Preanalytical phase and patient outcome

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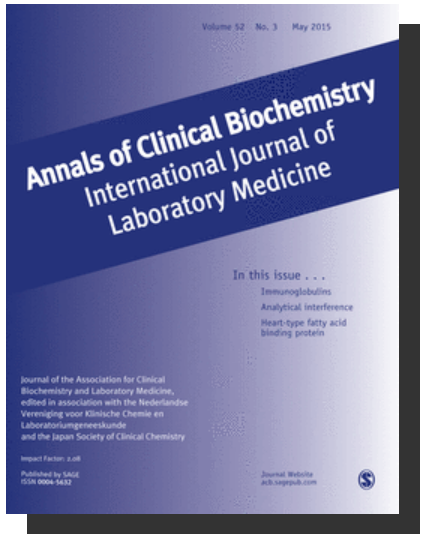
ZAGREB, CROATIA

I will talk about…

- why outcome? value?
- how to define value?
- link between preanalytical phase and outcomes
- examples
- problems in preanalytical outcome studies
- the way forward

”It is estimated that 70% of all medical decisions are based on the results of laboratory tests. „

‘70% claim’



Editorial

The ‘70% claim’: what is the evidence base?

Mike J Hallworth

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DOI: 10.1258/acb.2011.011177

Those involved in the practice of laboratory medicine are convinced of its value to effective and safe patient care, and usually have much anecdotal evidence of instances in decisions that doctors make that change the lives of patients (Critchfield GC, personal communication)’.[5] Becich goes on to say that ‘From anecdotal studies in pathology infor

- 70% claim is not based on published evidence (data),
- evidence is not available

Hallworth MJ. The '70% claim': what is the evidence base? Ann Clin Biochem. 2011;48(Pt 6):487-8.

The IFCC Task Force on the Impact of Laboratory Medicine on Clinical Management and Outcomes

established in 2012

Aim:

- Evaluate the available evidence,
- Develop the study design for future studies

Hallworth M, et al. Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine. Clinical Chemistry 2015:61;589–599

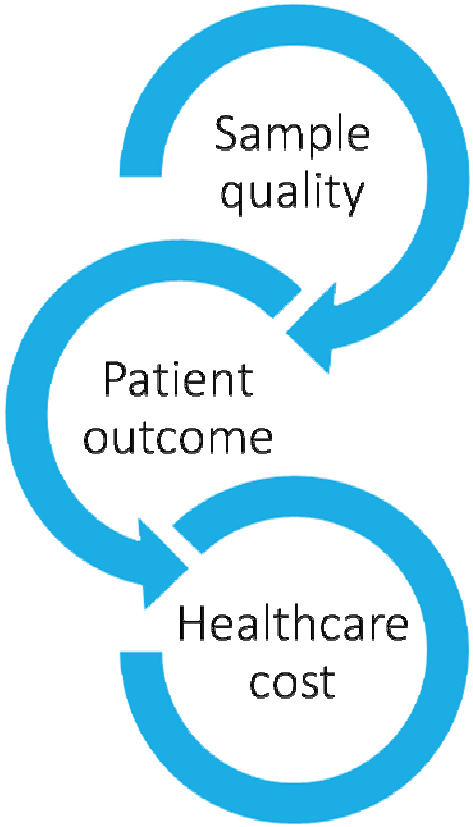
IFCC TF: Contribution of the laboratory to the patient outcome?

- The available evidence is poor
- To obtain the evidence for the contribution of laboratory medicine to the healthcare, we need:
  - better understanding of the mechanisms by which value is added or reduced
  - original data,
  - well designed clinical studies.

Hallworth M, et al. Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine. Clinical Chemistry 2015:61;589–599

Do we know the contribution of preanalytical errors to the value of laboratory medicine?

The objective evidence is missing for the effect of many preanalytical errors on the:



Value?

- Clinical value *(improvement of health-related outcomes)*
- Economical value *(cost-efficiency or effectiveness)*

Net value = benefit – harm*

**(undesirable effects of testing)*

- Show the increase in benefit (difficult)
- Show a reduction of harm

Hallworth M, et al. Current Evidence and Future Perspectives on the Effective Practice of Patient-Centered Laboratory Medicine. Clinical Chemistry 2015:61;589–599

Value-based agenda

Instead of studying the process defects, we should focus more on studies that show a reduction of harm and cost.

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013;22 Suppl 2:ii6-ii10

We need better preanalytical outcome studies

Most of the studies so far:

- have been descriptive
- have been reporting process defects without a connection to the patient harm/outcome:
  - TAT
  - sample haemolysis,
  - clotted samples, insufficient quantity of sample, etc…

Important sources of patient harm are overlooked.

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013;22 Suppl 2:ii6-ii10

Harms?

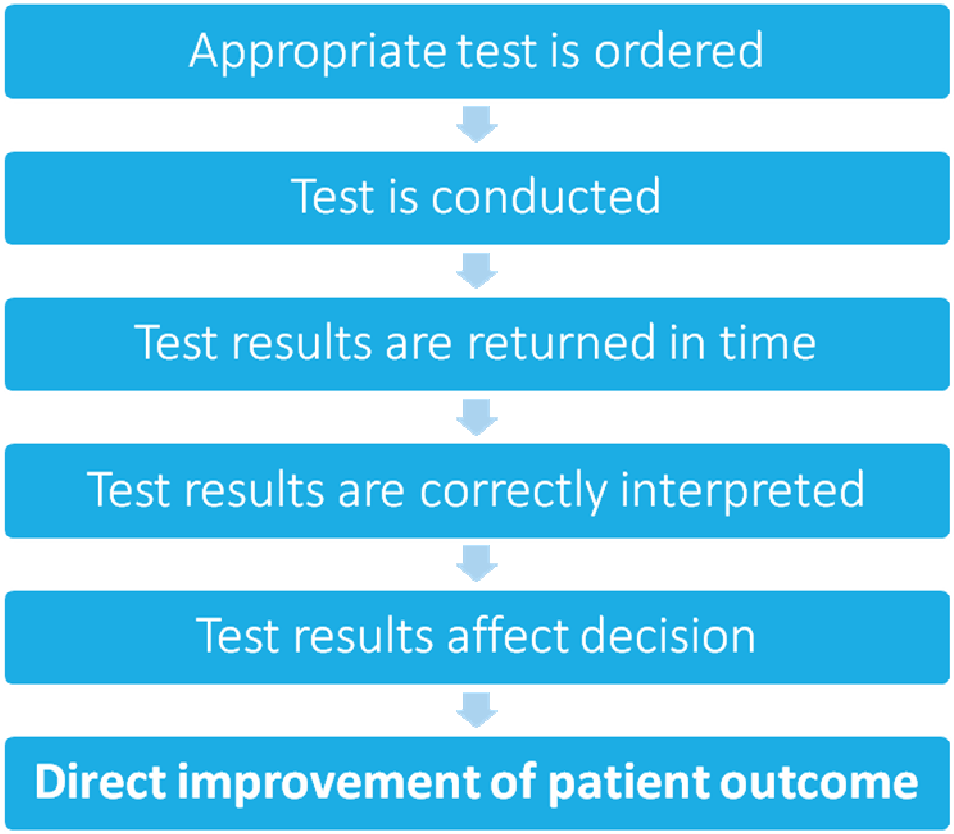
Box 1: Five causes taxonomy of testing-related diagnostic error

