What is the future of Laboratory Medicine?

Mauro Panteghini

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Key reasons why we need Laboratory Medicine

- It is integral to many clinical decisions on prevention, diagnosis, treatment, managing disease of patients
- Supplies healthcare professionals with the data necessary to provide high quality, safe, effective and appropriate care to patients

The LEWIN GROUP®

2008

The ‘70% claim’

- “70% of medical decisions depend on laboratory data”
- “70% of diagnoses depend on laboratory data”
- “70% of the information in physician’s notes is represented by laboratory data”
- ….but where does the evidence come from?

Hallworth MJ, Ann Clin Biochem 2011;48:487.

Laboratory Medicine perceptions and the need for change

- Test repertoire increasing (to al least 3500 tests)
- Workload increasing
- Uncontrollable demand
- Unnecessary testing
- Utilisation is varied
- New evidence
- Limited role in outcomes

Technological Advances:

- Total laboratory automation
- Molecular diagnostic techniques,
  - including high-throughput microarrays,
  - next generation sequencing,
  - genome-wide association studies (GWAS).
- POCT

Economic Pressures (limited budgets)

[global IVD market valued at $49 billion in 2012, growing at a rate of 7% from 2012 to 2017 (3-5% of healthcare costs)]

Clinical Laboratory

- As a main consequence of the 2 driving processes (i.e., new technologies and economic pressures), cost savings is frequently realized by consolidation and, in some cases, regionalization of laboratory services with the creation of individual laboratories serving multiple healthcare facilities.
- This may undermine the influence of laboratory professionals and isolate them from clinical problems (“deprofessionalization”).

Laboratory Medicine:

Poor Visibility as a Medical Discipline & as a Profession

Unknown and invisible profession in public

A BLACKBOX to most clinicians/nurses

"…laboratory scientists…are (often) perceived as managing machinery & equipment…(but) need to take a position of shared clinical leadership…"

Profession without a Face

What paths should we follow to ensure we become relevant to health care?

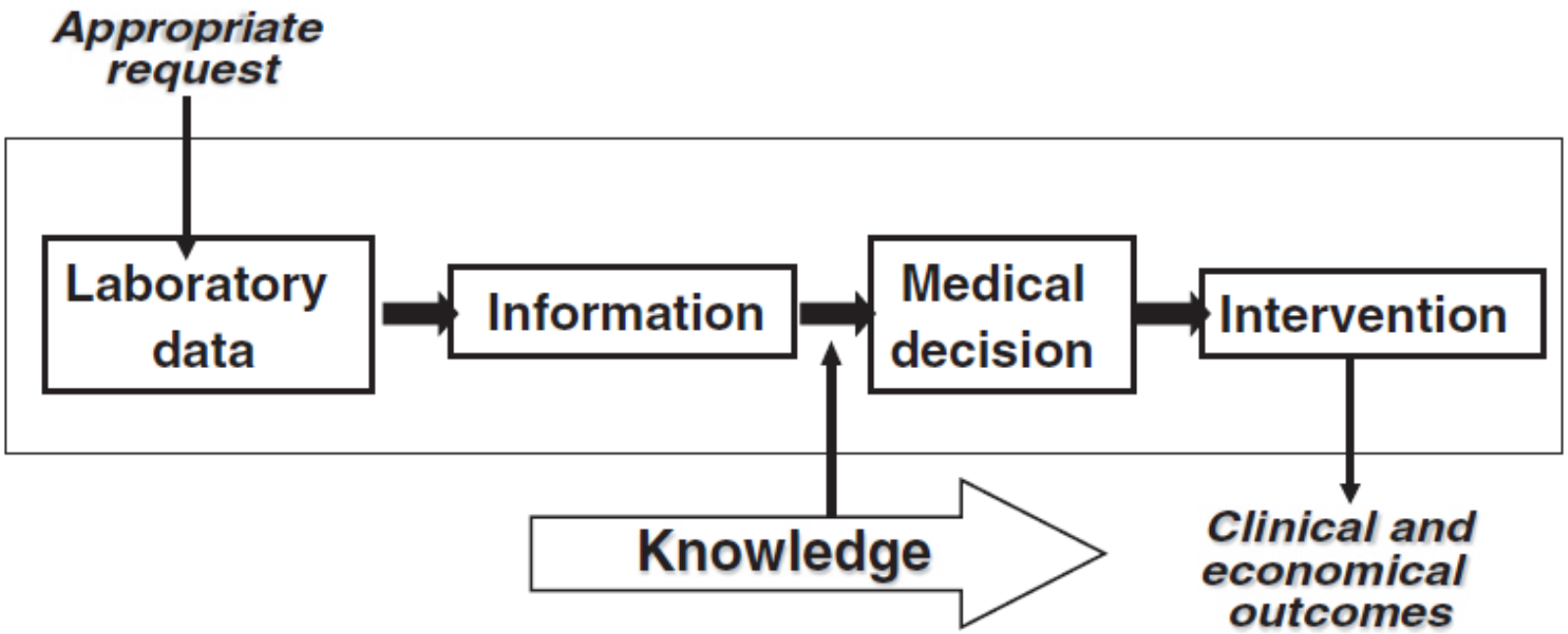


Fig. 1. Closing the loop of laboratory testing: A laboratory result should enable a decision to be made, which leads to an action being taken, yielding an improved outcome for the patient.

Plebani M & Panteghini M, Clinica Chimica Acta 432 (2014) 15.

NHS Atlas of Diagnostic Variation

- Large variations in clinician requesting that cannot easily be explained by differences in disease prevalence

Annual rate of use for CA125

From 0.11 to 9.0 per 1000 practice population

→ 80-fold variation

or

(after excluding 5 outliers)

from 0.92 to 8.4

→ **9-fold variation**

Suggested contributory factors?

- Differences in professional practice
- Differences in uptake of innovation post-NICE guidelines

UK National Audit of Tumour Marker Service Provision, 2012

What are the most common reasons for rejecting tumour marker requests in your laboratory?

- Panel of markers requested 41%
- CA125 in males 33%
- Timing – too soon 26%

Clinical (health) outcomes

- morbidity
- mortality
- quality of life

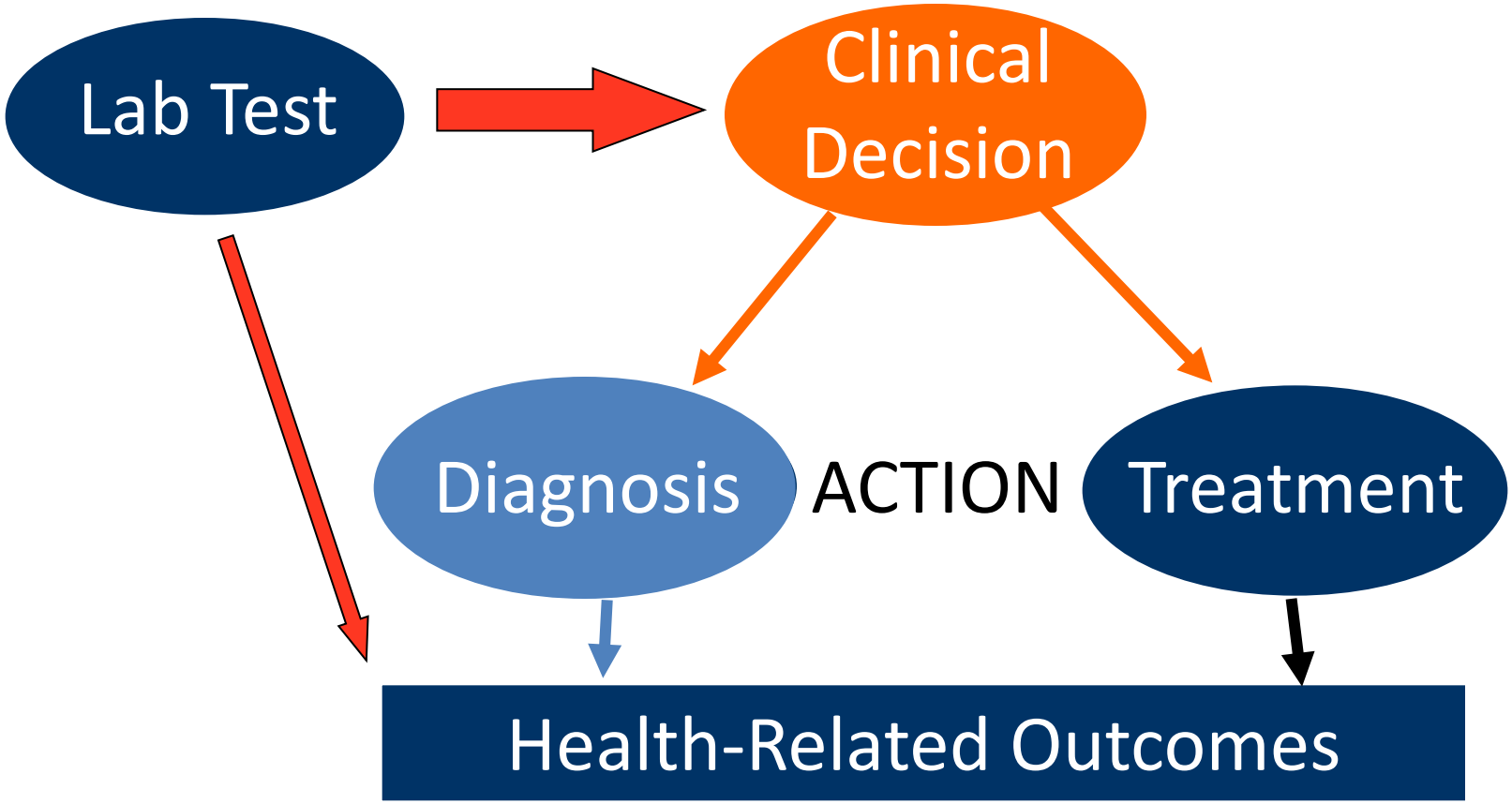
Additional outcomes

- emotional & cognitive effects (e.g. well-being)
- social effects (e.g. genetic)
- behavioural effects (e.g. adherence to treatment)

Surrogate outcomes

- Metric surrogates:
  - length of stay
  - readmission rate
  - complication rate
  - episode costs
  - treatment costs
- Medical surrogates:
  - number of clinic visits
  - therapeutic TAT
  - disease markers, e.g. HbA1c, LDL cholesterol

Challenge: Connecting Laboratory Testing to Outcomes



Demonstrating the value of lab tests on health outcomes is reliant on linking the test with processes that directly impact outcomes

Problems in the performance of outcome studies of laboratory tests

- Remoteness of outcome from performance of test
- High cost of studies relative to potential financial profit to corporate funders
- Risk of loss of financial profits if favourable outcomes are not achieved
- Large required number of patients/volunteers (sample size)
- Reluctance to withhold accepted test to do comparative trial
- Limited ability to conceal identity of tested vs. not-tested participants

Adapted from DE Bruns & JC Boyd, *Scandinavian Journal Clinical & Laboratory Investigation* 2010;70(Suppl 242):85

