Rosario Martínez^j, María Angeles Muñoz^k, Clara Rodríguez^l, Nieves Doménech^{b,*}, ProteoRed Spanish Biobanks Network:

J Biomol NMR (2011) 49:231–243

DOI 10.1007/s10858-011-9489-1

Giuseppe Lippi*, Geoffrey S. Baird, Giuseppe Banfi, Karin Bölenius, Janne Cadamuro, Stephen Church, Michael P. Cornes, Anna Dacey, Antoine Guillon, Georg Hoffmann, Mads Nybo, Lakdasa Devananda Premawardhana, María Salinas, Sverre Sandberg, Robbert Slingerland, Ana Stankovic, Sylte Marit Sverresdotter, Pieter Vermeersch and Ana-Maria Simundic, on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)

Improving quality in the preanalytical phase through innovation, on behalf of the European Federation for Clinical Chemistry and Laboratory Medicine (EFLM) Working Group for Preanalytical Phase (WG-PRE)

Clin Chem Lab Med 2017; 55(4): 489–500

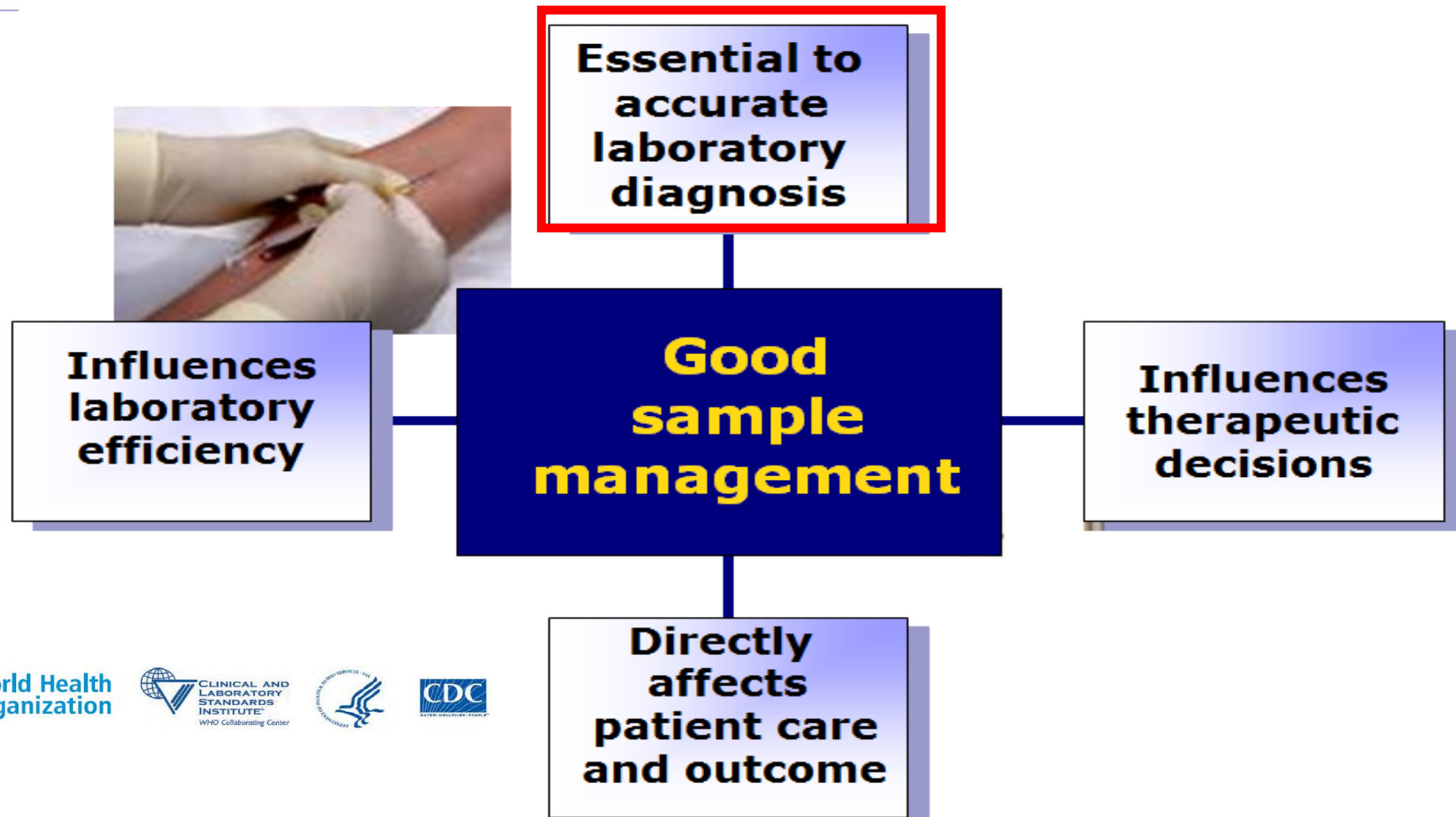
Preanalytical Aspects and Sample Quality Assessment in Metabolomics Studies of Human Blood

Peiyuan Yin,^{1†} Andreas Peter,^{2,3†} Holger Franken,^{4†} Xinjie Zhao,¹ Sabine S. Neukamm,^{2,3} Lars Rosenbaum,⁴ Marianna Lucio,⁵ Andreas Zell,⁴ Hans-Ulrich Häring,^{3,6} Guowang Xu,^{1*} and Rainer Lehmann^{2,3*}

Clinical Chemistry 59:5
833–845 (2013)