- An inappropriate test is ordered
- An appropriate test is not ordered
- An appropriate test result is misapplied
- An appropriate test is ordered, but a delay occurs somewhere in the total testing process
- The result of an appropriately ordered test is inaccurate

- Patient harm due to the laboratory testing

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013;22 Suppl 2:ii6-ii10

Appropriate test request helps the patient



Lundberg GD. Adding outcome as the 10th step in the brain-to-brain laboratory test loop. Am J Clin Pathol. 2014;141(6):767-9.

Why are laboratory tests requested?

- diagnosis, monitoring, screening, prognosis
- education,
- to confirm a clinical opinion,
- to both establish and complete a database,
- insecurity,
- curiosity,
- patient or family pressure,
- peer pressure,
- pressure from the recent literature,
- concern for liability (legal requirement),
- documentation,
- question of accuracy of a prior result,
- unavailability of a prior result,
- hospital policy,
- personal or hospital profit,
- hunting or fishing expeditions,
- frustration at nothing better to do ("I don't know what is wrong with this patient—better get some laboratory tests"),
- to buy time ("maybe by the time the laboratory results come back, I will have a better idea what is wrong with this patient or the patient may cure herself or himself"),
- simple availability,
- ease of doing,
- "what I learned in residency"
- pure habit.

Lundberg GD. Adding outcome as the 10th step in the brain-to-brain laboratory test loop. Am J Clin Pathol. 2014;141(6):767-9.

CIRME

Università degli Studi di Milano

Centro Interdipartimentale per la Riferibilità Metrologica in Medicina di Laboratorio (CIRME)

Under the auspices of:

JCTLM Accurate results for patient care

ifcc International Federation of Clinical Chemistry and Laboratory Medicine

EFLM European Federation of Clinical Chemistry and Laboratory Medicine

12th International Scientific Meeting

STANDARDIZATION IN LABORATORY MEDICINE AND PATIENT SAFETY

PROGRAMME

09:15 Registration

10:00 Meeting inauguration

MORNING SESSION
Chairpersons: A. Mosca (Italy), F. Ceriotti (Italy)

10:30 Standardization: a bumpy but necessary path
M. Panteghini (Italy)

11:00 Practical approaches to improve appropriateness of test request
S. Ferraro (Italy)

11:30 Preanalytical phase and patient outcome
A. M. Simundic (Croatia)

12:00 Harmonization of automated interference index assessment and use
A. Dolci (Italy)

Consequence?

- For the **laboratory**:
  - Unnecessary cost
  - Prolonged TAT for STAT tests (less time available)
  - Less resources available for other tests
- For the **patient**:
  - Patient anxiety
  - Diagnostic errors & patient harm

Misutilization of laboratory tests leads to diagnostic errors

Clinical Excellence Commission, 2015, Diagnostic Error: Learning Resource for Clinicians, Sydney: Clinical Excellence Commission

Diagnostic errors

- missed diagnosis

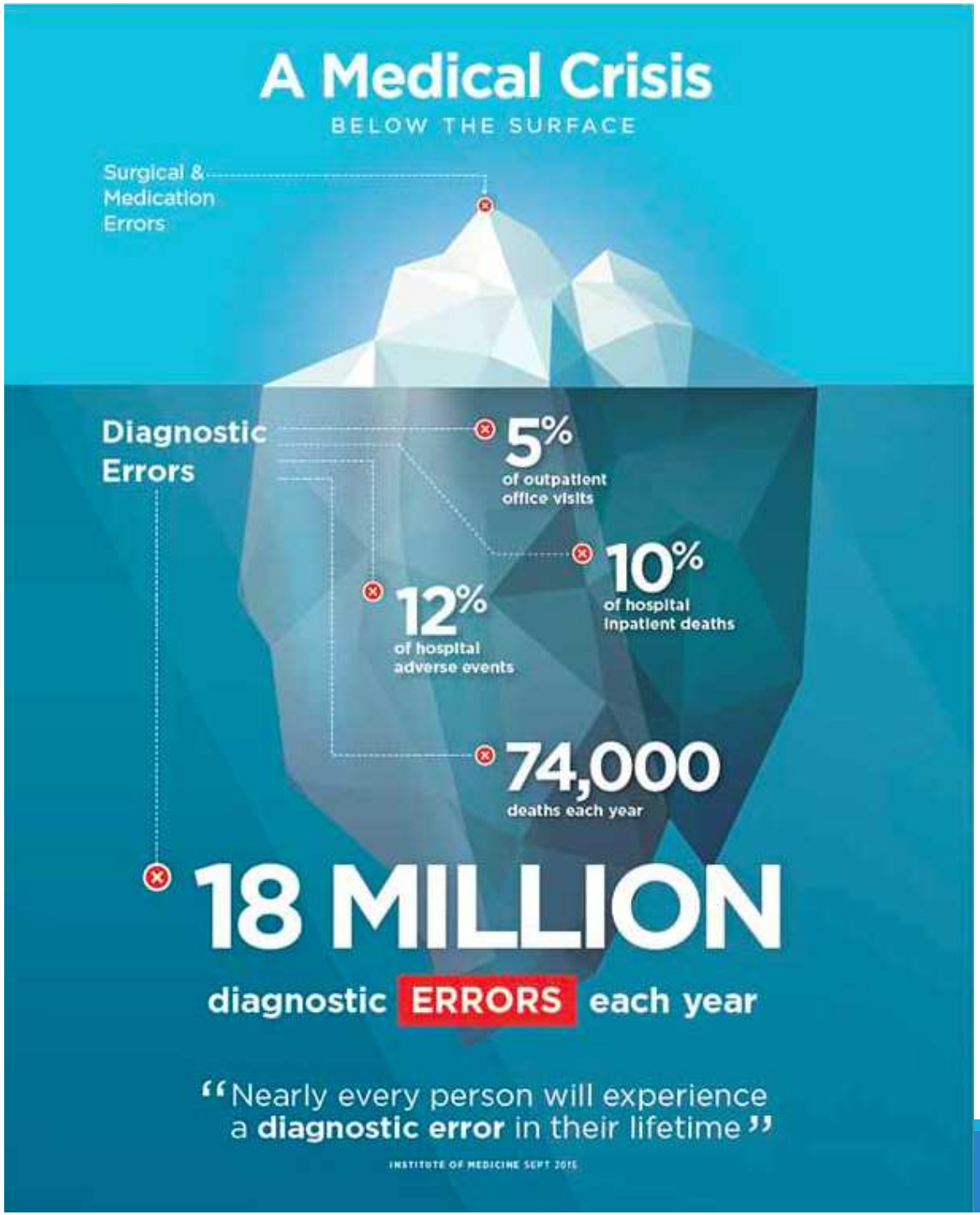
(No diagnosis was ever made)