Hierarchical Levels of Laboratory-Related Patient Outcomes

1. The performance of the test in actual practice (analytical validity)
2. The predictive value of the test (clinical validity)
3. The probability of a change in health status of the patient based on the test result (clinical utility)

Adapted from DM Eddy, 1997

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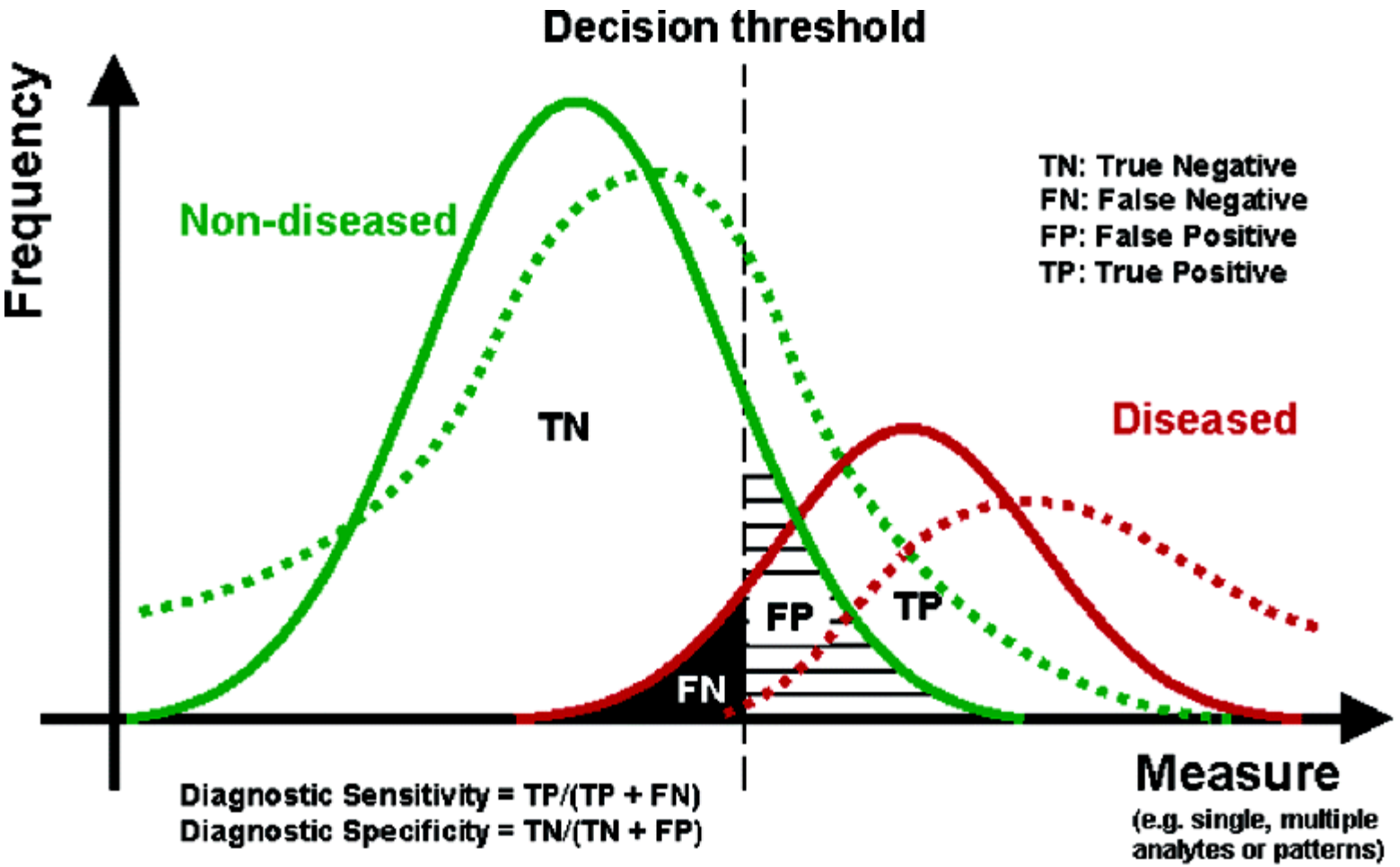
Adapted from DM Eddy, 1997

The standardization issue: an absolute priority for public health

→ Our customers (i.e., clinicians and patients) expect laboratory results to be ***equivalent and interpreted in a reliable and consistent manner***.



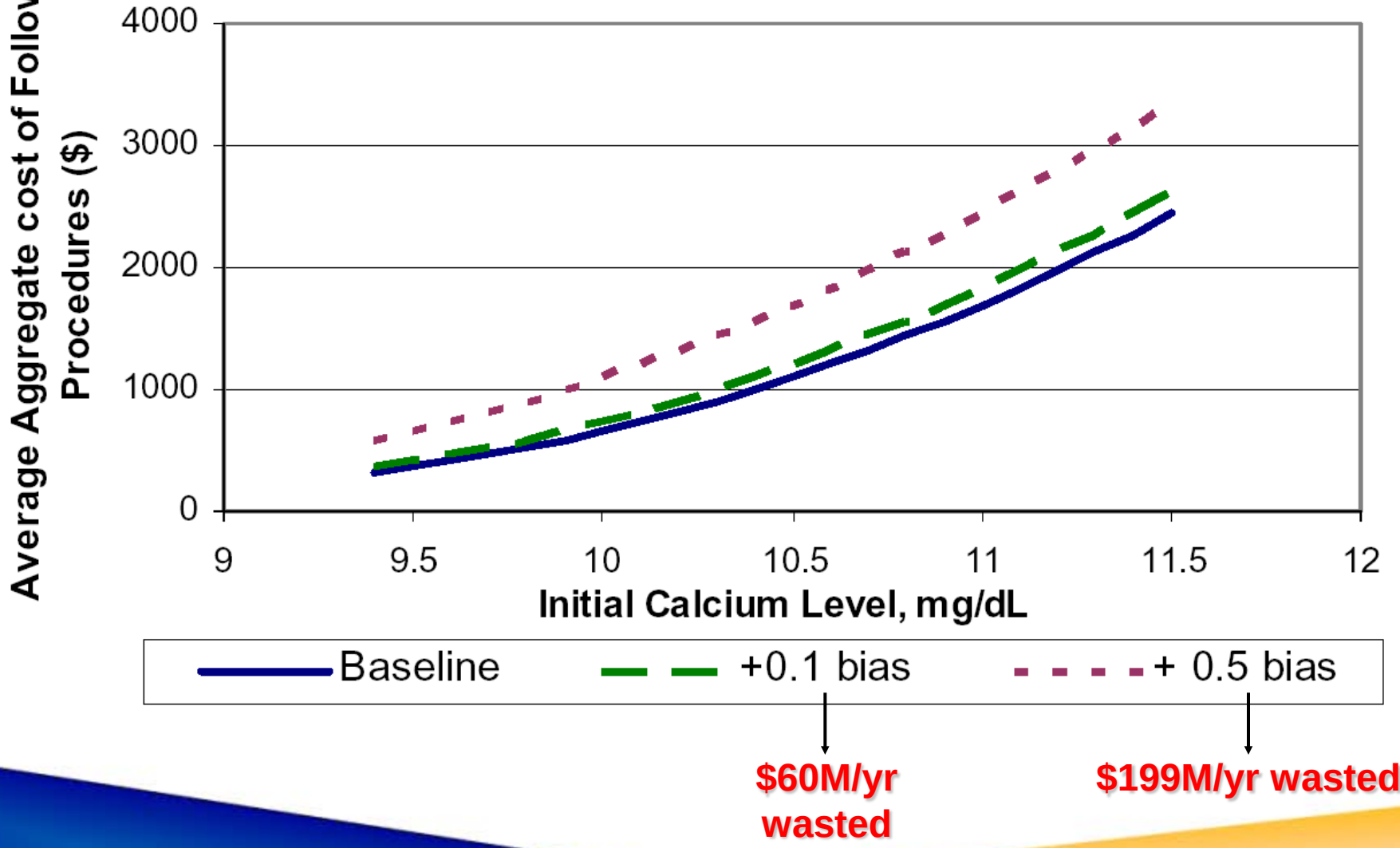
Diagnostic Sensitivity = TP/(TP + FN)
Diagnostic Specificity = TN/(TN + FP)

Positive Predictive Value (PPV) = TP/(TP + FP)
Negative Predictive Value (NPV) = TN/(TN + FN)

Disease frequency ($AUC_{diseased}/AUC_{non\text{-}diseased}$) affects PPV and NPV

Impact of test accuracy (bias shifts and imprecision skews and broadens curves)

Economic impact



Source: NIST Planning Report 04-1, 2004

In short: the lack of standardization may become an ethical issue

"Standardization of laboratory tests has an ethical dimension as it aims to affect the way diagnostic tests are used in order to guarantee optimal care for patients in a global world."

Analytical improvements are matter of patient safety and key to future

Bossuyt X et al., Ann Rheum Dis 2008;67:1061.

EU 98/79/EC-IVD Directive

What did IVD-MD Directive 98/79/EC mean to Clinical Laboratory Professionals, Clinicians, Patients?

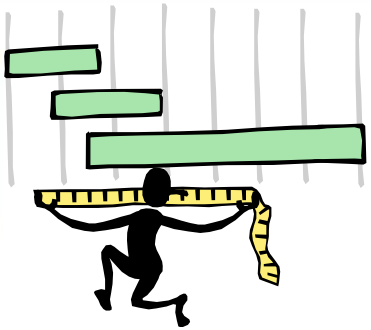
"To ensure that IVDs do not compromise the health and safety of patients, users and third parties and attain the performance levels attributed to them by their manufacturer. "

"The IVD-MD Directive is a call to improve comparability of measurement results through more structured and understood approaches for standardization."

Future EU regulatory framework

- Supervision of Notified Bodies
- Post-market safety and surveillance activities, with enhanced involvement of healthcare professionals and patients
- Transparency
  - Summary of safety and performance data
  - Traceability of devices
- Access to external expertise (scientific experts, reference laboratories)

European Commission



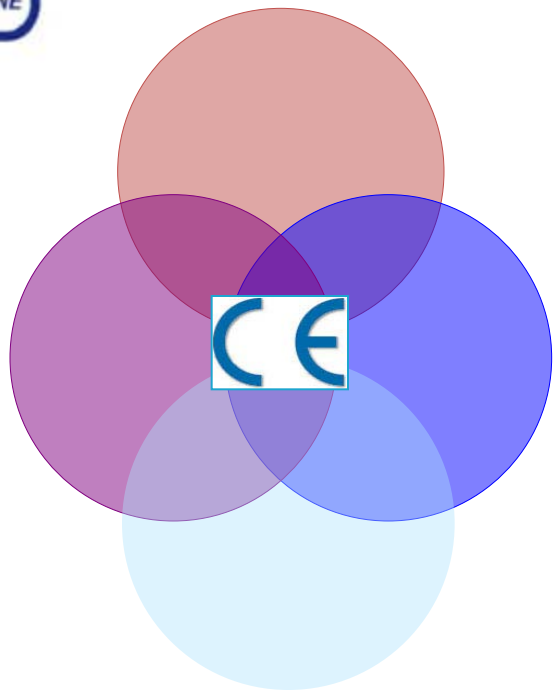
Basic requirements to establish traceability

- Establishment of a calibration hierarchy
- Establishment of the metrological traceability for the measurement results (understand the measurements)
- Elimination of measurement bias
- Adequate estimation of measurement uncertainties

Role of IVD manufacturers

IVD manufacturers should define a calibration hierarchy to assign traceable values to their system calibrators and to fulfil during this process uncertainty limits, which represent a proportion of the uncertainty budget allowed for clinical laboratory results.