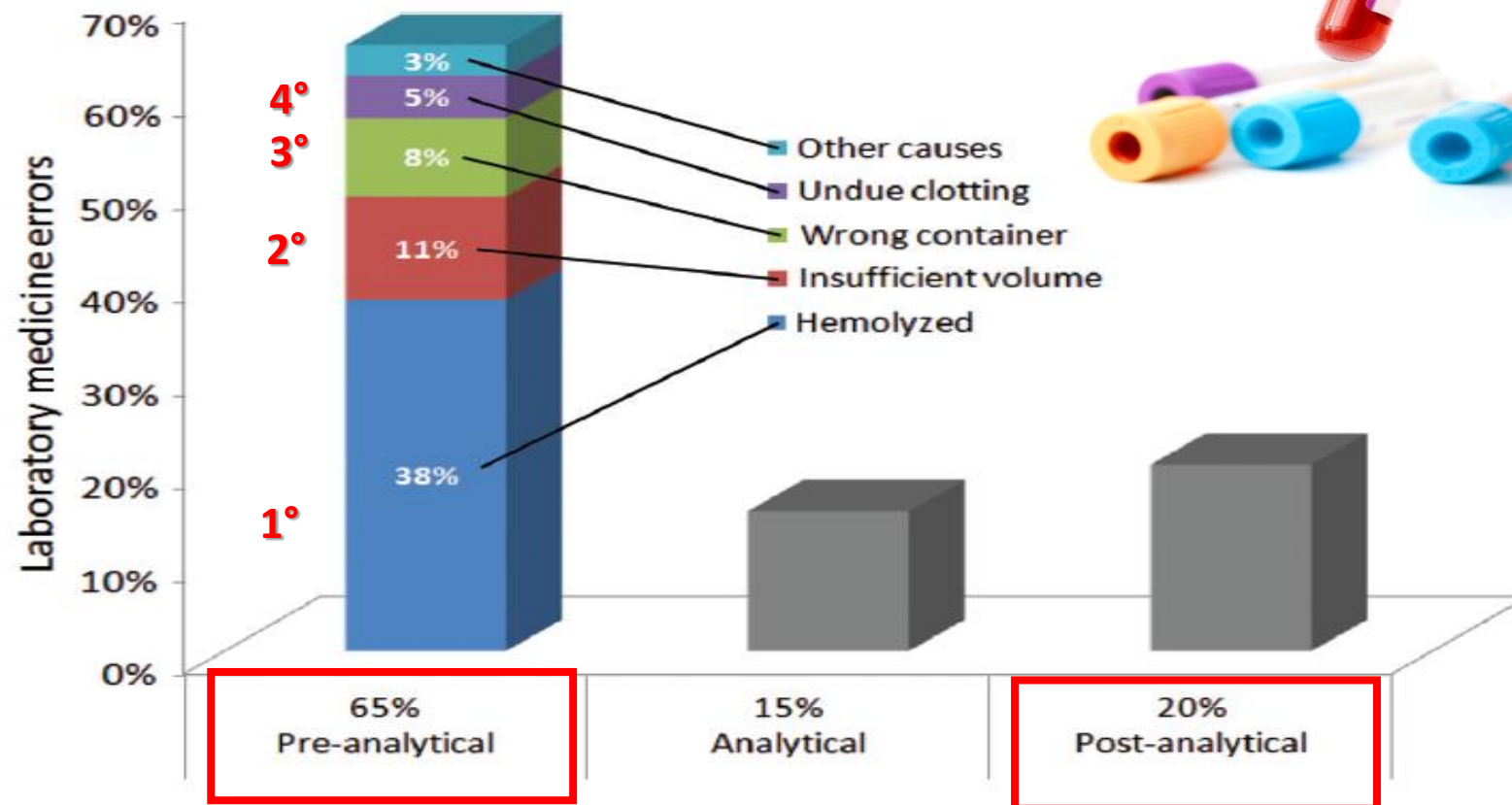
ARTICLE

Standard operating procedures for pre-analytical handling of blood and urine for metabolomic studies and biobanks



Diagnosis 2018; aop

Giuseppe Lippi*, Alexander von Meyer, Janne Cadamuro and Ana-Maria Simundic

Blood sample quality

Clinica Chimica Acta 432 (2014) 33–37

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

A.M. Simundic ^{a,b,*}, M. Cornes ^{b,c}, K. Grankvist ^{b,d}, G. Lippi ^{b,e}, M. Nybo ^{b,f}

1. Existing guidelines for phlebotomy need revision. Revised recommendations should include the exact definition of requirements for patient preparation for laboratory testing. Blood for all blood tests should be drawn preferably in the morning from 7 to 9 a.m. [30]. Fasting should last for 12 h, during which water consumption is permitted. Alcohol should be avoided for 24 h before blood sampling. In the morning before blood sampling, patients should refrain from cigarette smoking and caffeine containing drinks (tea, coffee, etc.).
2. Professional associations (IFCC, EFLM and other) should support harmonization efforts by disseminating standardized recommendations for fasting.
3. Laboratories worldwide should implement standardized procedures for blood sampling and patient preparation.
4. Laboratories should have policies for sample acceptance criteria related to fasting samples. Blood samples for routine testing should not be taken if a patient has not been appropriately prepared for sample collection. 'No sample is better than a bad sample' should always be the leading principle.
5. Laboratory professionals are responsible for disseminating information about fasting requirements to patients as well as to clinicians and general practitioners who are the preferred source of information for patients.

Fasting requirements

Patient preparation

Biological variability
Posture
Patient identification

Sample collection

Collection system
Needle
Venous stasis
Order of draw
Phlebotomy procedure
Contamination
Tube mixing

Sample transport

Transport condition
Pneumatic tube systems

Sample storage

Clin Chem Lab Med 2016; 54(5): 755–760
EFLM Opinion Paper

Giuseppe Lippi, Michael P. Cornes, Kjell Grankvist, Mads Nybo and Ana-Maria Simundic*,
on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of
Clinical Chemistry and Laboratory Medicine (EFLM)

**EFLM WG-Preanalytical phase opinion paper:
local validation of blood collection tubes in
clinical laboratories**

Patient preparation

Biological variability

Posture

Patient identification

Sample collection

Collection system

Needle

Venous stasis

Order of draw

Phlebotomy procedure

Contamination

Tube mixing

Sample transport

Transport condition

Pneumatic tube systems

Sample storage

Collection system validation

Table 1: Essential requisites for purchasing blood collection devices.

1. Components of the blood collection system In use (i.e. safety needle, butterfly needle, holder and blood tube) should be produced by the same manufacturer or else the combination / Integration of separate parts should be validated by accredited regulation organizations such as the European Community (EC) or the US Food and Drug Administration (FDA).
2. Manufacturers should demonstrate performance studies of their products following study subject recruitment.
3. Manufacturers should demonstrate ease of use, sustained plasma quality, perceived value compared to the comparative devices on the market and the risk associated with the use of their product.
4. Failure rates per 10,000 tubes should be stated for each tube type. The reasons for failures, including missing and excluded data, should also be stated during usability studies.
5. New suppliers should provide evidence of capacity to produce the product over longer period of time (at least 2 years).
6. The cost for the appropriate number of tubes and reagents for local validation should be charged to the manufacturers participating in the tender.
7. The validation study should be submitted for Ethical committee and/or Institutional review board approval.
8. The committee for a tender for blood collection devices should always include not less than one laboratory professional.