- delayed diagnosis

(The correct diagnosis was made, but not in a timely manner)

- wrong diagnosis

(A diagnosis was made, but not the correct diagnosis)



„Diagnostic error has moved to the center stage as a critical patient safety issue and is a matter of paramount importance for every caregiver."

https://thedoctorweighsin.com/

ECRI Institute's Top 10 Patient Safety Concerns for 2018

1. Diagnostic errors
2. Opioid safety across the continuum of care
3. Internal care coordination
4. Workarounds
5. Incorporating health IT into patient safety programs
6. Management of behavioral health needs in acute care settings
7. All-hazards emergency preparedness
8. Device cleaning, disinfection, and sterilization
9. Patient engagement and health literacy
10. Leadership engagement in patient safety

MS130

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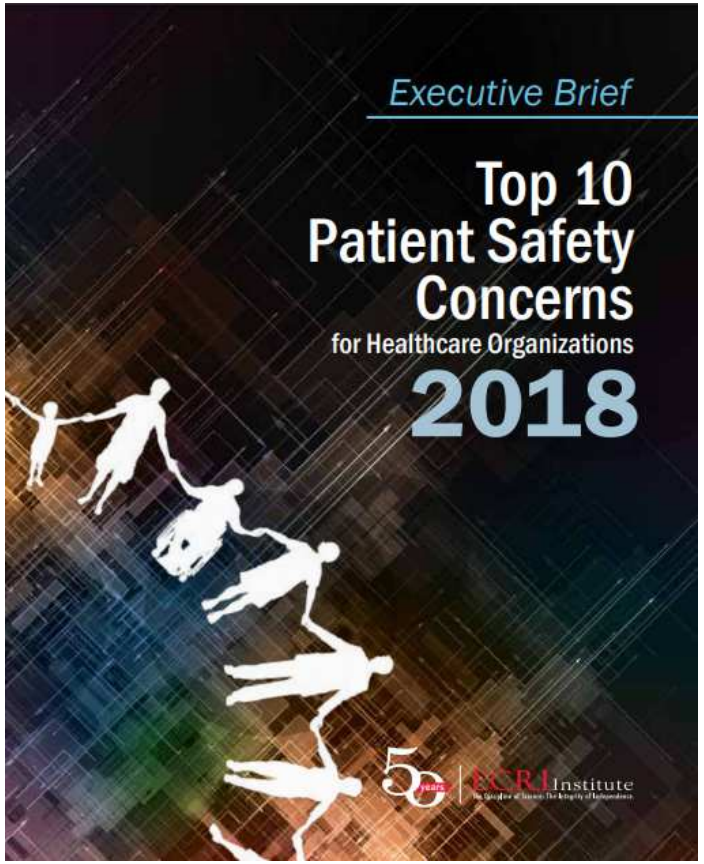
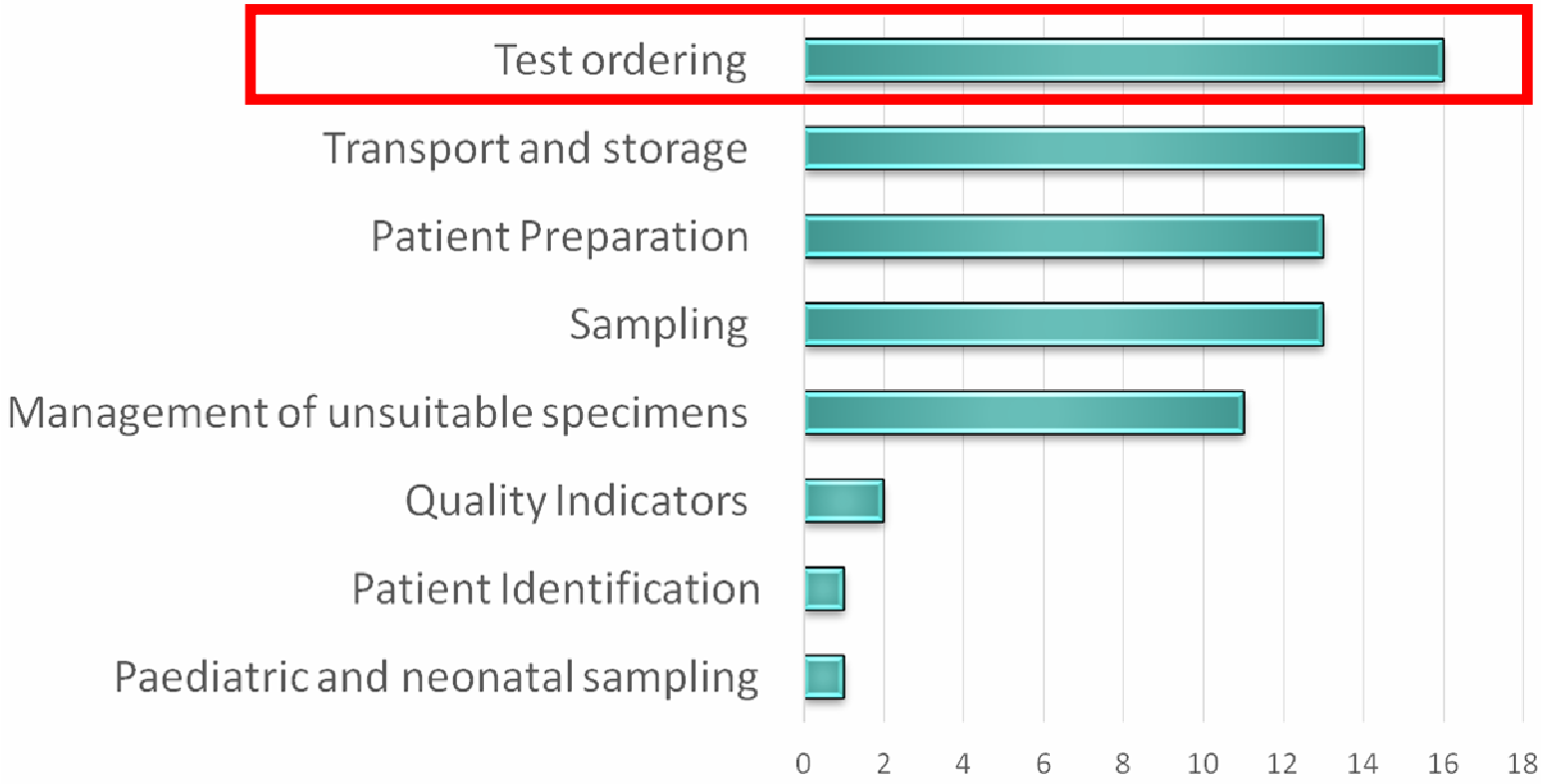