Platform

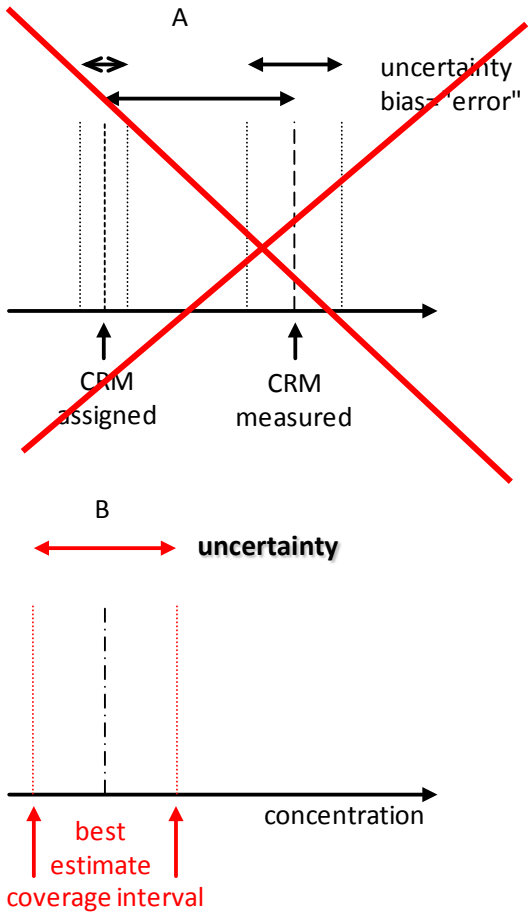


Reagents

Calibrators

Control material(s)

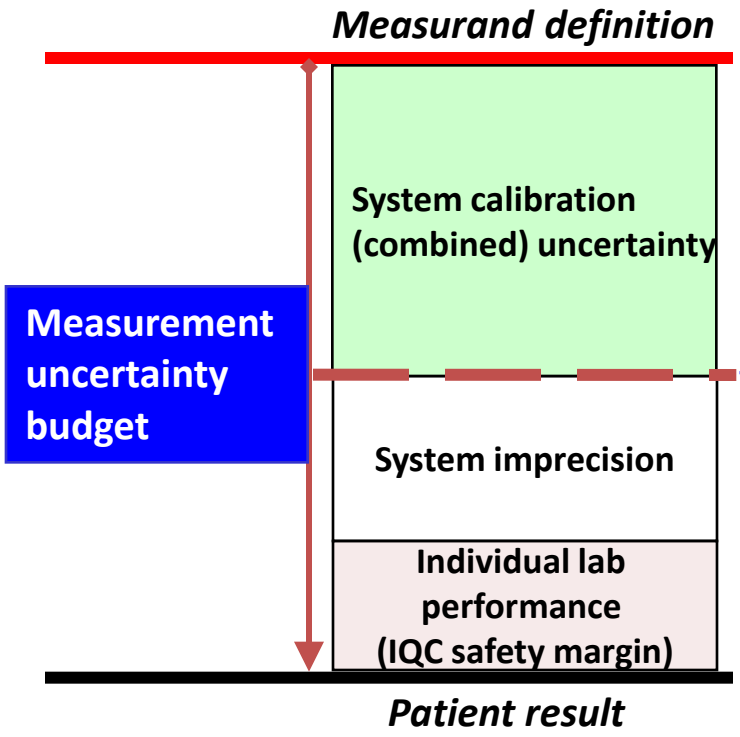
[Adapted from Braga F & Panteghini M, Clin Chim Acta 2014;432:55]



[Adapted from Kallner A, Scand J Clin & Lab Invest 2010; 70(Suppl 242): 34]

Thus, clinical laboratories need to rely on the manufacturers who must ensure traceability of their analytical system to the highest available level

Need to define criteria for manufacturers that can be achieved for their calibrators leaving enough uncertainty budget for the laboratories to produce clinically acceptable results.



→ **Allowable limit for the combined uncertainty of manufacturer's commercial calibrators @ 50% of the goals**

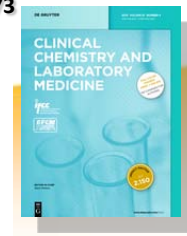
[note that these are goals for random variability, as at the calibrator level the systematic error (bias), in agreement with the metrological traceability theory, must be corrected if present in a non negligible amount]

Opinion Paper

Clin Chem Lab Med 2013; 51:973

Renze Bais*, Dave Armbruster, Rob T. P. Jansen, George Klee, Mauro Panteghini, Joseph Passarelli and Ken A. Sikaris on behalf of the IFCC Working Group on Allowable Error for Traceable Results (WG-AETR)

Defining acceptable limits for the metrological traceability of specific measurands



Opinion Paper

Federica Braga*, Ilenia Infusino and Mauro Panteghini

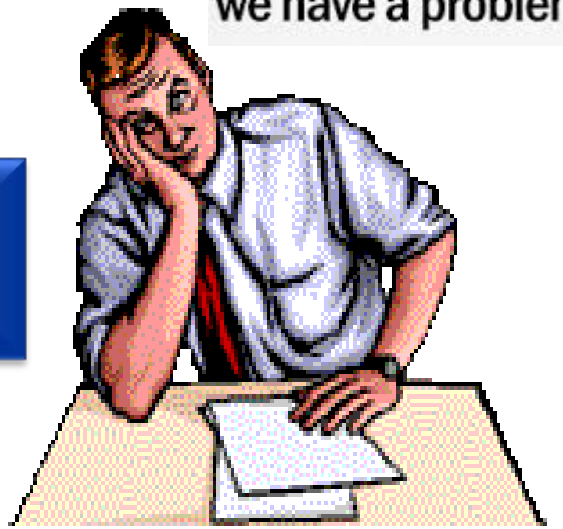
Performance criteria for combined uncertainty budget in the implementation of metrological traceability

Table 2: The information that in vitro diagnostics manufacturers should provide to laboratory users about the implementation of metrological traceability of their commercial systems. Adapted from [7].

a) An indication of higher order references (materials and/or procedures) used to assign traceable values to calibrators;
b) Which internal calibration hierarchy has been applied by the manufacturer, and
c) A detailed description of each step;
d) The (expanded) combined uncertainty value of commercial calibrators, and
e) Which, if any, acceptable limits for uncertainty of calibrators were applied in the validation of the analytical system.

EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

Houston
we have a problem.



Currently, the full information about calibration is usually not available

Manufacturers only provide the name of higher order reference material or procedure to which the assay calibration is traceable, without any description of implementation steps and their corresponding uncertainty.

Clinica Chimica Acta 432 (2014) 55–61

Contents lists available at ScienceDirect

Clinica Chimica Acta

journal homepage: www.elsevier.com/locate/clinchim

Verification of in vitro medical diagnostics (IVD) metrological traceability: Responsibilities and strategies

Federica Braga *, Mauro Panteghini

Centre for Metrological Traceability in Laboratory Medicine (CIRME), University of Milan, Milan, Italy

Table 1

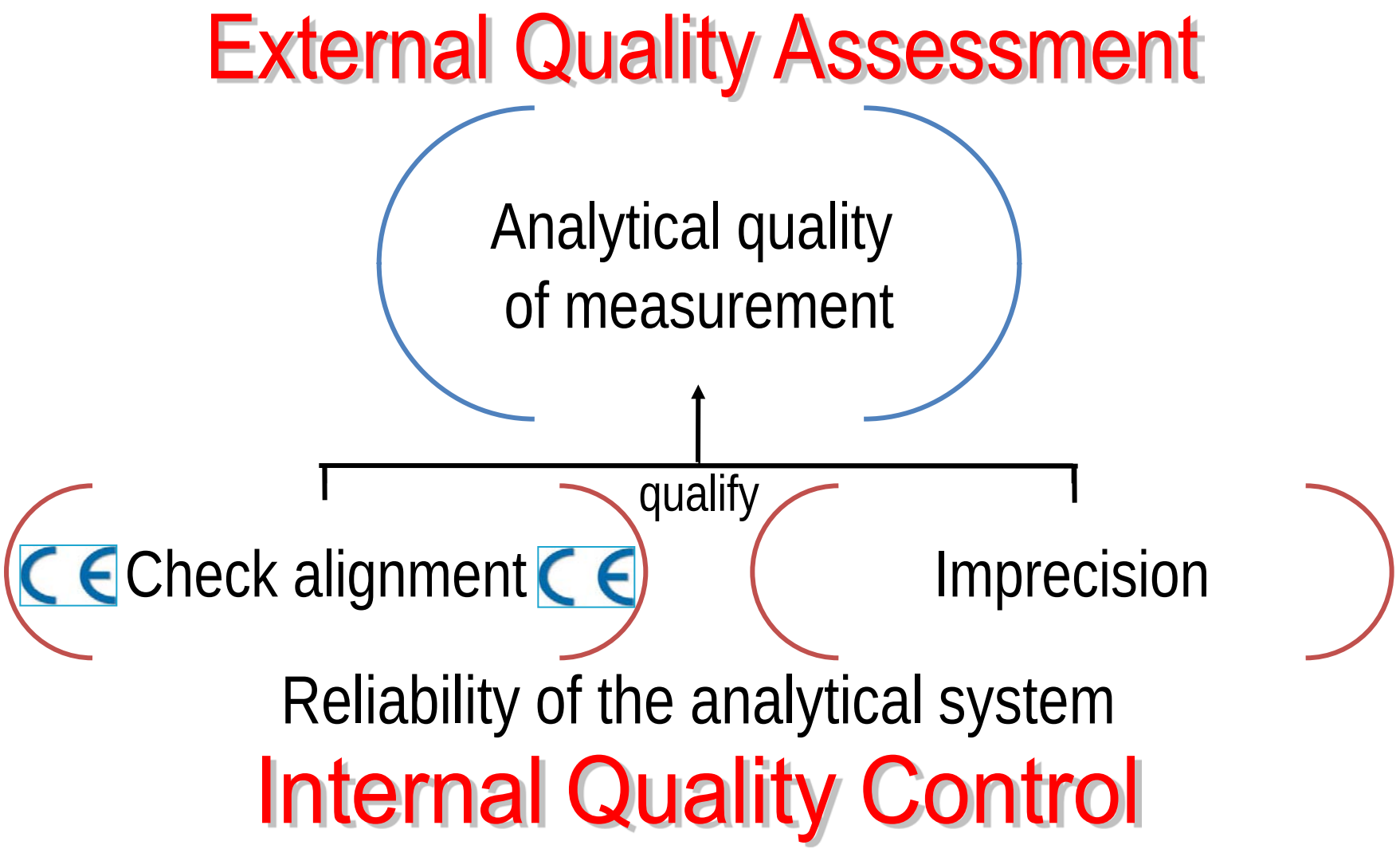
Metrological traceability and uncertainty information derived from calibrator package inserts of commercial systems measuring blood glucose marketed by four IVD companies.