Clin Chem Lab Med 2011;49(6):xxx-xxx © 2011 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2011.600

Preanalytical quality improvement: from dream to reality

Giuseppe Lippi^{1,*}, Jeffrey J. Chance², Stephen Church³, Paola Duzzi⁴, Rossana Fontana⁵, Davide Giavarina⁶, Kjell Grankvist⁷, Wim Huisman⁸, Timo Kouri⁹, Vladimir Palicka⁸, Mario Plehant⁹, Vincenzo Puro¹⁰, Gian Luca Salvagno¹¹, Sverre Sandberg¹², Ken Sikaris¹³, Ian Watson¹⁴, Ana K. Stankovic³ and Ana-Maria Simundic¹⁵

It is important to keep in mind that sample **transport**, **maintenance** and **storage** conditions, together with the time interval between collection and testing, can have an important effect on the quality of test results.



Patient preparation

Biological variability

Posture

Patient identification

Sample collection

Collection system

Needle

Venous stasis

Order of draw

Phlebotomy procedure

Contamination

Tube mixing

Sample transport

Transport condition

Pneumatic tube systems

Sample storage

Data relating to sample stability may strongly depend on the **tube type** used for blood collection, (including any **separation gels**, **anticoagulants** and **other additives** present), the **temperature of storage** prior to testing, and the **laboratory method** used for determination. The **mode of transporting** samples to the laboratory may be relevant, as well

Patient preparation

- Biological variability

- Posture

- Patient identification

Sample collection

- Collection system

- Needle

- Venous stasis

- Order of draw

- Phlebotomy procedure

- Contamination

- Tube mixing

Sample transport

- Transport condition

- Pneumatic tube systems

Sample storage

Clin Chem Lab Med 2016; 54(5): 755–760
EFLM Opinion Paper

Giuseppe Lippi, Michael P. Cornes, Kjell Grankvist, Mads Nybo and Ana-Maria Simundic*,
on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of
Clinical Chemistry and Laboratory Medicine (EFLM)

**EFLM WG-Preanalytical phase opinion paper:
local validation of blood collection tubes in
clinical laboratories**

Editorial

Biological samples transportation by drones: ready for prime time?

Giuseppe Lippi¹, Camilla Mattiuzzi²
Ann Transl Med 2016;4(5):92
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Table 1 Leading approaches for transportation of biological samples

- Hand transportation
- Transportation by “wheels” (motorcycles, cars, tracks, other motor vehicles)
- Planes or helicopters
- Pneumatic transport systems
- Drones



Page 1 of 4

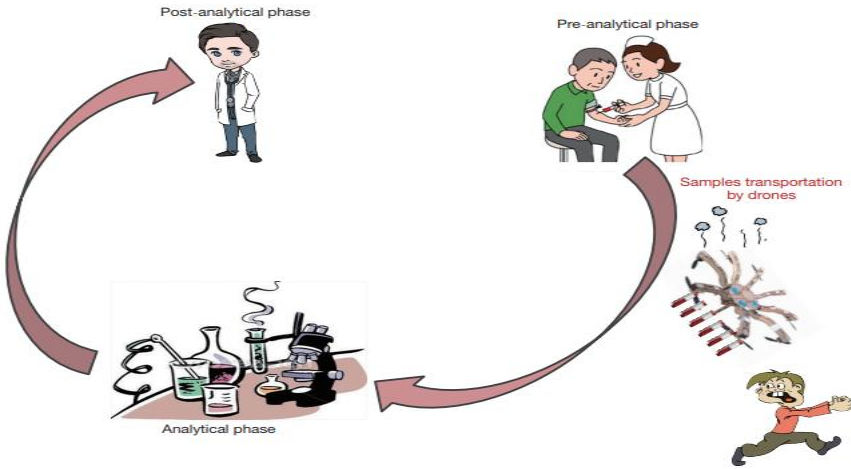


Table 2 The many unresolved issues of flying drones for shipping blood specimens

- High risk of collision and crashes with birds and humans
- Need for specific regulation for manufacturing, functioning and healthcare usage
- Approval for usage by national or international regulatory bodies
- Specific manufacturing entailing
 - Cooler or heating systems
 - Specific packaging of blood containers
 - Avoidance of excessive light exposure
 - Speed and injury control
- Identification of areas for safe take-off and landing

The 13 commandments:

Separate serum or plasma from blood cells ASA
but not later than 4 h

Use tube separators or aliquot serum and plasma ASAP

Keep tubes and aliquots safely capped

Keep tubes in vertical position during transport

Use validated biohazard containers for transport

Use first/second/third level containers

Ensure stable conditions of temperature (i.e., 18-25°C) and humidity

Avoid light exposure

Prevent trauma of specimens

Deliver to the corelab as ASAP

Record transportation time (from start to arrival to the lab)

Monitor conditions throughout transportation

Reject samples with unsuitable conditions of transport



Clin Chem Lab Med 2016; 54(5): 755–760
EFLM Opinion Paper

Giuseppe Lippi, Michael P. Cornes, Kjell Grankvist, Mads Nybo and Ana-Maria Simundic*,
on behalf of the Working Group for Preanalytical Phase (WG-PRE), European Federation of
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**EFLM WG-Preanalytical phase opinion paper:
local validation of blood collection tubes in
clinical laboratories**

Anal Bioanal Chem
DOI 10.1007/s00216-015-8565-x

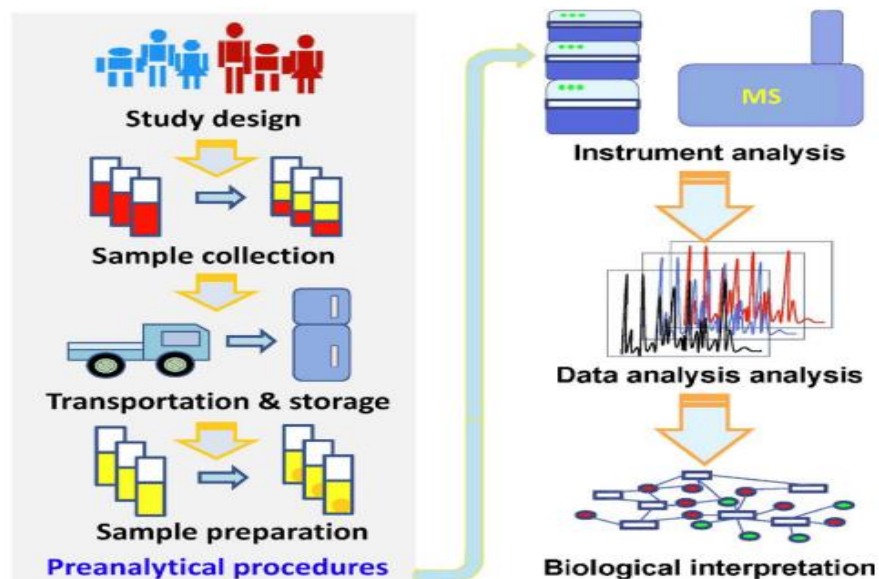
REVIEW

Effects of pre-analytical processes on blood samples used in metabolomics studies

...not only clinical chemistry lab...