Key preanalytical issues identified which require urgent harmonization?



Cornes MP, Church S, van Dongen-Lases E, Grankvist K, Guimarães JT, Ibarz M, Kovalevskaya S, Kristensen GB, Lippi G, Nybo M, Sprongl L, Sumarac Z, Simundic AM. The role of EFLM WG-PRE in standardization and harmonization of the preanalytical phase in Europe. Ann Clin Biochem 2016;53(Pt 5):539-47

AMSTERDAM

24-25 March 2017

4TH EFLM-BD EUROPEAN CONFERENCE ON PREANALYTICAL PHASE
Improving quality in the preanalytical phase trough innovation

AMSTERDAM
24-25 March 2017

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Session: Demand management - part I

Chairs: Ana-Maria Simundic and João Tiago Guimarães

13:30-14:00 Managing laboratory demand strategies: Some actual examples of their usefulness
Maria Salinas

14:00-14:30 Targeted thyroid testing in acute illness - achieving success through audit and teaching
Lakdasa Devananda Premawardhana

14:30-15:00 Solutions for lean and effective usage of laboratory services by an Intensive Care unit
Robert Tepaske and Prim de Bie

Session: Demand management - part II

Chairs: Kjell Grankvist and Janne Cadamuro

15:30-16:00 Diagnostic pathways – When? How? Benefits
Georg Hoffmann

16:00-16:30 Drivers for and examples of demand management in the UK
Michael Cornes

16:30-17:00 American Board of Internal Medicine's "Choosing Wisely" campaign - Practical examples
Geoffrey Baird

Mercedes Ibarz

WG-PRE

Project gruoup: Demand management

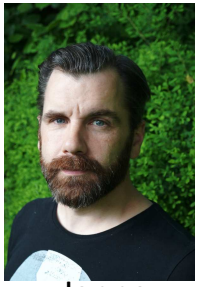
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Aim:

- to see what demand management strategies are in use in European labs;
- to see how clinicians see the role of laboratory professionals in demand management

Zorica Sumarac

Mads Nybo



Janne Cadamuro

Joao Tiago Guimaraes

Pieter Veermersch

Michael Cornes

Svetlana Kovalevskaya

Harm is also caused by delays in reporting the test results….

Box 1: Five causes taxonomy of testing-related diagnostic error

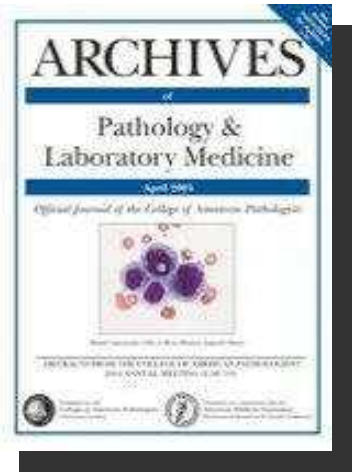
- An inappropriate test is ordered
- An appropriate test is not ordered
- An appropriate test result is misapplied
- An appropriate test is ordered, but a delay occurs somewhere in the total testing process
- The result of an appropriately ordered test is inaccurate

→ delayed diagnosis

- Patient harm due to the laboratory testing

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013;22 Suppl 2:ii6-ii10

Example 1: Specimen rejection related harm



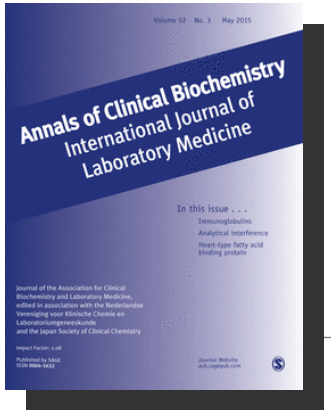
Repeated sampling:

- 86.8% of rejected blood specimens led to repeated phlebotomy.
- 13.8% of rejected urine specimens required recatheterization of the patient to collect a new urine sample.
- inconvenience and discomfort for the patient, potential for patient complications.

Delay in reporting of the results:

- the median specimen processing delay was 65 minutes
- potential for the failure to provide adequate care in a timely manner

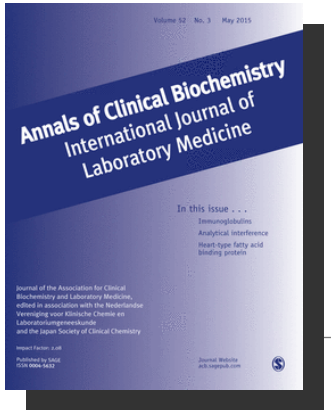
Karcher DS, et al. Clinical Consequences of Specimen Rejection: A College of American Pathologists Q-Probes Analysis of 78 Clinical Laboratories. Arch Pathol Lab Med. 2014;138:1003-8.



Example 2: The impact of centrifugation on ↑ K

- Hemolysis was frequent in sera collected in distant primary care locations (↑ K)
- False hyperkalemia may lead to inappropriate admission to the hospital and delays due to the need to repeat the test.
- Study lasted six months prior to and after the intervention
- Intervention: on-site centrifugation.

Turner HE, et al. The impact of centrifugation in primary care on pseudohypokalaemia: a retrospective evaluation. Ann Clin Biochem 2013;50: 371–3.