Company	Platform	Principle of commercial method	Calibrator	Declared standard uncertainty[a]	Higher-order reference employed		Type of traceability chain used[b]	Combined standard uncertainty associated with the used chain[c]
					Method	Material		
Abbott	Architect	ND	Multiconstituent calibrator	2.70%	IDMS	NIST SRM 965	A	1.22-1.45%[d]
Beckman	AU	Hexokinase	System calibrator	ND	ND	NIST SRM 965	A	1.22-1.45%[d]
	Synchron	Hexokinase	Synchron multicalibrator	ND	ND	NIST SRM 917a	D	1.60-3.00%[e]
Roche	Cobas c	Hexokinase	C.f.a.s.	0.84%	IDMS	ND	B	1.70%
	Integra	Hexokinase	C.f.a.s.	0.62%	IDMS	ND	B	1.70%
	Modular	Hexokinase	C.f.a.s.	0.84%	IDMS	ND	B	1.70%
		GOD		0.84%	IDMS	ND	B	1.70%
Siemens	Advia	Hexokinase	Chemistry calibrator	1.30%	Hexokinase	NIST SRM 917a	C	1.88-3.26%[f]
		GOD		0.80%	Hexokinase	NIST SRM 917a	C	1.88-3.26%[f]

The role of the Laboratory Profession: “check”

- Availability and quality of information about IVD metrological traceability and uncertainty
- Daily surveillance of IVD system traceability

Analytical Quality Control in the Traceability Era



Panteghini M, Clin Chem Lab Med 2010;48:7
Braga F & Panteghini M, Clin Chim Acta 2014;432:55

Requirements for the applicability of EQAS results in the evaluation of the performance of participating laboratories in terms of traceability of their measurements

Feature	Aim
EQAS materials value-assigned with reference procedures by an accredited ref. laboratory	To check traceability of commercial system to reference systems
Proved commutability of EQAS materials	To allow transferability of participating laboratory performance to the measurement of patient samples
Definition and use of the clinically allowable measurement error	To verify the suitability of laboratory measurements in clinical setting

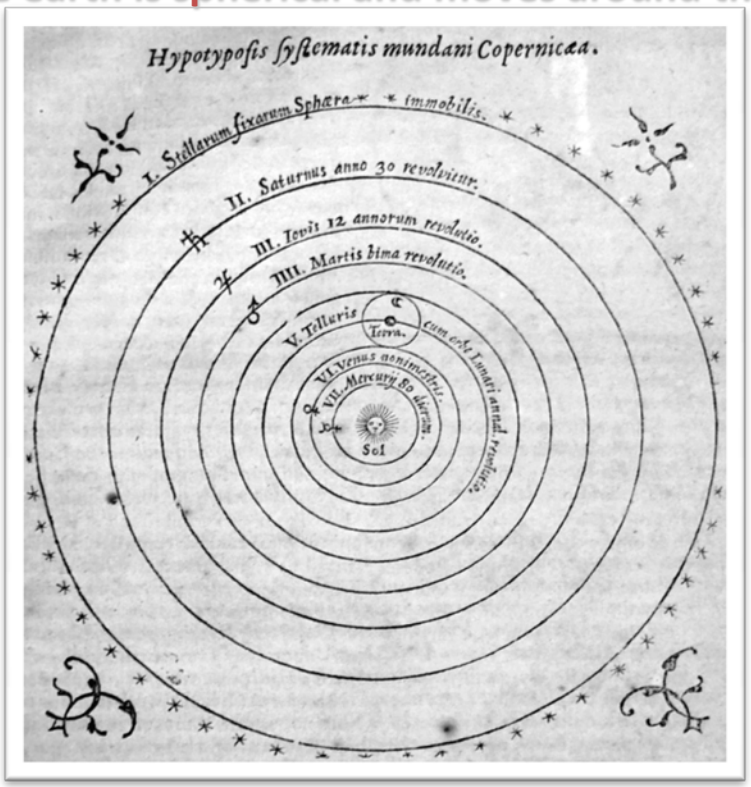
Panteghini M, CCLM 2010;48:7
Infusino I et al., CCLM 2010;48:301
Braga F & Panteghini M. CCLM 2013;51:1719
Braga F & Panteghini M, Clin Chim Acta 2014;432:55

What COPERNICUS did was take the existing ‘a priori’ concept of the world and pose an alternative ‘a priori’ concept

The earth is flat and fixed in space

Equivalency-based grading

The earth is spherical and moves around the sun



Trueness-based grading

What TRACEABILITY does is take the existing ‘a priori’ concept of the Quality Control and pose an alternative ‘a priori’ concept

Unique benefits of EQAS meeting metrological criteria

- Giving objective information about quality of individual laboratory performance
- Creating evidence about intrinsic standardization status/ equivalence of the examined assays
- Serving as management tool for the laboratory and IVD manufacturers, forcing them to investigate and eventually fix the identified problem
- Helping manufacturers that produce superior products and systems to demonstrate the superiority of those products
- Identifying analytes that need improved harmonization and stimulating and sustaining standardization initiatives that are needed to support clinical practice guidelines
- Abandonment by users (and consequently by industry) of nonspecific methods and/or of assays with demonstrated insufficient quality

Steps of the process and different responsibilities in implementing traceability of patient results and defining their uncertainty

Profession
(e.g., JCTLM, IFCC, EFLM):

Define analytical objectives: reference measurement systems (traceability chain) and associated clinically acceptable uncertainty (fitness for purpose)

Diagnostic manufacturers:

Implement suitable analytical systems (platform, reagents, calibrators, controls) fulfilling the above established goals

End users (clinical laboratories):

Survey assay and laboratory performance through IQC and EQA redesigned to meet metrological criteria

Adapted from Panteghini M, Clin Chem Lab Med 2010;48:7.

Sverre Sandberg*, Callum G. Fraser, Andrea Rita Horvath, Rob Jansen, Graham Jones, Wytze Oosterhuis, Per Hyltoft Petersen, Heinz Schimmel, Ken Sikaris and Mauro Panteghini

Defining analytical performance specifications: Consensus Statement from the 1st Strategic Conference of the European Federation of Clinical Chemistry and Laboratory Medicine

Model 1: Based on the effect of analytical performance on clinical outcomes

a. Done by direct outcome studies – investigating the impact of analytical performance of the test on clinical outcomes;

b. Done by indirect outcome studies – investigating the impact of analytical performance of the test on clinical classifications or decisions and thereby on the probability of patient outcomes, e.g., by simulation or decision analysis.

Model 2: Based on components of biological variation of the measurand.

Model 3: Based on state of the art of the measurement (i.e., the highest level of analytical performance technically achievable).

Hierarchical Levels of Laboratory-Related Patient Outcomes

1. The performance of the test in actual practice (analytical validity)
2. The predictive value of the test (clinical validity)
3. The probability of a change in health status of the patient based on the test result (clinical utility)

Adapted from DM Eddy, 1997

When is evaluating diagnostic accuracy (clinical validity) alone adequate?

- *Accuracy studies suffice if a new diagnostic test is safer (or cheaper) or more specific than, but of similar sensitivity to, an old test → less false positive*
- If a new test is more sensitive (where specificity, harms and costs are the same) than an old test, it leads to the detection of extra cases of disease. In this case, it needs to wait for results from randomized trials assessing treatment efficacy in cases detected by the new diagnostic test, unless that the new test detects the same spectrum and subtype of disease as the old test.

Lord SJ et al. Ann Intern Med. 2006;144:850.

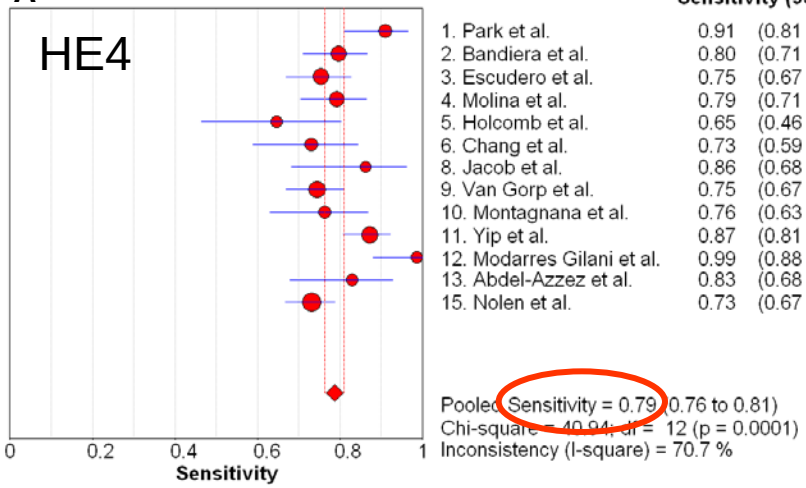
Review

Serum human epididymis protein 4 vs carbohydrate antigen 125 for ovarian cancer diagnosis: a systematic review

Simona Ferraro,[1] Federica Braga,[1] Monica Lanzoni,[2,3] Patrizia Boracchi,[2,3] Elia Mario Biganzoli,[2,3] Mauro Panteghini[1]

J Clin Pathol 2013;66:273.