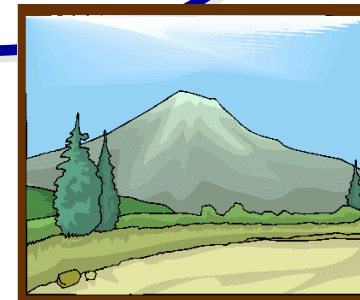
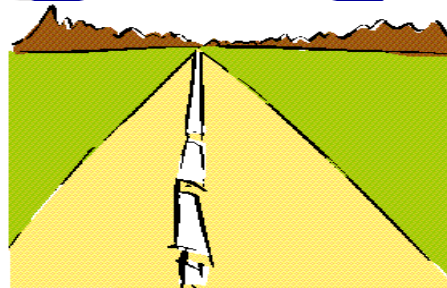
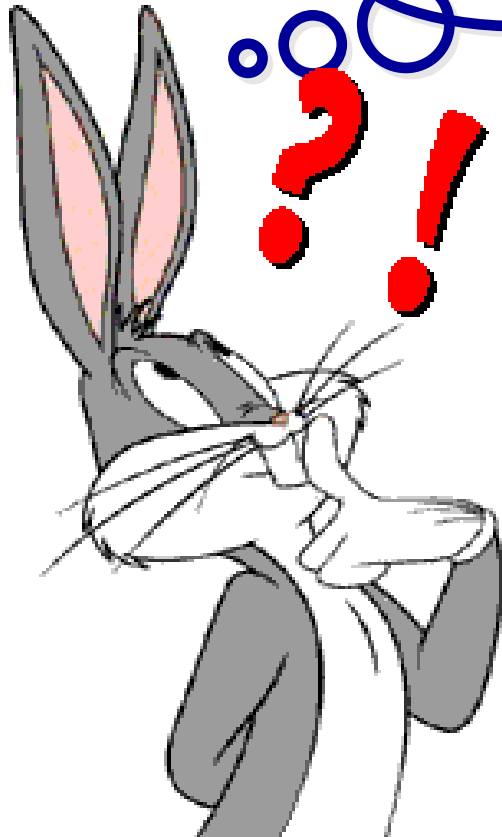
Peivuan Yin • Rainer Lehmann • Guowang Xu

Received: 13 October 2014 / Revised: 13 February 2015 / Accepted: 13 February 2015
© The Author(s) 2015. This article is published with open access at Springerlink.com

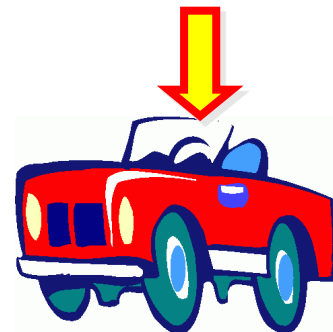


From the practical perspective it should be mentioned that in most clinical studies it is feasible to separate blood cells from plasma within 2 h, and it should be possible in almost all studies to separate the cells from plasma within 4 h. Cooling of whole-blood samples at once in iced water is recommended for short-term preservation before centrifugation and separation of plasma. For the generation of serum a strictly controlled fixed time at room temperature (at least 30 min) followed by immediate cooling is suggested.

"Which is the best choice?"



Or.....



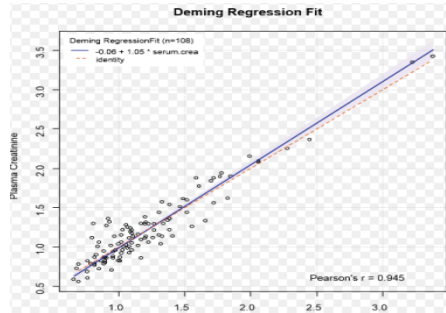


5.4 Pre-examination procedures

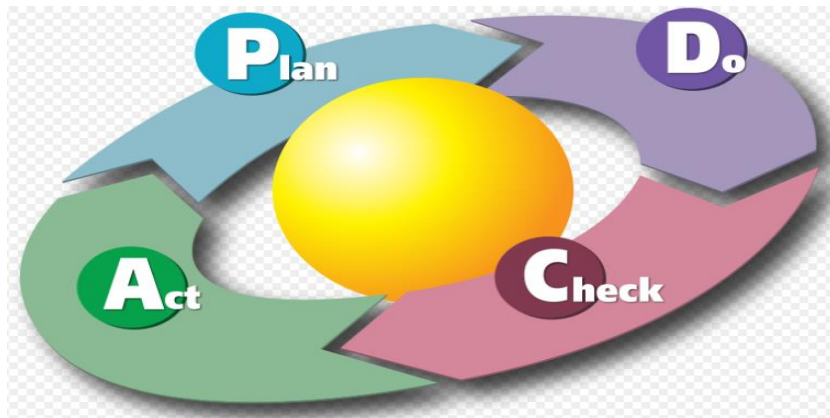


Implementation of a process that includes definition of criteria for request forms, collection, identification, handling, transportation and receipt of primary samples. Criteria for accepting and rejecting samples must be defined. **Samples collection procedures must be described in a manual.**

Deming...not only regression.....