Example 2: The impact of centrifugation on ↑ K

Result – a significant decrease in the number of:

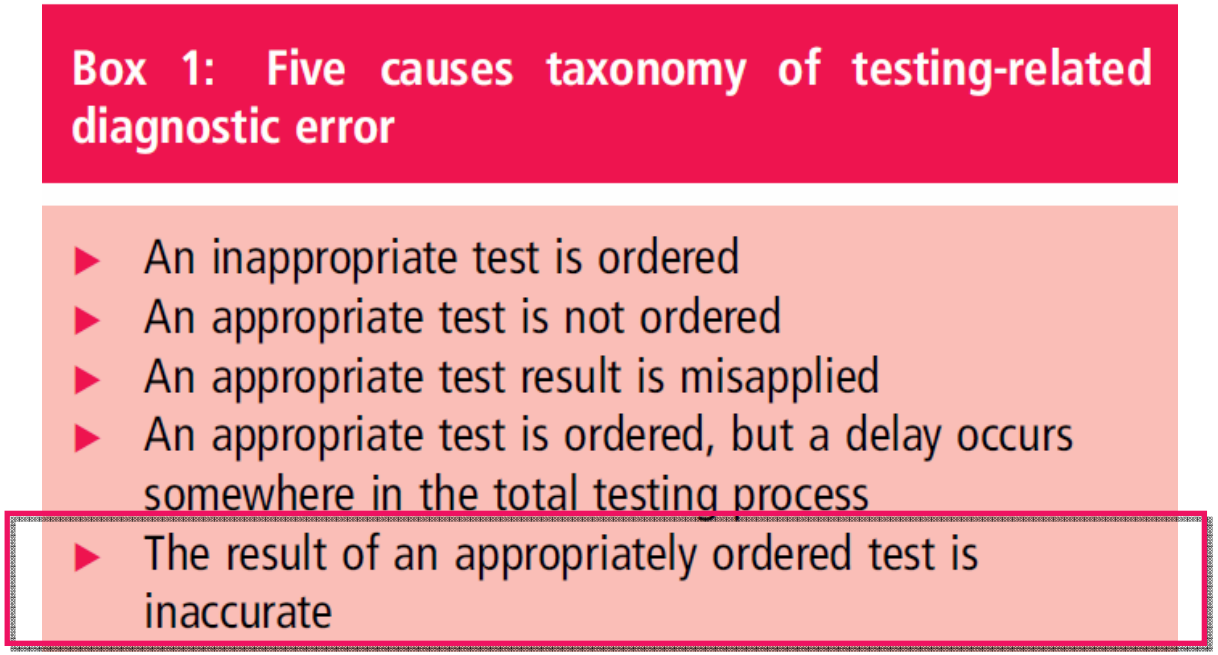
- hyperkalemic samples following the implementation (2244 vs. 524; P<0.0001).
- inappropriate hospital admissions (22 vs. 6 cases).

Conclusions:

- The centrifugation of serum samples in primary care improves the sample quality and the integrity of the potassium results
- Also, improvement in patient management and quality of care was demonstrated.

Turner HE, et al. The impact of centrifugation in primary care on pseudohypokalaemia: a retrospective evaluation. Ann Clin Biochem 2013;50: 371–3.

Harm is caused by reporting the inaccurate test results….



missed or wrong diagnosis

- Patient harm due to the laboratory testing

Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf. 2013;22 Suppl 2:ii6-ii10

Example 1: liquid citrate tube leads to missclassification of DM patients

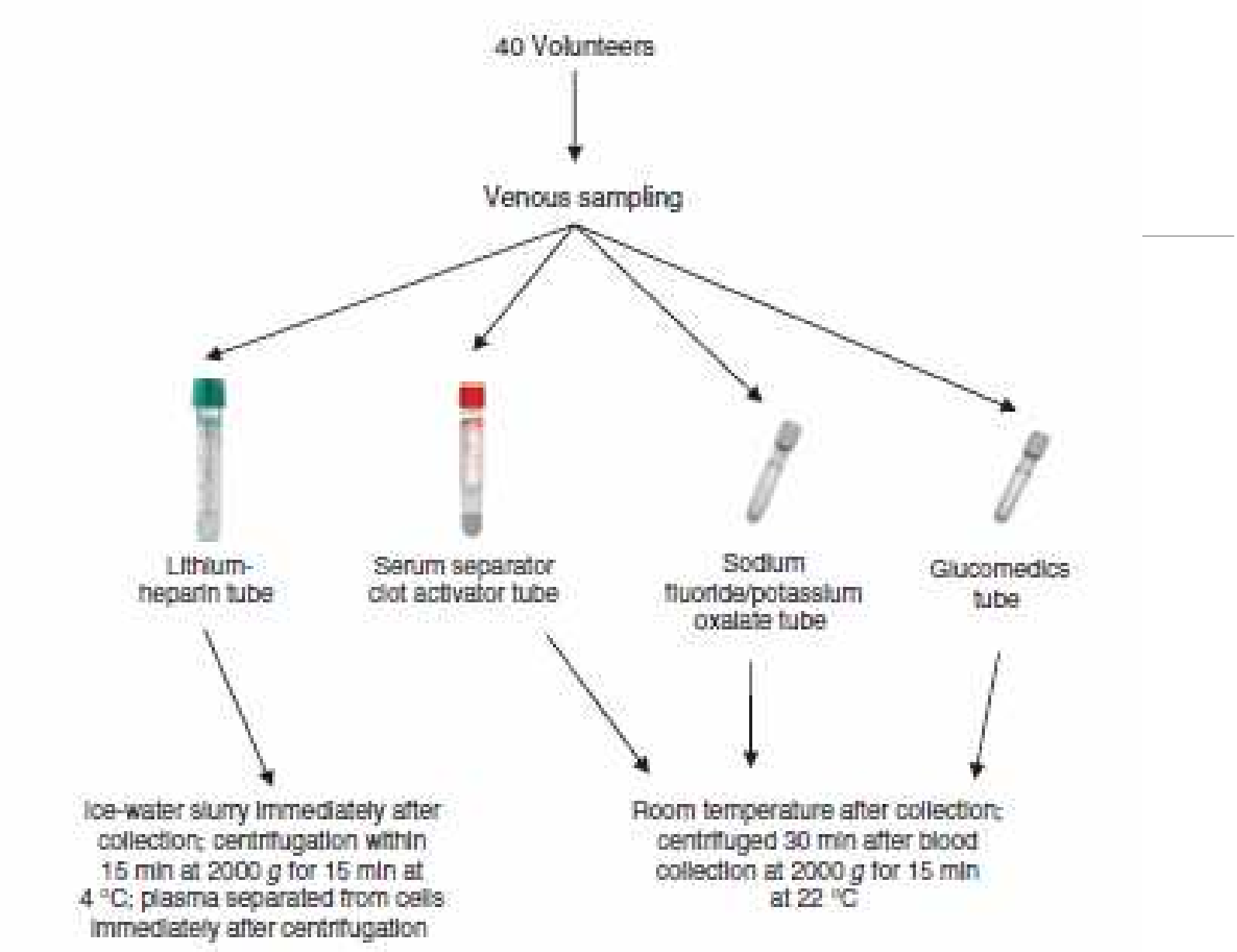
DE GRUYTER

Clin Chem Lab Med 2016; 54(2): 363–371

Gordana Juricic*, Lara Milevoj Kopcinovic, Andrea Saracevic, Ana Bakliza and Ana-Maria Simundic