A



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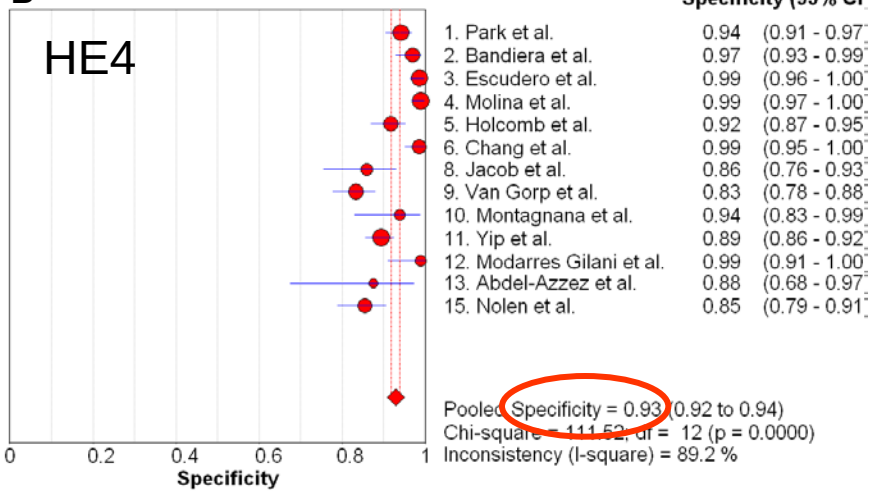

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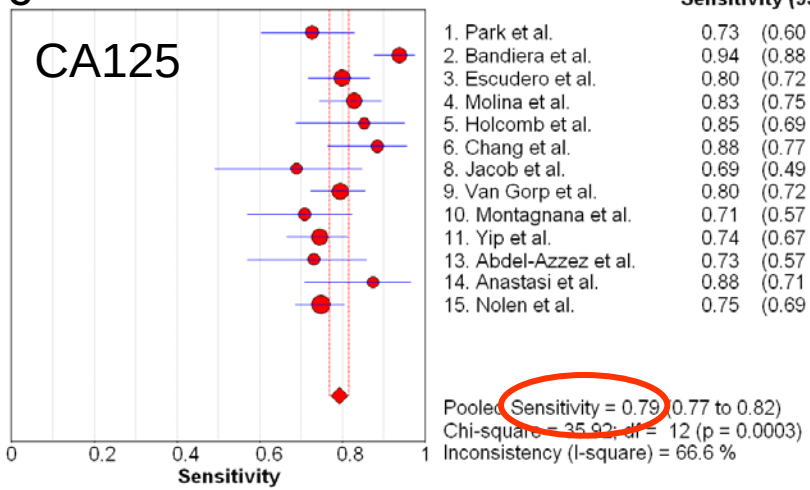

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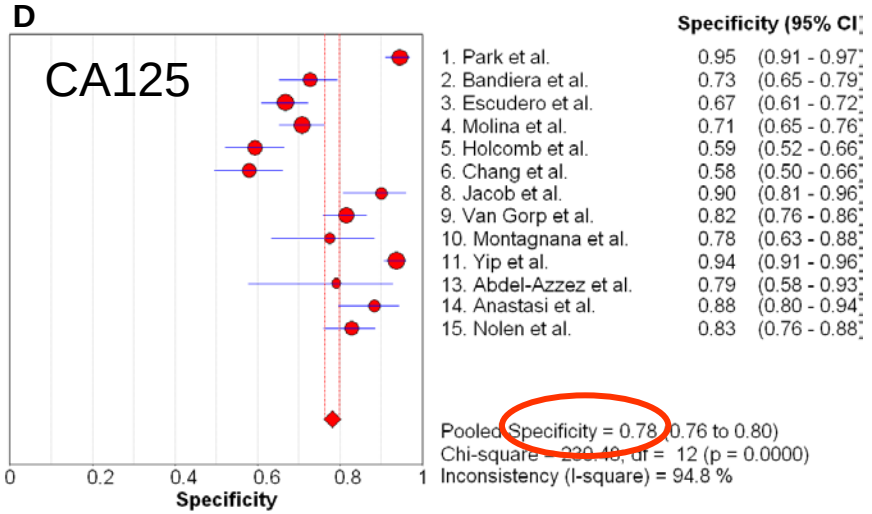


Diagnostic or prognostic accuracy and classification of the condition are not 'true' health outcomes

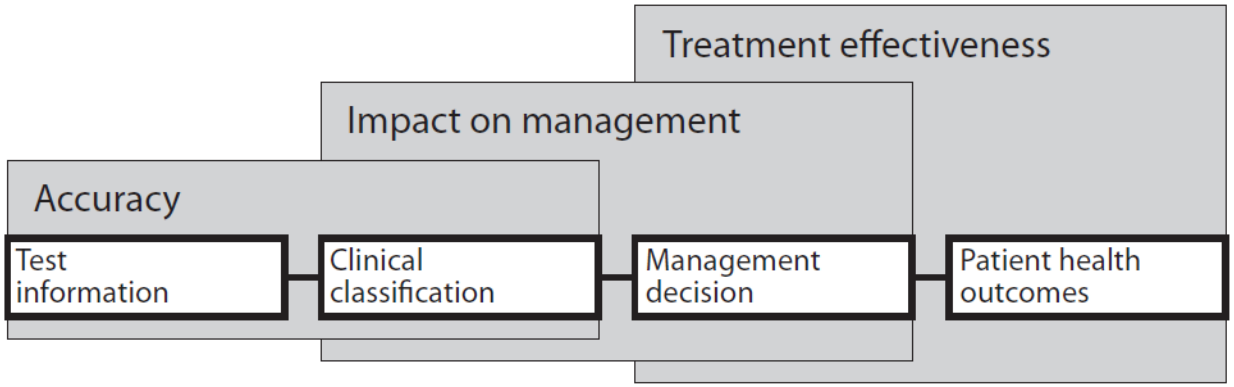


Figure 1 Test-treatment pathway showing Accuracy, Impact on management and Treatment effectiveness as determinants of health outcomes. Adapted from Staub et al. [9]

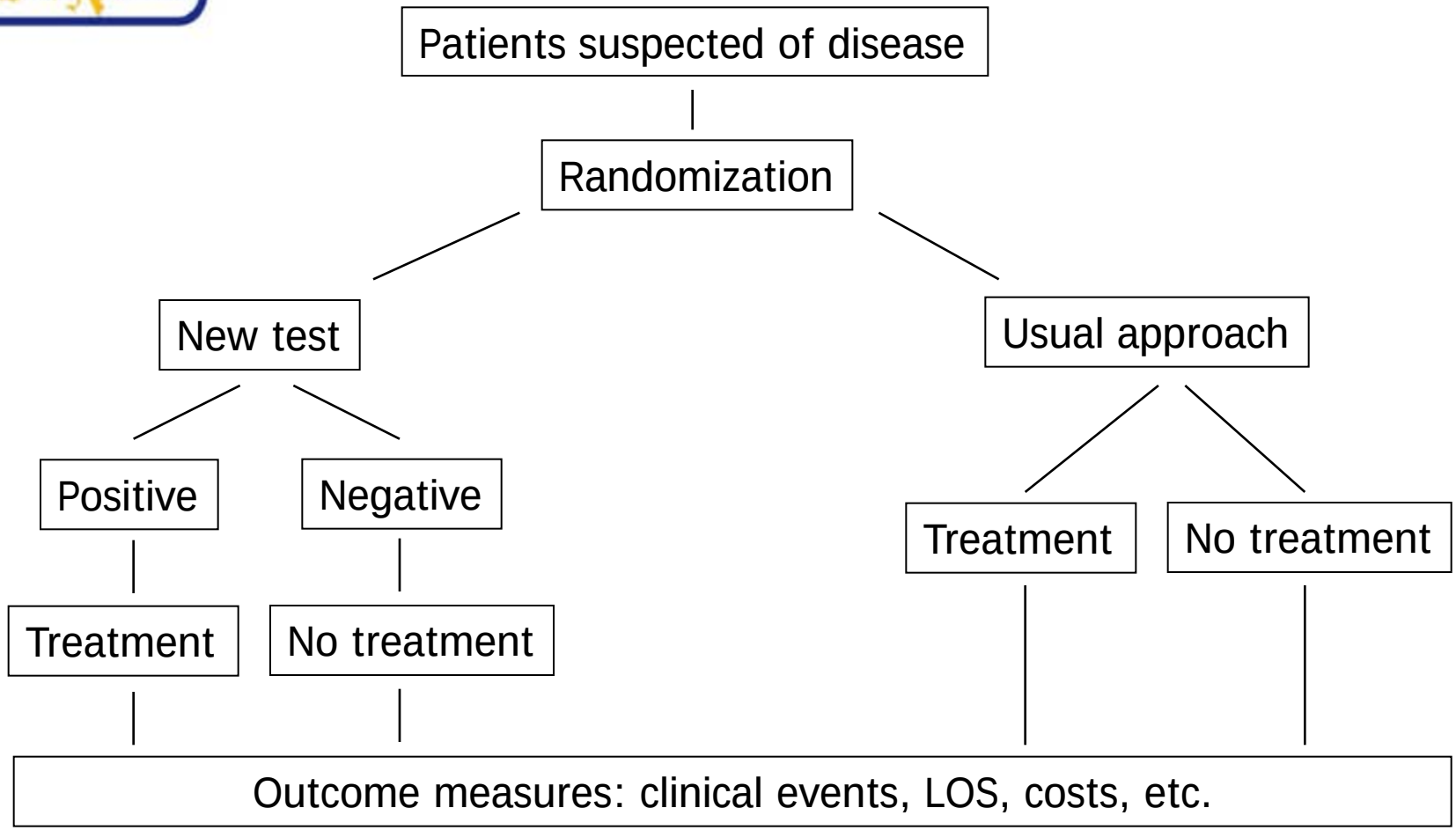
- Studies of diagnostic accuracy ask:

  "Does the result of the test predict an outcome of interest (e.g. disease diagnosis)?"
- Health outcome studies ask:

  "Is the use of the test associated with improved patient outcomes?"

"The value of a diagnostic test is not only measured by its accuracy, but ultimately depends on how it affects patient health."