Deming circle plan-do-check-act



Biochemia Medica 2010;20(2):131–43

Overview on patient safety in healthcare and laboratory diagnostics

Giuseppe Lippi^{1*}, Ana-Maria Simundic², Camilla Mattiuzzi³

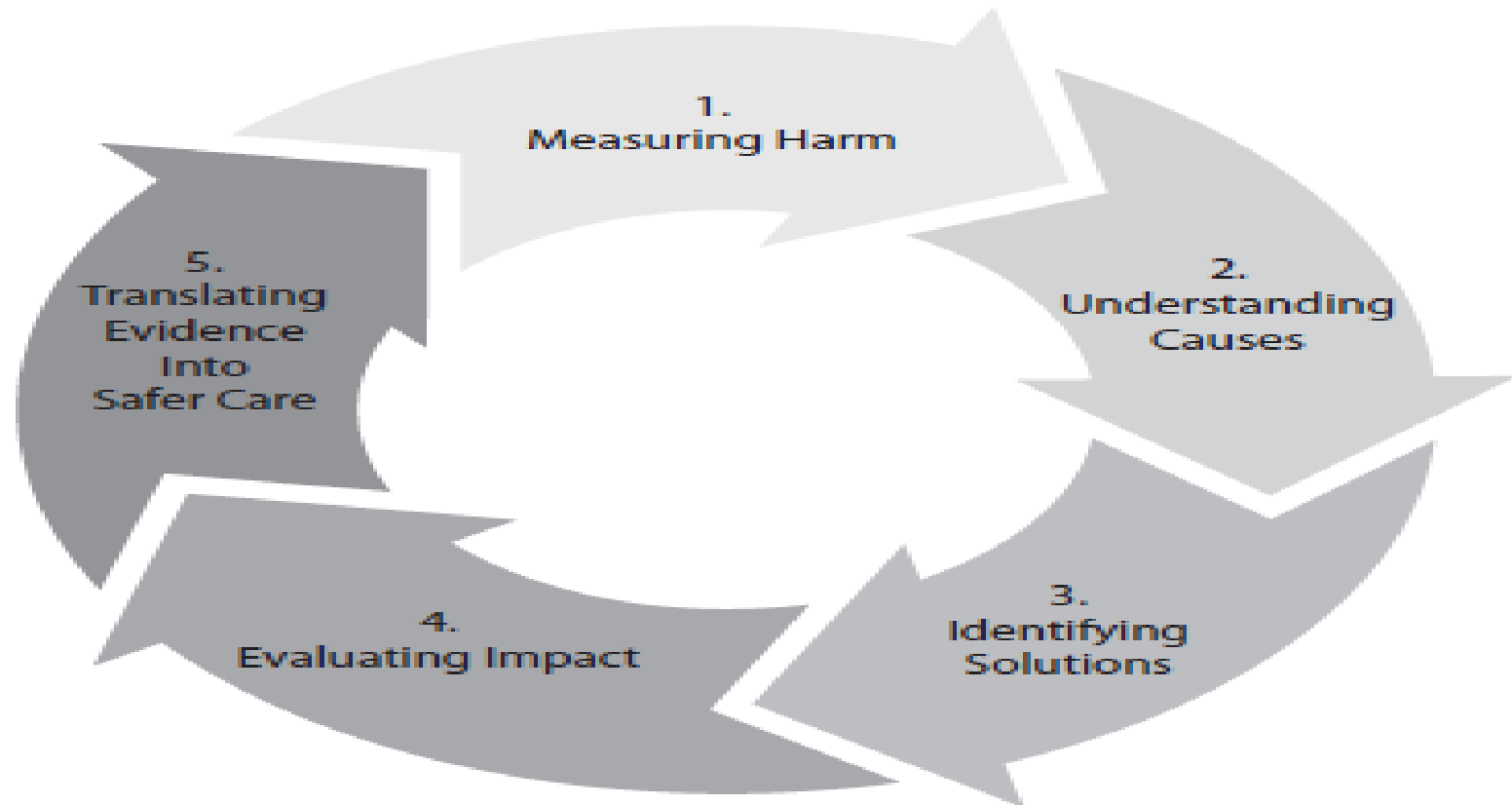


FIGURE 2. The virtuous path of enhancing safety in healthcare.

Technology and IT aids for reducing lab errors

1. Computerized Physician Order Entry (CPOE)

2. Positive patient identification by:

- Traditional barcodes
- Smart cards
- Radio-Frequency Identification (RFID)
- Optical Character Recognition & Voice Recognition Devices

3. “Active tubes” (lab-on-a-chip integrated containers)

- Store patient data, measure physical (temperature/humidity/flow rate) & metabolic data (glucose concentration)

4. Transport systems

- Data loggers
- Pneumatic tubes conveyer
- Robots

5. Instrumentation tools

- Query-host communication
- Volume/clotting/bubbles sensors
- Serum indices

6. Automatic validation, expert systems, delta check technology



In terms of technology deployment, a broad pattern can be discerned:

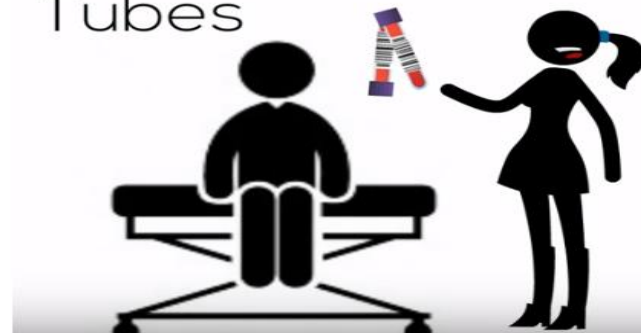
- ▶ Barcode technology
 - 1 Dimensional (1D)
 - 2 Dimensional (2D)
- ▶ RFID Tags
- ▶ Infrared (IR)-based patient tracking
- ▶ Patient smart cards
- ▶ Biometric technologies
 - optical recognition
 - voice recognition
 - fingerprints



**Automatic
Identification by
RFID test tube**



Pre-Barcoded
Tubes



Clinica Chimica Acta 404 (2009) 79–85

The IFCC Working Group on laboratory errors and patient safety

Laura Sciacovelli ^{a,*}, Mario Plebani ^{a,b}

Annals of Clinical Biochemistry 2011; 1

Quality indicators for laboratory diagnostics: consensus is needed

Mario Plebani¹, Laura Sciacovelli¹ and
Giuseppe Lippi²

Clin Chem Lab Med 2011;49(5):835–844 © 2011 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2011.128

Quality Indicators in Laboratory Medicine: from theory to practice

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

Review

Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety

Mario Plebani ^{a,*}, Laura Sciacovelli ^a, Mariela Marinova ^a, Jessica Marcuccitti ^a, Maria Laura Chiozza ^b