Liquid citrate acidification introduces significant glucose bias and leads to misclassification of patients with diabetes

Juricic G, Milevoj Kopcinovic L, Saracevic A, Bakliza A, Simundic AM. Liquid citrate acidification introduces significant glucose bias and leadsto missclassificatioon of patients with diabetes. CCLM, 2016;54(2):363-71



Juricic G, Milevoj Kopcinovic L, Saracevic A, Bakliza A, Simundic AM. Liquid citrate acidification introduces significant glucose bias and leadsto missclassificatioon of patients with diabetes. CCLM, 2016;54(2):363-71

Table 1: Mean baseline glucose concentrations, differences and mean absolute bias from reference sample for all tubes tested in healthy volunteers (n=40).

Tube type	Baseline glucose, mmol/L	p-Value	Difference between baseline glucose concentrations in each tube type (P[b])				Mean absolute bias, %	Recommended ADA bias, %
			vs. LiH	vs. serum	vs. NaF/KOx	vs. Glucomedics		
LiH	5.7±1.0	<0.001[a]	–	<0.001[a]	<0.001[a]	<0.001[a]	–	2.2
Serum	5.5±1.0		<0.001[a]	–	0.026[a]	<0.001[a]	3.2[c]	
NaF/KOx	5.6±1.0		<0.001[a]	0.026[a]	–	<0.001[a]	2.4[c]	
Glucomedics	6.2±1.1		<0.001[a]	<0.001[a]	<0.001[a]	–	9.9[c]	

[a]Statistically significant difference; [b]Pairwise comparisons, Bonferroni corrected; [c]clinically significant difference. ADA, American Diabetes Association; LiH, lithium heparin; NaF/Kox, sodium fluoride.

Table 3: Classification of patients based on original (NaF/KOx tubes) results and after correction with calculated difference for Glucomedics tubes.

ADA criteria					Total number of patients (n): 3249
	Glucose, mmol/L	NaF/KOx, n (%)	Recalculation (Glucomedics), n (%)	χ^2	p-Value
Hypoglycemia	<3.9	5 (0.2)	3 (0.1)	0.5	0.471
Normal range	3.9–5.5	700 (21.6)	295 (9.1)	194.4	<0.001[a]
Impaired fasting glucose	5.6–6.9	659 (20.3)	722 (22.2)	3.39	0.066
Diabetes	>7.0	1885 (58.0)	2229 (68.6)	78.1	<0.001[a]

Juricic G, Milevoj Kopcinovic L, Saracevic A, Bakliza A, Simundic AM. Liquid citrate acidification introduces significant glucose bias and leadsto missclassificatioon of patients with diabetes. CCLM, 2016;54(2):363-71

Example 2: Collection tubes related diagnostic error

ELSEVIER

Alzheimer's & Dementia ■ (2013) 1–7

Alzheimer's & Dementia

Research Article

Impact of harmonization of collection tubes on Alzheimer's disease diagnosis

Sylvain Lehmann[a,*], Susanna Schraen[b], Isabelle Quadrio[c], Claire Paquet[d,e], Stéphanie Bombois[f], Constance Delaby[a,g], Aline Dorey[h], Julien Dumurgier[d], Christophe Hirtz[a], Pierre Krolak-Salmon[h], Jean-Louis Laplanche[i], Olivier Moreaud[j], Katell Peoc'h[i], Olivier Rouaud[k], Bernard Sablonnière[b], Eric Thouvenot[l], Jacques Touchon[l], Olivier Vercruysse[f], Jacques Hugon[d,e], Audrey Gabelle[l], Florence Pasquier[f], Armand Perret-Liaudet[c]

[a]*CHU de Montpellier, IRB, INSERM-UM1 1040, Montpellier, France*
[b]*Université Lille Nord de France, INSERM U837, Lille University Hospital, Center of Biology and Pathology, Lille, France*
[c]*Service de Neurobiologie, Hospices Civils de Lyon, Université Lyon 1–CNRS UMR5292–INSERM U1028, Lyon, France*
[d]*CMRR Paris Nord Ile de France, Lariboisiere-Fernand Widal Hospital, APHP, University 7-Denis Diderot, Paris, France*
[e]*INSERM U942, Paris, France*
[f]*Université Lille Nord de France, EA1046, DISTALZ, Memory Center, CHU 59000, Lille, France*
[g]*Paris 7, Faculté de Médecine Xavier Bichat, Paris, France*
[h]*CMRR Lyon, Hôpital des Charpennes, HCL Lyon, Lyon, France*
[i]*Laboratoire de Biochimie, Lariboisière-Fernand Widal Hospital, APHP, University Paris 7-Denis Diderot, University Paris Descartes, Paris, France*
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[l]*CMRR, CHU de Montpellier, Montpellier, France*

Lehmann S, et al. Impact of harmonization of collection tubes on Alzheimer's disease diagnosis. Alzheimers Dement. 2014;10(5 Suppl):S390-S394.e2.

Example 2: Collection tubes related diagnostic error

Tube	Center	Manufacturer	Catalog numbers	Aβ42 × factor to S tube	Tau × factor to S tube	P-tau × factor to S tube
A	Montpellier	Greiner	18 82 81	1.56 (1.40–1.62)	1.03 (0.99–1.06)	0.95 (0.89–0.97)
B	Lille	Becton Dickinson	Falcon 35 2097	1.72 (1.54–1.92)	1.04 (0.97–1.09)	1.00 (0.98–1.02)
C	Lyon	VWR	216.0154	1.65 (1.44–1.72)	1.01 (0.98–1.02)	0.94 (0.84–1.05)
D	Paris	CML	TC10PCS	NP	NP	NP
S	Montpellier Lille Lyon	Sarstedt	62.610.201*	NP	NP	NP

Abbreviation: NP, not performed.

