Harmonising EQA schemes the next frontier

Challenging the status quo

December 2019

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Abstract: Standardization of clinical laboratory test results has progressed through several stages. External quality assessment (EQA) identified that results were not equivalent in different laboratories in the 1950s.

Perspective

Pa

The standardization journey and the path ahead

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External quality assessment (EQA) can assess the need for harmonization of test results and monitor the success of procedures to achieve harmonization of clinical laboratory test results.

Figure 1 Timeline for key develo… …boratory results. AACC, American Association for Clinical Chemistry; CAP, C… …ase Control and Prevention; CRM, Certified Reference Material; EQA, extern… …nd Drug Administration; IFCC, International Federation for Clinical Chemistry and Laboratory Medicine; ISO, International Organization for Standardization; NBS, National Bureau of Standards; NRSCL, National Reference System for the Clinical Laboratory; RMP, reference measurement procedure; USA, United States of America.

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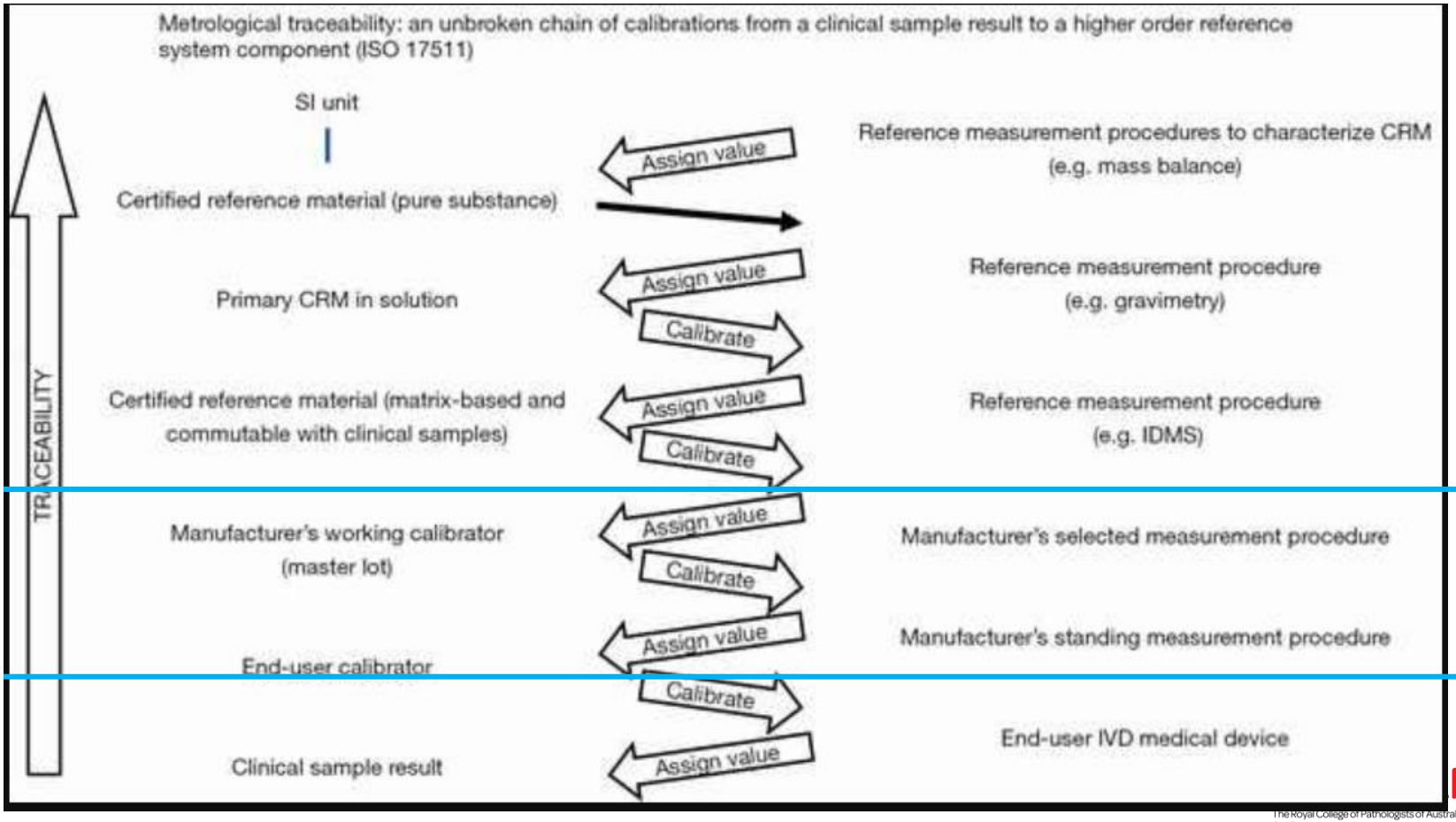
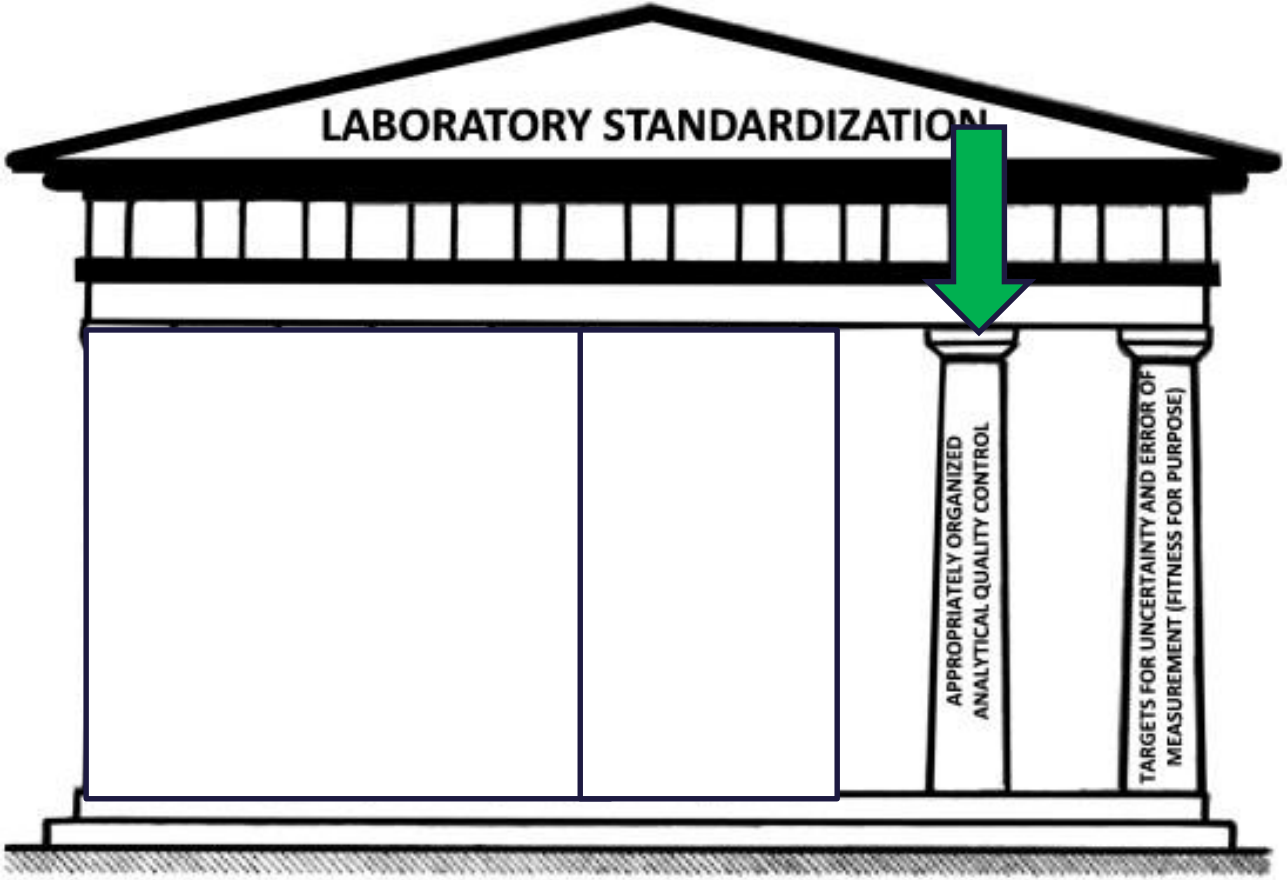
RESPONSIBILITY





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Review

Measurement uncertainty: Friend or foe?