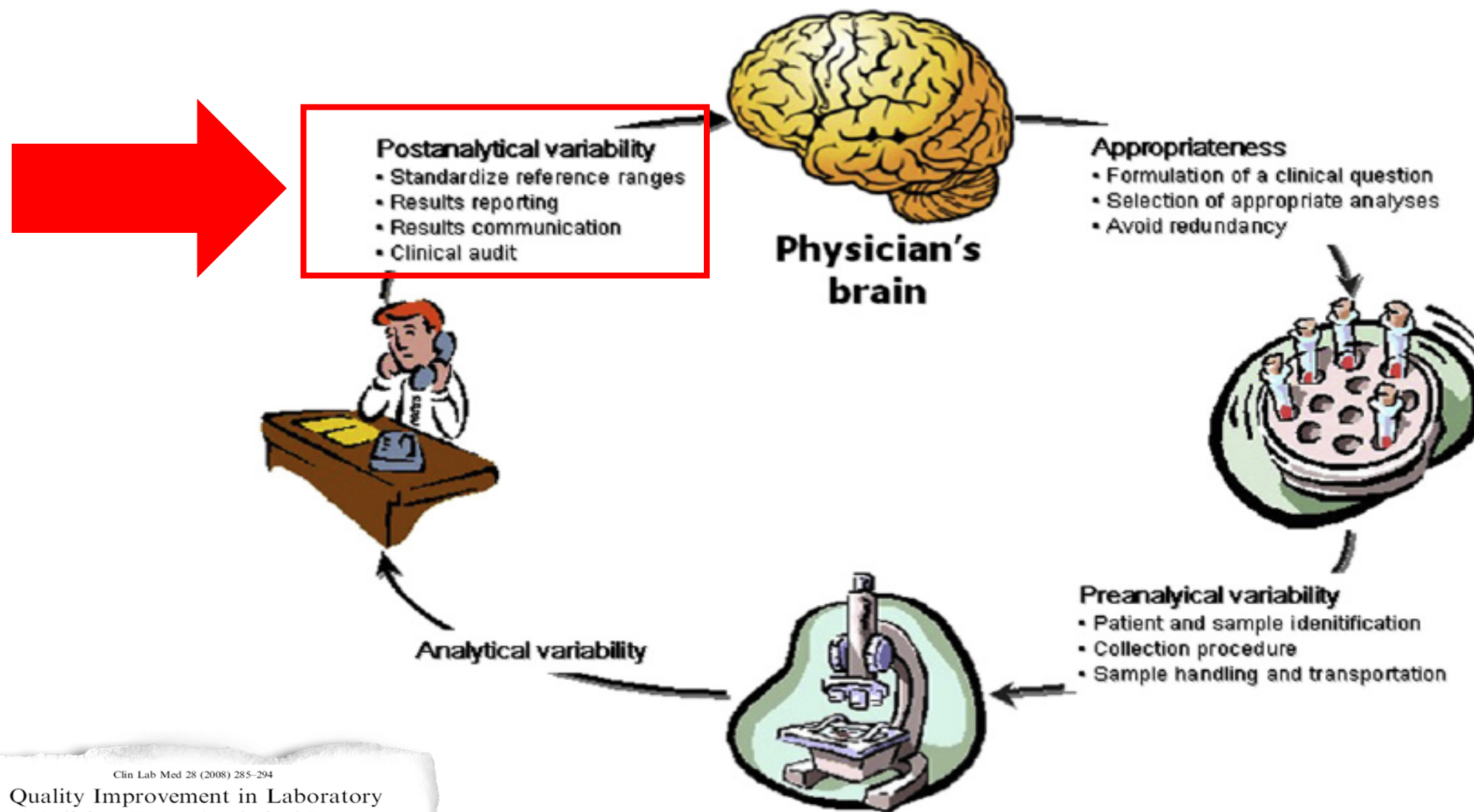
DE GRUYTER

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

Mini Review

Mario Plebani*, Maria Laura Chiozza and Laura Sciacovelli

Towards harmonization of quality indicators in laboratory medicine



Clin Lab Med 28 (2008) 285–294

Quality Improvement in Laboratory
Medicine: Extra-Analytical Issues

Giuseppe Lippi, MD^{a,*}, Roberto Fostini, MD^b,
Gian Cesare Guidi, MD^a

Development of laboratory errors throughout the total testing process.

DE GRUYTER

Clin Chem Lab Med 2016; 54(12): 1881–1891

Opinion Paper

Mario Plebani*

Towards a new paradigm in laboratory medicine: the five rights

FINAL
DRAFTINTERNATIONAL
STANDARDISO/FDIS
15189

ISO/TC 212

Secretariat: ANSI

Voting begins on:
2012-08-09Voting terminates on:
2012-10-09**Medical laboratories — Requirements for
quality and competence***Laboratoires d'analyses de biologie médicale — Exigences concernant
la qualité et la compétence*

The ISO 15189 standard for medical laboratory quality [39] defines the post-analytical phase as the processes following the examination. In terms of the quality of the clinical laboratory report, the post-analytical phase includes the result validation, formatting, releasing, reporting and retaining test results for future access.

FINAL
DRAFTINTERNATIONAL
STANDARDISO/FDIS
15189

ISO/TC 212

Secretariat: ANSI

Voting begins on:
2012-08-09Voting terminates on:
2012-10-09

Medical laboratories — Requirements for quality and competence

Laboratoires d'analyses de biologie médicale — Exigences concernant la qualité et la compétence

5.7 Post-examination processes

5.7.1 Review of results

The laboratory shall have procedures to ensure that authorized personnel review the results of examinations before release and evaluate them against internal quality control and, as appropriate, available clinical information and previous examination results.

When the procedure for reviewing results involves automatic selection and reporting, review criteria shall be established, approved and documented (see 5.8.4).

5.7.2 Storage, retention and disposal of clinical samples

The laboratory shall have a documented procedure for identification, collection, retention, indexing, access, storage, maintenance and safe disposal of clinical samples.

DE GRUYTER

Clin Chem Lab Med 2016; 54(12): 1881–1891

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

To facilitate the interpretation and clinical decision-making process, essential information should be introduced in the laboratory report to convert raw data to information thus making data meaningful.