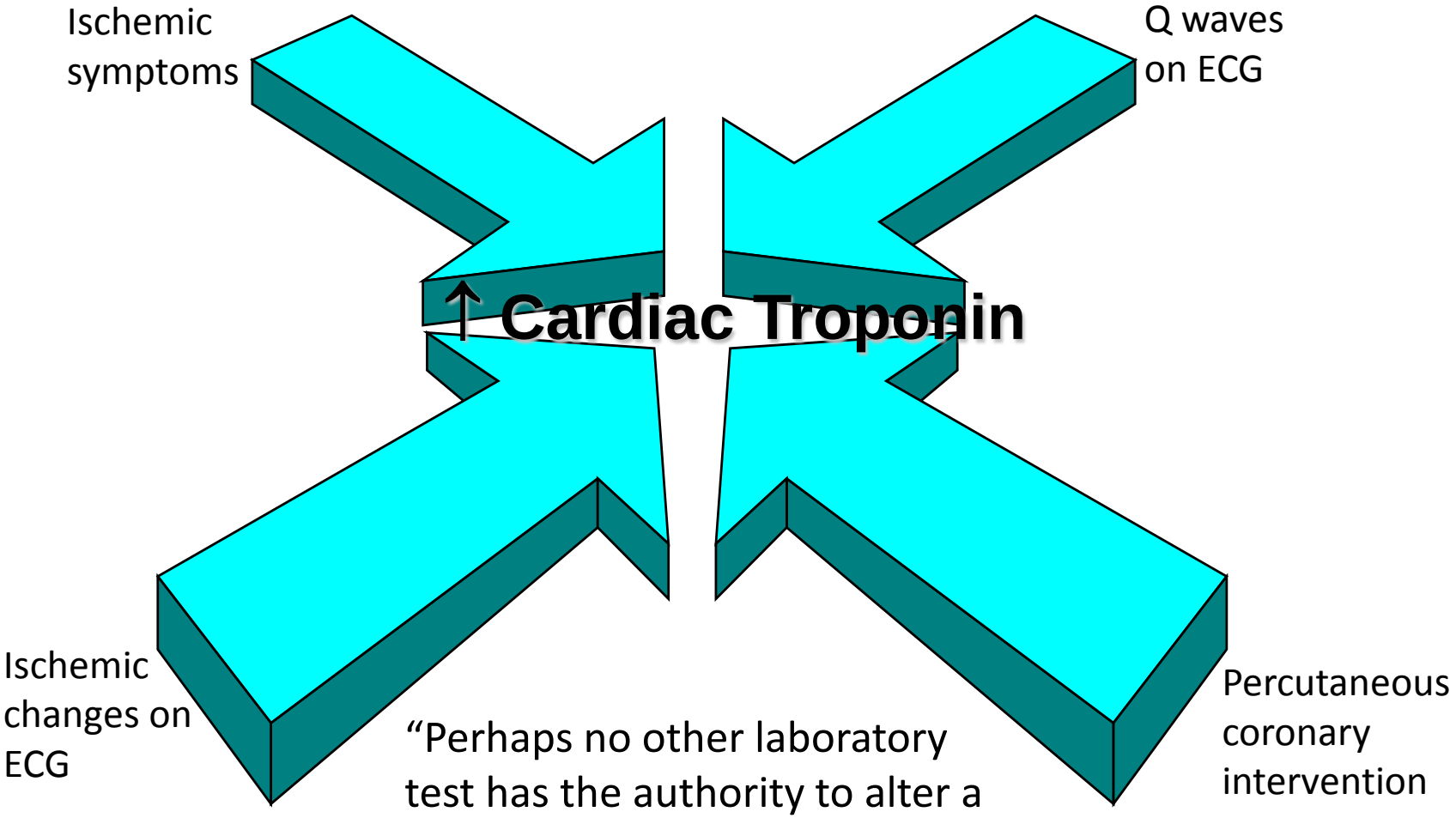
Cost-effectiveness trial



Do patients who undergo the new test fare better (in terms of health outcomes) than those who have the old test?

Panteghini M. Scand J Clin & Lab Investig 2010;70(Suppl 242):66.

New millennium criteria for acute, evolving or recent MI



"Perhaps no other laboratory test has the authority to alter a patient's clinical course and cost of care so broadly." *SW Sharkey*

Dolci A & Panteghini M, CCA 369 (2006) 179.

Troponin role in altering patient management and enabling earlier discharge from a UK district general hospital

Unstable angina pts	Median length of stay	Median cost
Test group	4 days	£ 910
Control group	5 days	£ 1125
Non-ischemic chest pain pts		
Test group	2 days	£ 235
Control group	9 days	£ 1125

"Control" indicates use of the traditional enzymatic approach.

"Test" indicates use of cardiac troponin protocol.

Owen A et al., Ann Clin Biochem 2001.

Impact of troponin introduction on an US hospital resource utilization and costs

Acute coronary syndrome pts	Length of stay	Charges
Troponin group	3.7 days	$ 15,000
CK-MB control group	4.6 days	$ 19,200
Non-ACS pts		
Troponin group	1.2 days	$ 4,487
CK-MB control group	1.6 days	$ 6,187

Zarich S et al., Am J Cardiol 2001.

Impact of troponin on diagnostic classification of patients with suspected acute coronary syndrome

5% of all admissions, who were diagnosed as non-Q wave MI using WHO criteria, were found to have normal troponin values and to have been incorrectly classified as myocardial infarction.

"We would estimate the potential annual drug cost for treatment of these patients to be approximately £ 56,000. The 10-year estimated cost would therefore be close to £ 0.5 million in wasted resources."

Collinson PO et al., Ann Clin Biochem 2003.

Removal from the test menu of obsolete and useless tests

- Removing tests that offer little incremental information would save money, avoid additional investigations arising from incidental and clinically irrelevant abnormalities, and improve the risk to benefit ratio.

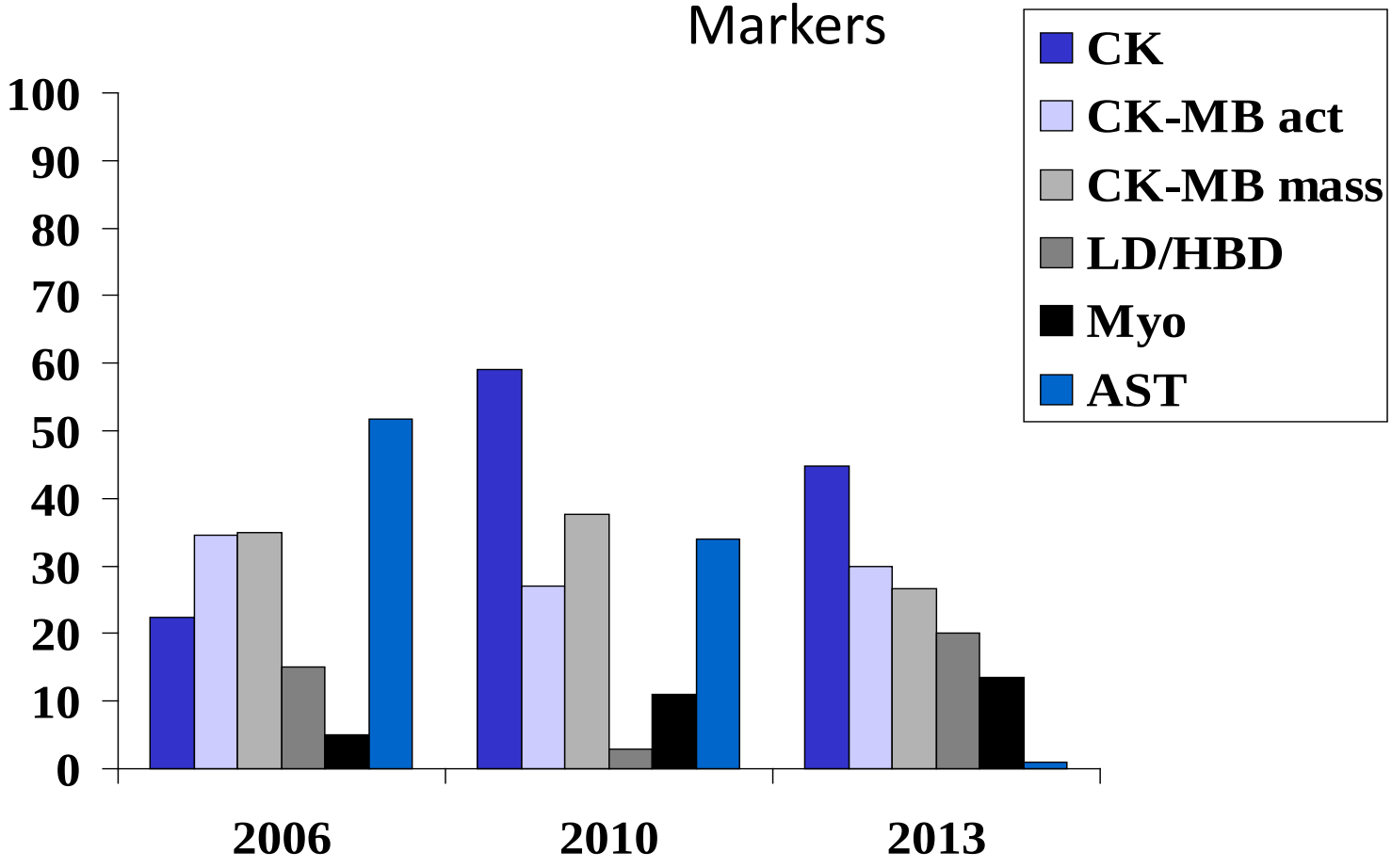
Plebani M & Panteghini M, Clin Chim Acta 2014;432:15

- For instance, deleting myoglobin, total creatine kinase (CK) and CK MB isoenzyme determinations from laboratory order forms in patients admitted to ED leads to significant cost saving and reduces possible confusion in data interpretation and patient management → Overall testing costs were reduced by € 104,871 per annum.

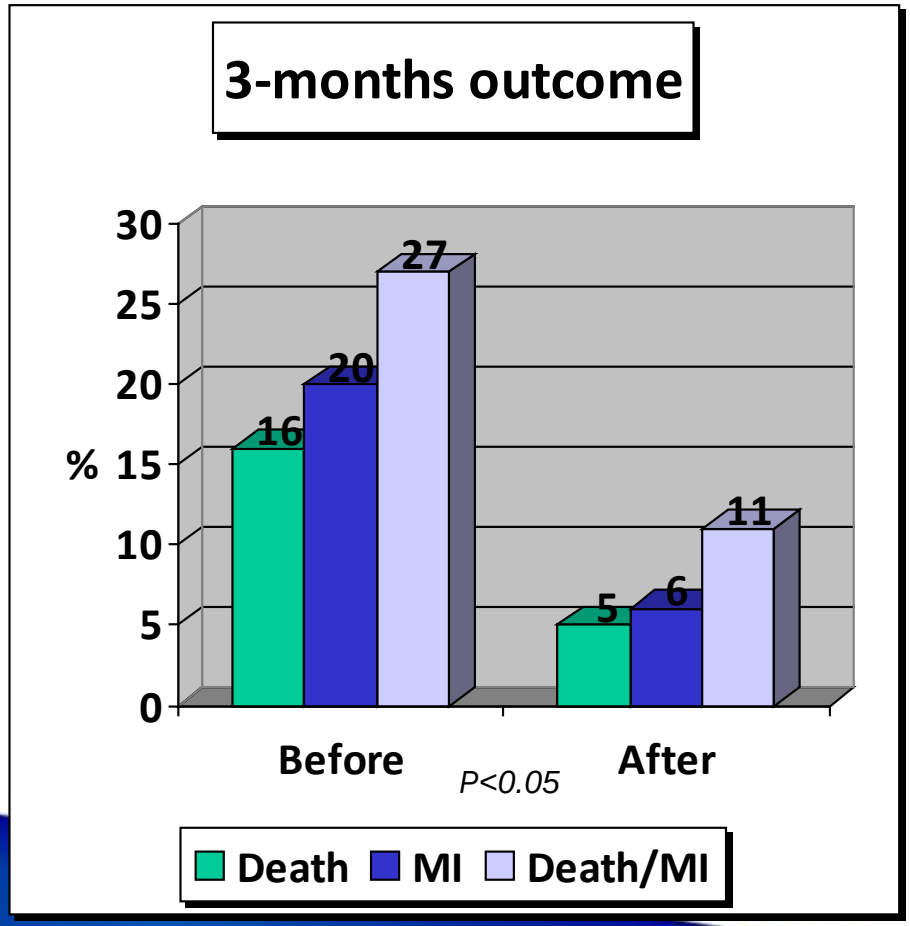
Dominici R et al, Clin Chem Lab Med 2007;45:S229