NOTE. Collection tubes used in the different centers and multiplication factors obtained by measuring the same series of CSF samples collected in two different sets of tubes.

Objective: The objective of this study was to analyze differences in biomarker outcomes before and after harmonization of cerebrospinal fluid (CSF) collection tubes in Alzheimer's disease (AD) diagnosis.

Methods: We analyzed data from French memory centers that switched from different CSF collection tubes to a common one. A total of 1966 patients were included in the study. CSF concentrations of β-amyloid 1–42 (Aβ42), total tau, and phosphorylated tau (p-tau181) were measured in each center using the same commercial enzyme-linked immunoabsorbent assay (ELISA) kits. The diagnostic value of CSF biomarkers according to the type of tube used was then assessed using different cutoffs.

Lehmann S, et al. Impact of harmonization of collection tubes on Alzheimer's disease diagnosis. Alzheimers Dement. 2014;10(5 Suppl):S390-S394.e2.

Example 2: Collection tubes related diagnostic error

Lehmann S, et al. Impact of harmonization of collection tubes on Alzheimer's disease diagnosis. Alzheimers Dement. 2014;10(5 Suppl):S390-S394.e2.

Results:

- predictive values of biomarkers highly affected by the type of the collection tube
- clinical effect of tube harmonization
- 42% reduction of false-negative diagnoses of AD (204/487)
- 17% increase in false-positive diagnoses of AD (56/330)
- overall accuracy significantly improved

Conclusion:

- In a routine clinical environment, the selection of the collection tube makes a major difference in AD biological diagnosis.
- The use of a common collection tube among different centers reduces the risk of misdiagnosis and incorrect patient stratification

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National Institutes of Health

Keywords used:

("preanalytical phase") AND patient outcomes

("pre-analytical phase") AND patient outcomes
Items: 16

Search date: 28 Nov, 2018

Search results

Items: 6

1. Standardizing in vitro diagnostics tasks in clinical trials: a call for action.
Lippi G, Simundic AM, Rodriguez-Manas L, Bossuyt P, Banfi G.
Ann Transl Med. 2016 May;4(9):181. doi: 10.21037/atm.2016.04.10.
PMID: 27275494 Free PMC Article
Similar articles

2. The cost of poor blood specimen quality and errors in preanalytical processes.
Green SF.
Clin Biochem. 2013 Sep;46(13-14):1175-9. doi: 10.1016/j.clinbiochem.2013.06.001. Epub 2013 Jun 14. Review.
PMID: 23769816
Similar articles

3. Reducing preanalytical laboratory sample errors through educational and technological interventions.
Lillo R, Salinas M, Lopez-Garrigos M, Naranjo-Santana Y, Gutiérrez M, Marín MD, Miralles M, Uris J.
Clin Lab. 2012;58(9-10):911-7.
PMID: 23163106
Similar articles

4. Incident reporting practices in the **preanalytical phase**: Low reported frequencies in the primary health care setting.
Söderberg J, Grankvist K, Brulin C, Wallin O.
Scand J Clin Lab Invest. 2009;69(7):731-5. doi: 10.3109/00365510903007018.
PMID: 19929714
Similar articles

5. Risk management in the **preanalytical phase** of laboratory testing.
Lippi G, Guidi GC.
Clin Chem Lab Med. 2007;45(6):720-7. Review.
PMID: 17579523
Similar articles

6. Effects of preanalytical variables on peptide and protein measurements in human serum and plasma: implications for clinical proteomics.
Rai AJ, Vitzthum F.
Expert Rev Proteomics. 2006 Aug;3(4):409-26. Review.
PMID: 16901200
Similar articles

Medical Subject Headings (MeSh)

Pre-Analytical Phase MeSH Descriptor Data 2018

Details | Qualifiers | MeSH Tree Structures | Concepts

MeSH Heading	Pre-Analytical Phase
Tree Number(s)	E01.370.225.955
Unique ID	D000073623
Scope Note	Laboratory processes prior to specimen analysis. These processes include study design, compliance of the subjects investigated, compliance in adherence to protocols, choice of specimens utilized and sample collection.
Entry Term(s)	Preanalytical Phase
Public MeSH Note	2018
History Note	2018
Date Established	2018/01/01
Date of Entry	2017/07/11
Revision Date	2017/01/14

https://meshb.nlm.nih.gov

Medical Subject Headings (MeSh)

Outcome Assessment (Health Care) MeSH Descriptor Data 2018

Details | Qualifiers | MeSH Tree Structures | Concepts

MeSH Heading	Outcome Assessment (Health Care)
Tree Number(s)	H01.770.644.145.431 N04.761.559.590 N05.715.360.575.575
Unique ID	D017063
Annotation	note category: for admin aspects of patient assessment; outcome only: for outcome assessment with process assessment, OUTCOME AND PROCESS ASSESSMENT (HEALTH CARE) and TREATMENT OUTCOME are available: DF: OUTCOME ASSESS
Scope Note	Research aimed at assessing the quality and effectiveness of health care as measured by the attainment of a specified end result or outcome. Measures include parameters such as improved health, lowered morbidity or mortality, and improvement of abnormal states (such as elevated blood pressure).
Entry Version	OUTCOME ASSESS
Entry Term(s)	Assessment, Outcomes Outcome Measures Outcome Studies Outcomes Assessment Outcomes Research
Previous Indexing	Outcome and Process Assessment (Health Care) (1979-1991)
Public MeSH Note	92; PATIENT OUTCOME ASSESSMENT was see OUTCOME AND PROCESS ASSESSMENT (HEALTH CARE) 1979-91
Online Note	use OUTCOME AND PROCESS ASSESSMENT (HEALTH CARE) to search PATIENT OUTCOME ASSESSMENT 1979-91
History Note	92; PATIENT OUTCOME ASSESSMENT was see OUTCOME AND PROCESS ASSESSMENT (HEALTH CARE) 1979-91
Date Established	1992/01/01
Date of Entry	1991/06/20
Revision Date	2015/01/09

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Medical Subject Headings (MeSh)