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

**In this phase the “five rights” rule to
be assured is:**

the right turnaround time

the right data validation

the right units,

the right reference intervals/decision limits

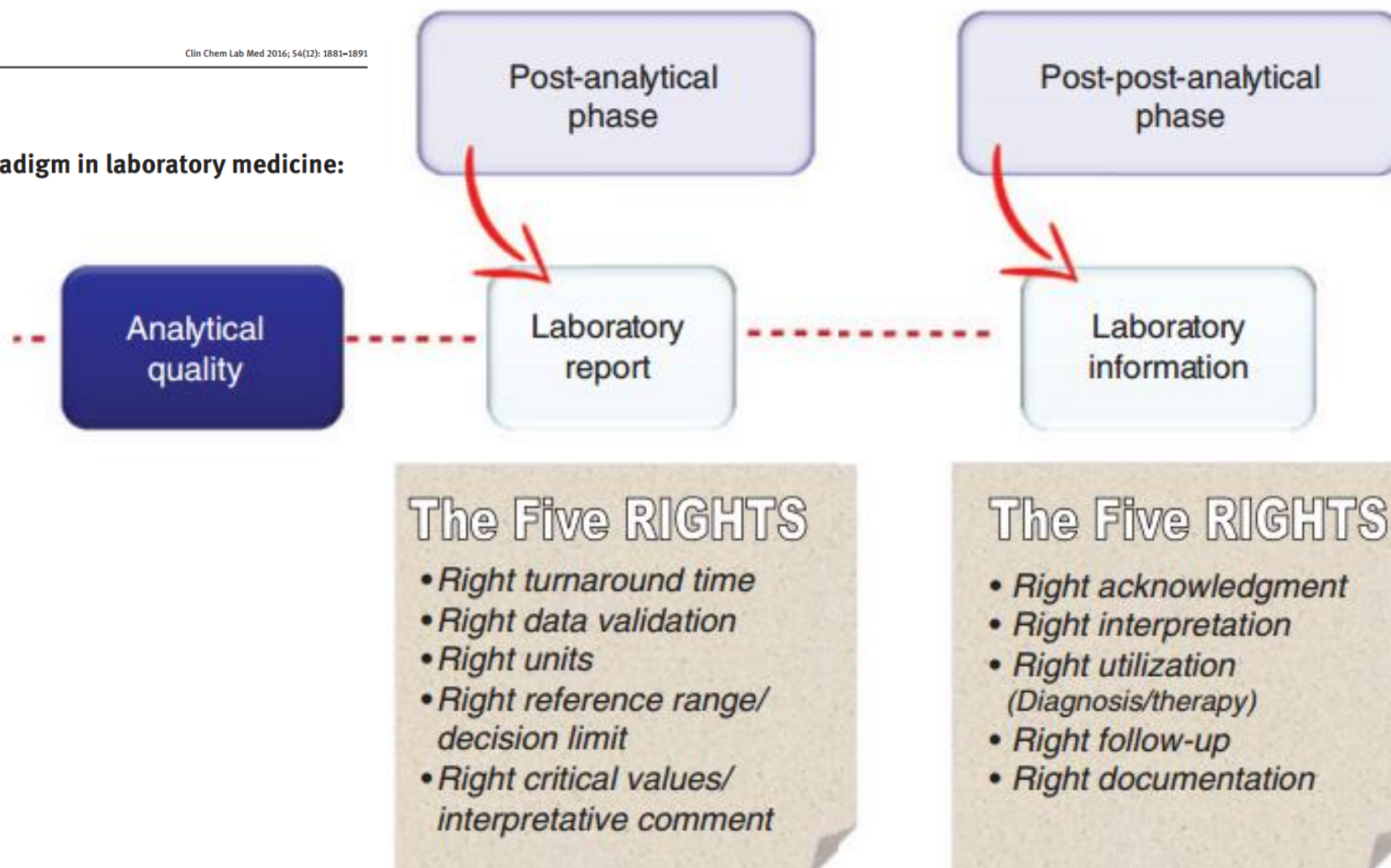
the right interpretative comment/critical values notification”

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Clin Chem Lab Med 2016; 54(12): 1881–1891

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

The five rights in the post-analytical phases

Turnaround time (TAT)

DE GRUYTERClin Chem Lab Med 2016; 54(12): 1881-1891Opinion PaperMario Plebani***Towards a new paradigm in laboratory medicine:
the five rights**

Timeliness of results is a quality attribute, as most clinicians judge the adequacy of laboratory services by the speed with which its results are reported [41]. Slow TATs have a number of adverse effects and can lead to duplicate test requests, increased STAT testing and a longer hospital stay [42]. The rapid growth in point-of-care testing (POCT) testifies to the fact that clinicians are seeking faster test results, while sometimes overlooking negative aspects, such as reduced accuracy, a higher risk of interferences and increased costs.

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

The provision of a system for interpreting numerical data against reference limits or clinical decision values is a mandatory requirement in any laboratory report (ISO 15189; 5.8.5j) [39]. However, particularly for some complex tests, the need for interpretative comments is being recognized increasingly often as important in improving outcomes and safeguarding the patient [40].

Data validation

Verification and validation of analytical results is another fundamental step in the post-analytical phase. One of the most serious laboratory errors threatening the patient's safety is still related to the erroneous manual transcription of data [44, 45]; this must be addressed by using reliable procedures.

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Clin Chem Lab Med 2016; 54(12): 1881–1891

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

Data validation

Automated informatics systems for verifying and validating laboratory results enhance the reliability of laboratory reports, not only allowing an enormous number of results to be analyzed, but also allowing a plausibility check between different tests thus adding clinical value to the individual laboratory report [46, 47]

DE GRUYTER

Clin Chem Lab Med 2016; 54(12): 1881–1891

Opinion Paper

Mario Plebani*

**Towards a new paradigm in laboratory medicine:
the five rights**

Delta Control: Reference change values (RCVs)

Accred Qual Assur (2002) 7:455–460
DOI 10.1007/s00769-002-0526-3

GENERAL PAPER

© Springer-Verlag 2002

Callum G. Fraser
Heather P. Stevenson
Ian M.G. Kennedy

**Biological variation data are necessary
prerequisites for objective autoverification
of clinical laboratory data**

Reference change values (RCVs) can then be calculated as $RCV = 2^{1/2} \times Z \times (CV_A^2 + CV_I^2)^{1/2}$. RCVs are easy to calculate. Z is the standard deviate appropriate for the chosen probability and is found in standard statistical tables – most often 1.96 is used as significant, that is, $P < 0.05$, and 2.58 is used for highly significant, that is, $P < 0.01$. CV_A is the analytical precision obtained from internal quality control at the appropriate clinical decision making level and should be available for all analytes in all laboratories. CV_I is the mean within-subject biological variation taken from the comprehensive easily available literature [1, 3, 4].

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Ferruccio Ceriotti*, Pilar Fernandez-Calle, George G. Klee, Gunnar Nordin, Sverre Sandberg, Thomas Streichert, Joan-Lluis Vives-Corrons and Mauro Panteghini, on behalf of the EFLM Task and Finish Group on Allocation of laboratory tests to different models for performance specifications (TFG-DM)

Criteria for assigning laboratory measurands to models for analytical performance specifications defined in the 1st EFLM Strategic Conference

The 1st EFLM Strategic Conference, held in 2014 in Milan, defined three models to be used to derive analytical performance specifications (APS) [1]:

- Model 1: based on the effect of analytical performance on the clinical outcome;
- Model 2: based on components of biological variation (BV) of the measurands;
- Model 3: based on the state of the art of the measurement, defined as the highest level of analytical performance technically achievable.