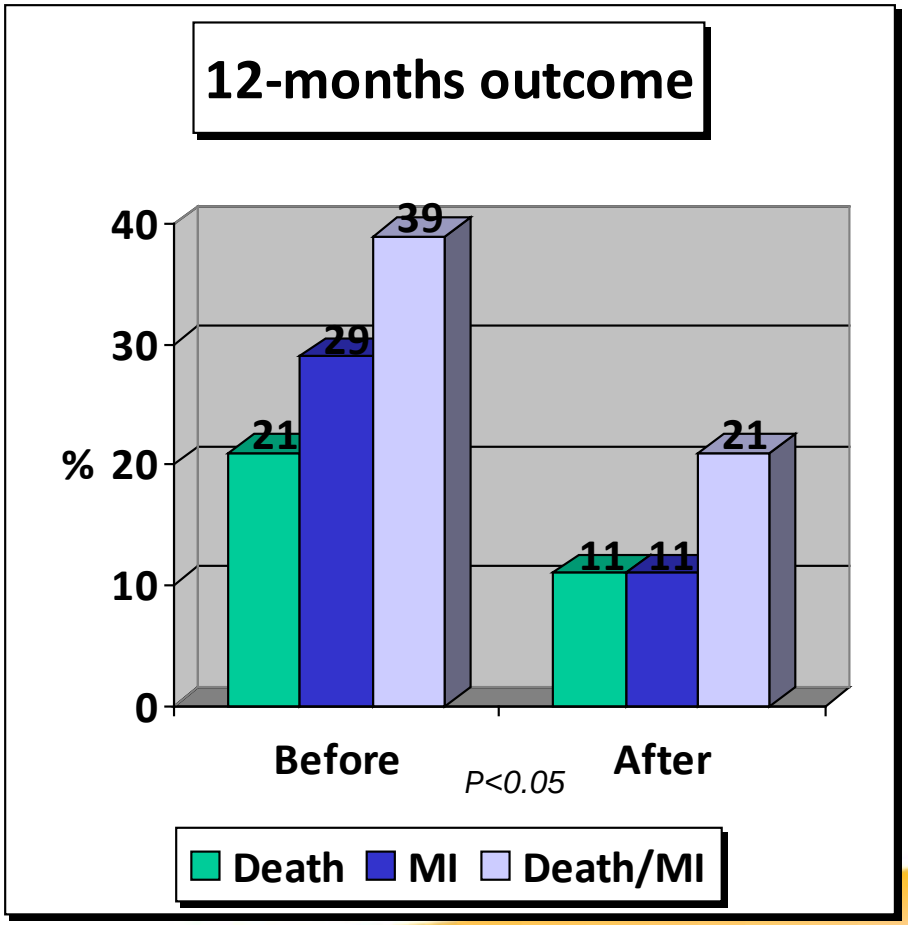
Markers still used for the diagnosis of AMI in addition to troponin

The Cardiac Marker Guideline Uptake in Europe (CARMAGUE) Study of the EFLM WG Cardiac Markers



Clinical outcomes of patients with only hs troponin positive before and after the introduction of a sensitive troponin assay





Mills NL et al, JAMA 2011;305:1210.

ORIGINAL ARTICLE

Cost-effectiveness of presentation versus delayed troponin testing for acute myocardial infarction

Praveen Thokala,[1] Steve W Goodacre,[1] Paul O Collinson,[2] John W Stevens,[1] Nicholas L Mills,[3] David E Newby,[3] Francis Morris,[4] Jason Kendall,[5] Matt D Stevenson[1]

Heart 2012;98:1498.

	Total costs (£)	Total quality-adjusted life years (QALYs)	Incremental cost-effectiveness ratio or cost per QALY gained
No testing (hypothetical)	965,994	26,227	–
hs-TnT 3h testing	1,806,910	26,379	£ 7487/QALY
TnT 10h testing	2,016,540	26,386	£ 27,546/QALY

Biomarker measurement: issues to keep in mind when evaluating clinical studies

- Often the analytical characteristics of the assays are not adequately described
- We need to know how the samples need to be collected and/or preserved for accurate measurements
- We need to know the stability of the samples over time (use of archived samples)
- Populations studied are often convenience populations for initial studies (need of confirmation in unselected populations)
- Publication bias

Adapted from Apple FS et al, Clin Chem 2005;51:810.

DE GRUYTER DOI 10.1515/cclm-2012-0574 — Clin Chem Lab Med 2013; 51(6): 1217–1226

Kristin M. Aakre*, Michel R. Langlois, Joseph Watine, Julian H. Barth, Hannsjörg Baum, Paul Collinson, Païvi Laitinen and Wytze P. Oosterhuis

Critical review of laboratory investigations in clinical practice guidelines: proposals for the description of investigation

Topic	Laboratory medicine specialist involved	Laboratory medicine specialist not involved	p-Value of difference
Sample type	3/4	0/8	0.02
Sample transportation	2/4	0/8	0.09
Sample pre-treatment (maximum delay)	2/4	0/8	0.09
Analytical variation	3/4	1/8	0.07
Maximum storage time (at specified temperature)	2/4	0/8	0.09
Recommended to comment on reported results	2/4	0/8	0.09

Table 4 Number of guidelines that included information about a topic stratified according to involvement of laboratory medicine specialist in the development process (n=12).

The advantages of including laboratorians early-on in studies and guidelines preparation are clear!

EFLM EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

DE GRUYTER

Clin Chem Lab Med 2014; aop

Review

Simona Ferraro* and Mauro Panteghini

Laboratory medicine as the science that underpins medicine: the "high-sensitivity" troponin paradigm

Crucial to application of biomarkers is laboratorians' role in closely scrutinizing proposed assays and limiting their clinical use before the evidence for them is solid.

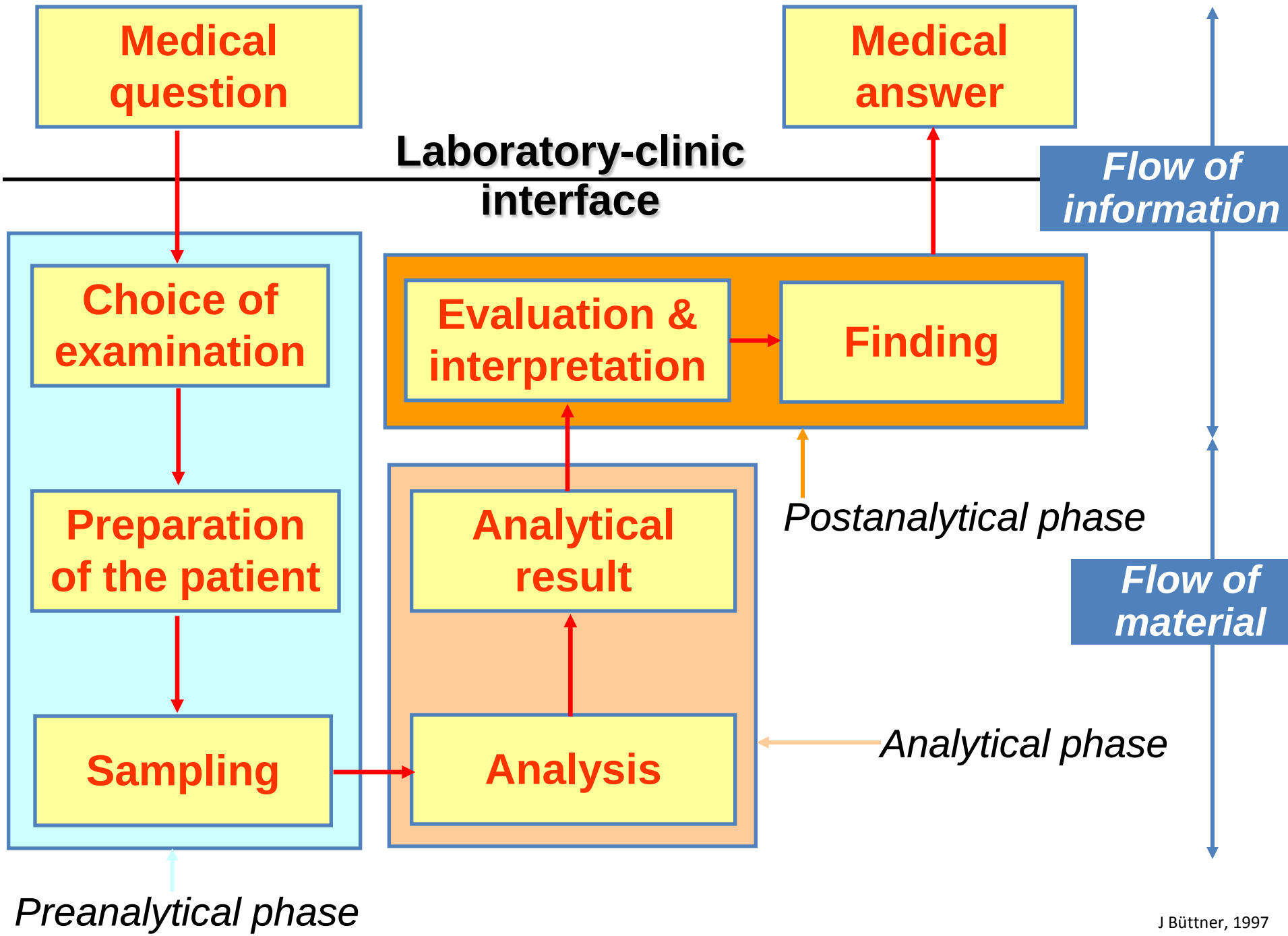
POCT: an issue of laboratory governance

- Any tensions that have existed between POCT programs and labs will ease in the future.
- We are much more realistic now that in certain situations POCT is a better way to go and in other cases it's better and cheaper to send the sample through the main lab. Laboratorians are better now at helping understand the balance of those two opposing forces.
- It’s quite clear that the trueness and precision of POCTs are probably not adequate for the some settings.
- More outcome-based research related to POCT is needed.

Lab-related causes of diagnostic error

- Inappropriate test ordered (20%)
- Appropriate test not ordered (45%)
- Appropriate test result inaccurate
- Appropriate test result not used properly
  - Knowledge deficit
  - Failure of synthesis (no results integration)
  - Misleading result (unaware of test limitations)
- Appropriate test result delayed/missed

Adapted from Epner PL et al. BMJ Qual Saf 2013;22:ii6
and Zhi M et al. PLoS ONE 2013;8:e78962.