Outcome Assessment (Health Care) MeSH Descriptor Data 2018

Details | Qualifiers | MeSH Tree Structures | Concepts

MeSH Heading	Outcome Assessment (Health Care)
Tree Number(s)	H01.770.644.145.431 N04.761.559.590 N05.715.360.575.575
Unique ID	D017063
Annotation	note category: for admin aspects of patient assessment; outcome only: for outcome assessment with process assessment, OUTCOME AND PROCESS ASSESSMENT (HEALTH CARE) and TREATMENT OUTCOME are available; DF: OUTCOME ASSESS
Scope Note	Research aimed at assessing the quality and effectiveness of health care as measured by the attainment of a specified end result or outcome. Measures include parameters such as improved health, lowered morbidity or mortality, and improvement of abnormal states (such as elevated blood pressure).
Entry Version	OUTCOME ASSESS
Entry Term(s)	Assessment, Outcomes Outcome Measures Outcome Studies Outcomes Assessment Outcomes Research
Previous Indexing	Outcome and Process Assessment (Health Care) (1979-1991)
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PubMed.gov
US National Library of Medicine
National Institutes of Health

Keywords used:

("pre-analytical phase") AND outcome assessment (Health Care)

Search results

Items: 2

1. A Six Sigma approach to the rate and clinical effect of registration errors in a laboratory.
Vanker N, van Wyk J, Zemlin AE, Erasmus RT.
J Clin Pathol. 2010 May;63(5):434-7. doi: 10.1136/jcp.2009.072058. Epub 2010 Mar 18.
PMID: 20299386
Similar articles

2. The development of a system for the reporting, classification and grading of quality failures in the clinical biochemistry laboratory.
O'Kane MJ, Lynch PL, McGowan N.
Ann Clin Biochem. 2008 Mar;45(Pt 2):129-34. doi: 10.1258/acb.2007.007097.
PMID: 18325174
Similar articles

Search date: 28 Nov, 2018

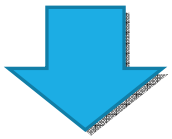
We need better preanalytical outcome studies

…and studies need to be properly indexed in PubMed

The future (outcome based) preanalytical studies must aim to ....

… obtain the evidence showing that...

- Reducing the number of unnecessary tests
- Increasing of the number of necessary tests
- Minimizing delays
- Ensuring that accurate results are reported



...leads to the improved patient outcome or reduced cost.

A good preanalytical outcome study…

- Assess the risk of preanalytical errors
- Focus on the errors that have the highest risk of patient harm
- Define a good study question (PICO): is the reduction of some preanalytical error associated with improved patient outcome and cost reduction?

- good outcome studies are difficult to do because:
  - the association of the intervention and the outcome is not always so obvious.
  - the outcome is affected by many other intermediate variables
  - data collection and reporting methods are not standardized

but not impossible…

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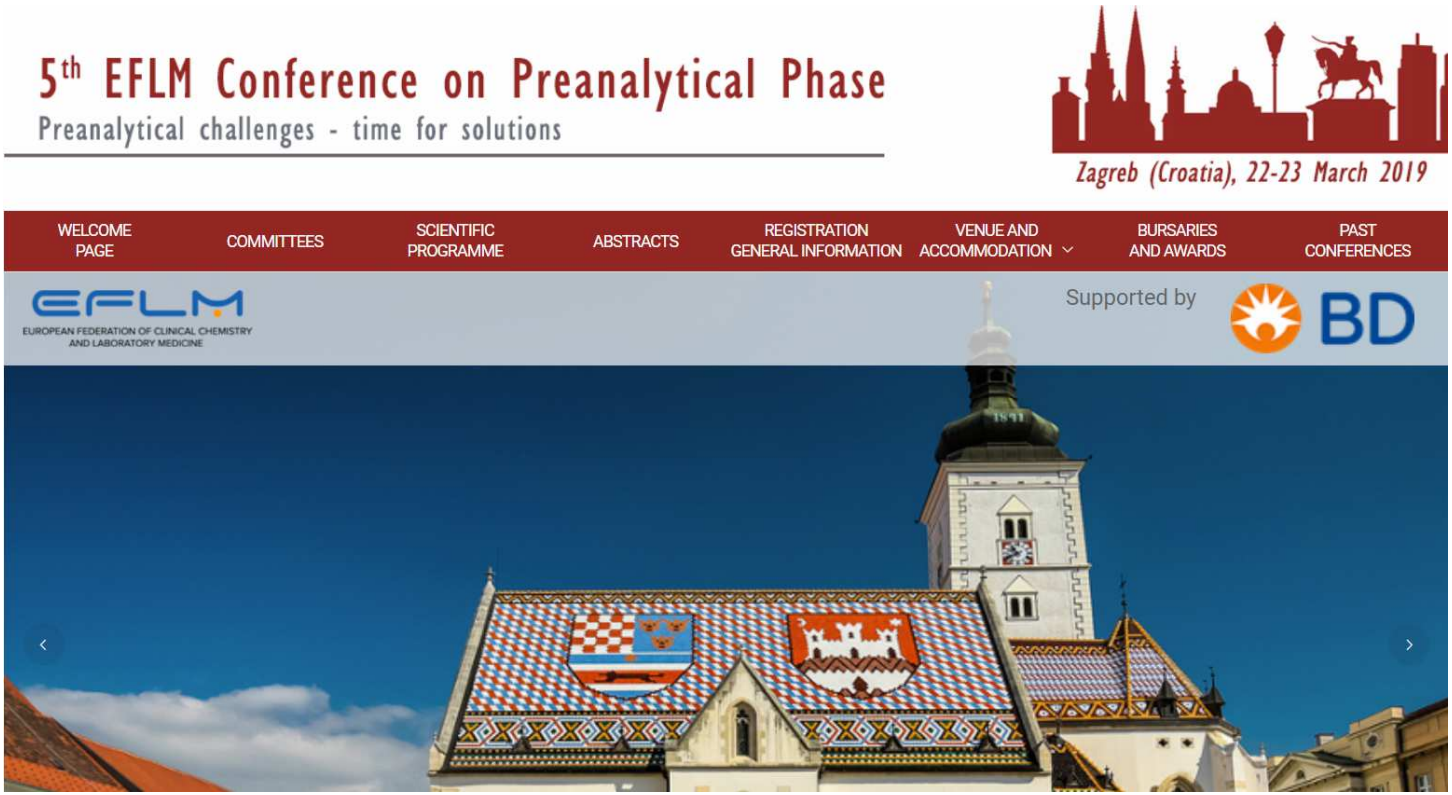
Gary S. Kaplan, MD, FACMPE
Charles D. Stokes, RN, BSN, FACHE
Co-Chairs of the Leading a Culture of Safety Project

http://safety.ache.org/pledge-and-assessment/

Thank you!



www.preanalytical-phase.org