Right units

The evidence of the urgent need to harmonize units used for reporting test results highlights the fact that variations in units incur a risk of clinical interpretation errors. For example, many laboratories are still reporting hemoglobin concentrations in g/dL, although the recommended unit is g/L. Units of measure should have been standardized following the 1971 publication defining SI Units, the mole being the measurement unit proposed. Yet current evidence collected in the UK and in Australia demonstrates significant variation in the units used for some tests and even more widespread variation in the way they are represented on monitors and paper as well as the way they appear in electronic messages. This, in turn, incurs a risk of misinterpretation of laboratory results thus compromising patient safety [49].

Right reference interval/decision limit

- **Reference intervals**, the tools most widely used in laboratory medicine decision-making, **underpin many interpretations of laboratory results**.
- As shown in numerous studies, **there are wide variations in reference intervals**, even when the same platforms and reagents are used, and this contributes to the risk of different clinical interpretations, with a consequent risk to patients and unnecessary test repetition

Right reference interval/decision limit

Unlike reference intervals, which are basically designed to confirm health with high specificity (usually 95%), **decision limits**, which are more clinically **focussed** and **generally aim to confirm** the presence of a particular disease or clinical risk with appropriate sensitivity, are used increasingly often in the clinical setting, **particularly when recommended in practice guidelines**.

Right interpretative comment/critical values notification:

In 1972, George D. Lundberg defined **critical values** as “a laboratory test representing a pathophysiological state so abnormal that (it) is life-threatening if action is not taken quickly and for which an effective action is possible”

Since then, the **recognition, documentation and notification of critical values** by clinical laboratories have been promoted as crucial to patient safety and good laboratory practice

DE GRUYTER

Clin Chem Lab Med 2016; 54(7): 1169–1176

Laura Sciacovelli, Ada Aita, Andrea Padoan, Michela Pelloso, Giorgia Antonelli, Elisa Piva, Maria Laura Chiozza and Mario Plebani*

Performance criteria and quality indicators for the post-analytical phase

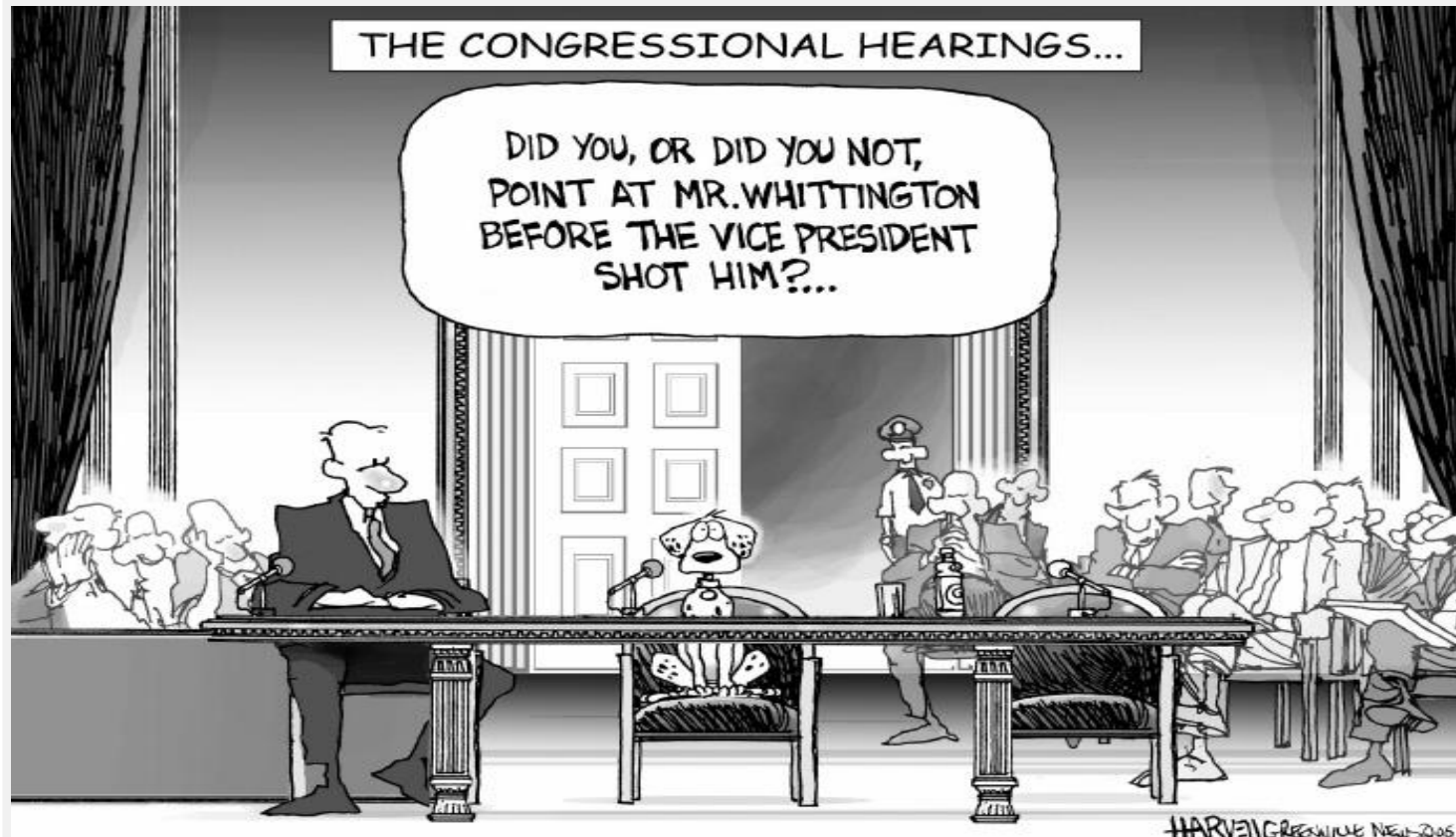
Review

Performance specifications of critical results management

Elisa Piva*, Laura Sciacovelli, Michela Pelloso, Mario Plebani

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Do we always know for sure who is guilty???



Whenever an error occurs,
BLAME your SYSTEM
(including you), and not only
your STAFF!



**THANKS FOR YOUR
ATTENTION**