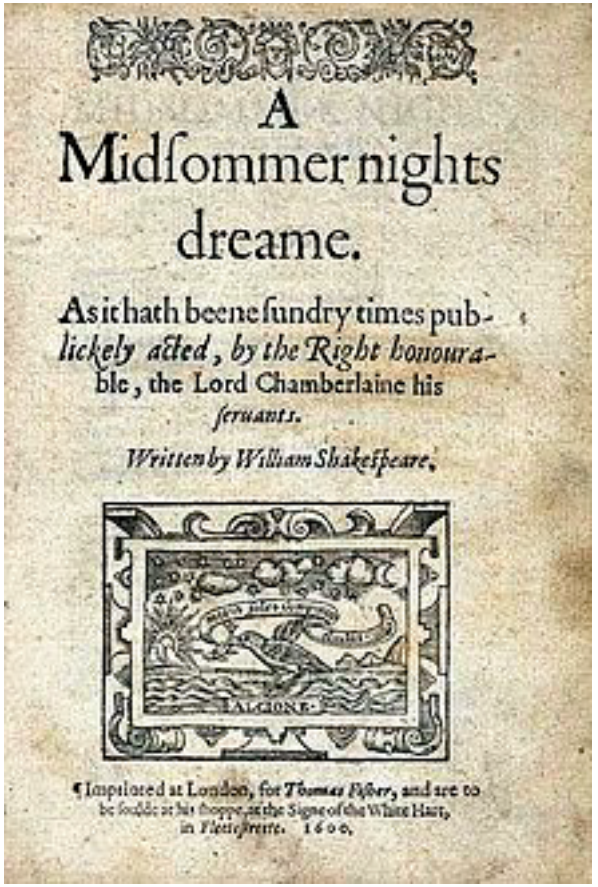
J Büttner, 1997

The Report

The product that underpins the effectiveness of the laboratory product

A synthesis of:

- data
- knowledge
- information


A
Midſommer nights
dreame.
As it hath beene ſundry times pub-
lickely acted, by the Right honoura-
ble, the Lord Chamberlaine his
ſeruants.
Written by William Shakeſpeare.
¶ Imprinted at London, for Thomas Fiſher, and are to
be ſolde at his ſhoppe, at the Signe of the White Hart,
in Fleetſtreete. 1600.

Challenges reported by US primary care physicians when using lab test results

	% of respondents reporting factor is very or extremely problematic
Receiving results	
Results not received in a timely manner	34
Previous results are not easily available	32
Errors in results are suspected	25
Results are inconsistent with patient's symptoms	24
Report format	
Lab-to-lab variation in normal range	22
Lab-to-lab variation in report formats	21
Lab report format is difficult to understand	18
Not enough information in lab report	16

Potentially affecting 13 million pts/yr, raising significant concerns about the safety and efficient use of lab tests

Hickner J et al, J Am Board Fam Med 2014;27:268.

→ To be interpreted results should be compared with:

– a population reference interval (transversal evaluation – biological level)

– a decision limit (transversal evaluation – nosological level)

Two fundamental issues drive improvement in defining and using reference intervals in clinical practice.

1) The ISO 15189:2012 clearly affirms that “biological reference intervals shall be periodically reviewed” and they should be verified every time a variation in analytical and/or pre-analytical procedures occurs.

2) There is the need to link the analytical standardization based on the principles of metrological traceability with the identification of appropriate reference intervals.

Plebani M, Lippi G. Clin Chem Lab Med 2012;50:761;
Panteghini M. Clin Chem Lab Med 2012;50:1237;
Plebani M, Panteghini M. Clinica Chimica Acta 432 (2014) 15.

Lack of proper reference intervals may hamper the implementation of standardization

- The implementation of standardization can modify the analyte results
- Without adequate R.I. this situation can impair the interpretation of the results and, paradoxically, worsen the patient's outcome
- The absence of reliable R.I. for the newly standardized commercial methods hampers their adoption

Ceriotti F, Hinzmann R, Panteghini M. Ann Clin Biochem 2009;46:8

Until today

Method-dependent results

↓

Method-dependent reference intervals

From today

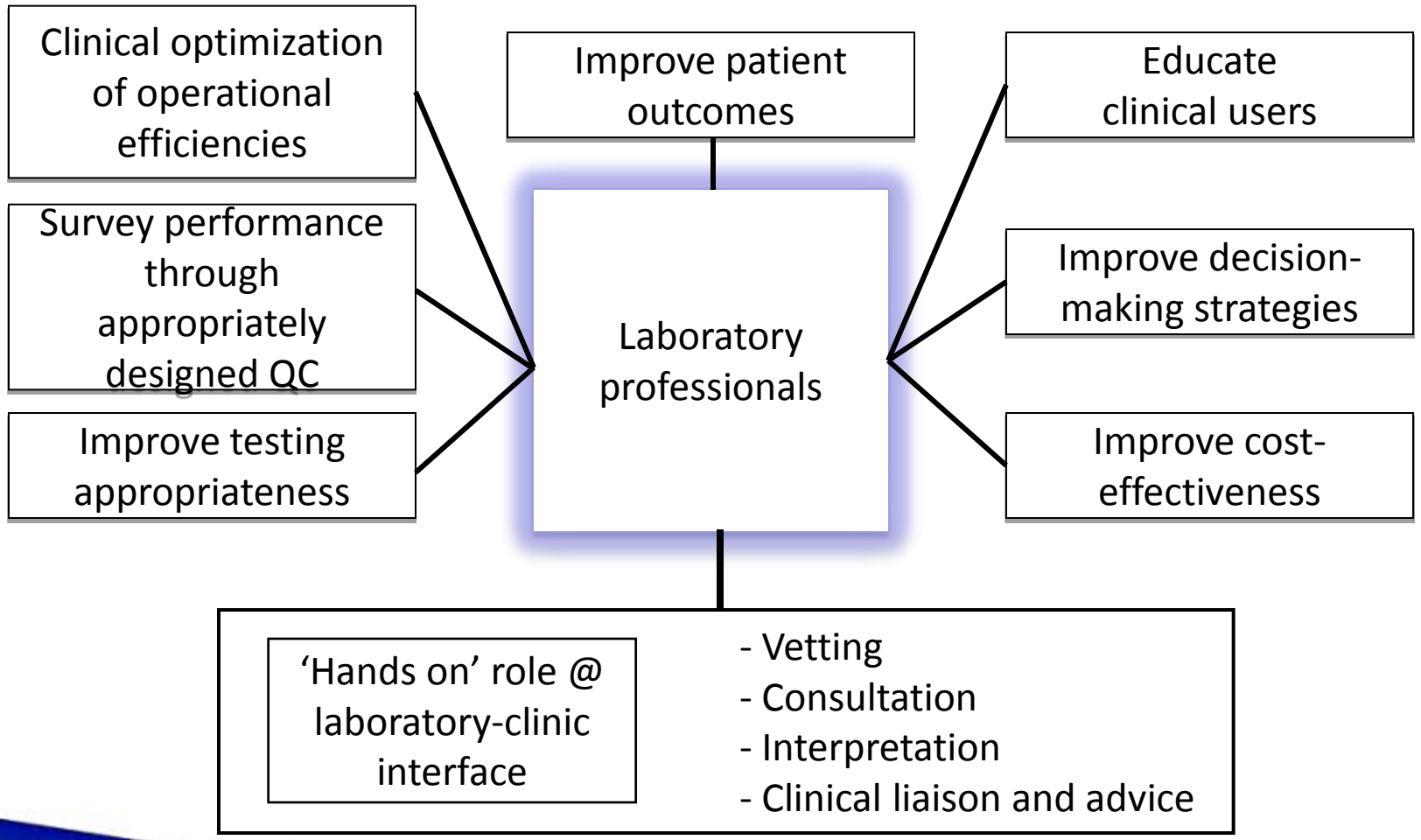
Standardized methods that provide traceable results

↓

Traceable reference intervals

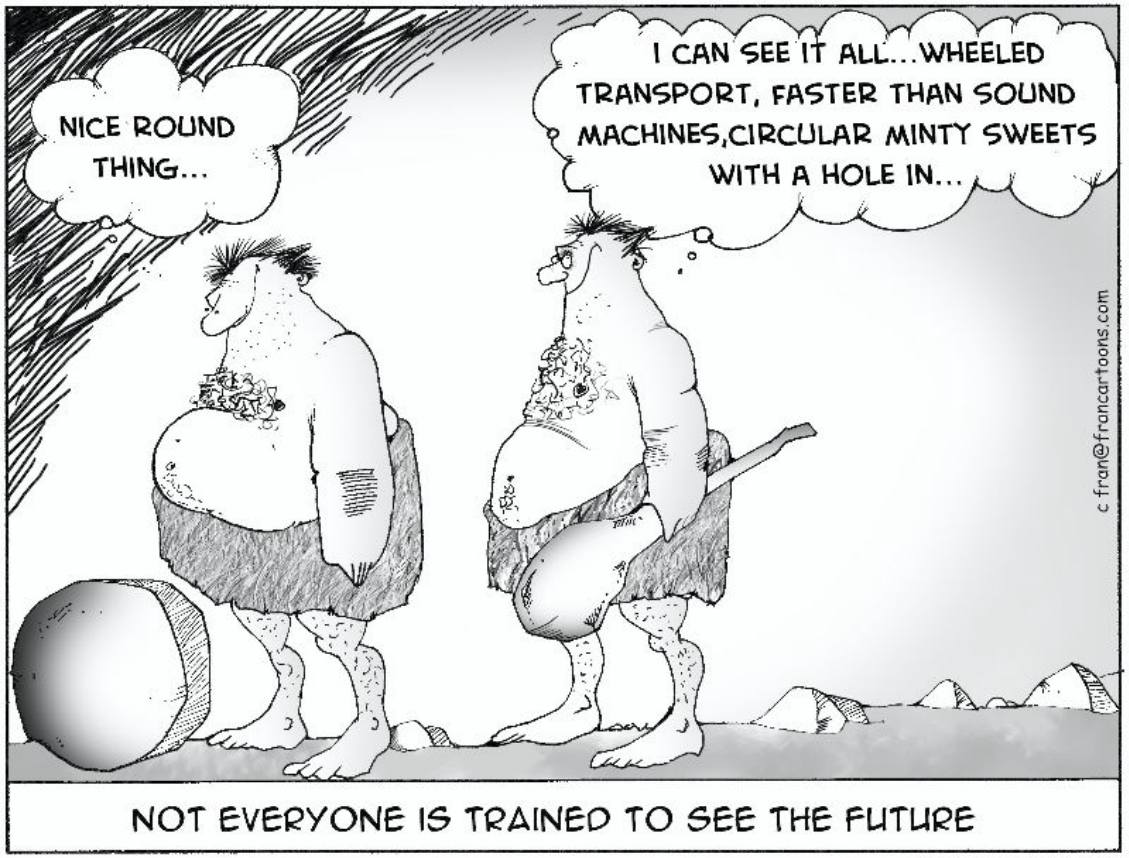
Infusino I et al. Clin Chem Lab Med 2010;48:301-7

Laboratory professionals can play a central role in improving clinical effectiveness



Challenges for the future

- To become relevant in the healthcare environment, laboratory professionals have to change their attitude from one of being introspective and defensive to one that is outward looking and innovative.
- By combining the talent of performing quality laboratory assays with knowledge of the pathophysiologic rationale behind the tests, laboratory professionals have the unique opportunity to use their expertise to advise their clinical colleagues in regard to the appropriate test selection and interpretation of laboratory results, and to create opportunities to define the value and the pivotal role of laboratory medicine by focusing on its overall impact in healthcare delivery.



Laboratorians can be assured of two certainties: change is inevitable and lab tests will continue to play a role in medicine. The question is: do you want to be proactive in changing or simply suffer it?