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Clin Chem Lab Med 2010;48(1):7–10 © 2010 by Walter de Gruyter • Berlin • New York. DOI 10.1515/CCLM.2010.020

Editorial

Application of traceability concepts to analytical quality control may reconcile total error with uncertainty of measurement

Mauro Panteghini

of measurement values from the highest hierar

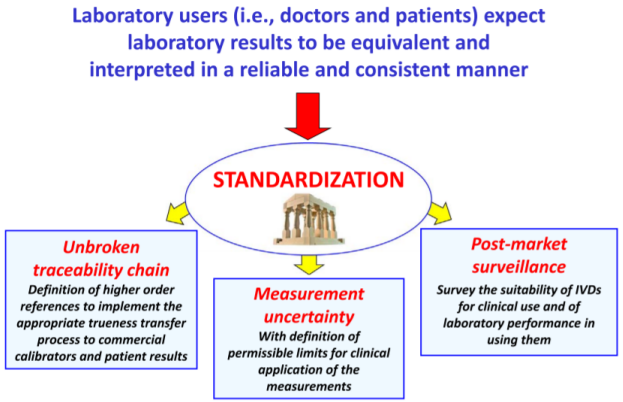

Fig. 2. Scheme describing the main components needed to produce standardized laboratory results. IVDs, in vitro diagnostics.

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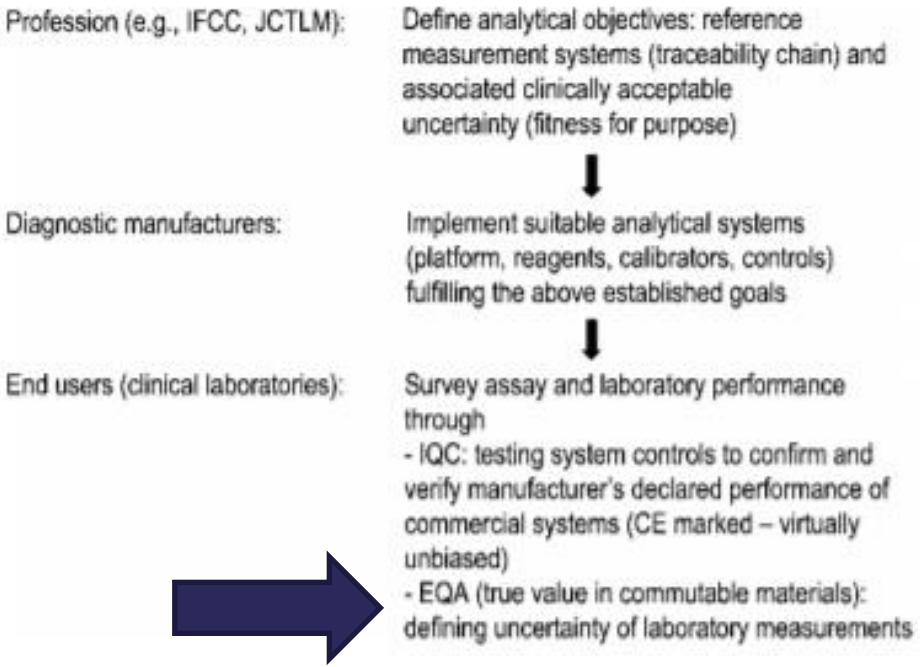

Figure 2 Steps of the process and different responsibilities for implementing traceability of patient results and defining their uncertainty.
IFCC, International Federation of Clinical Chemistry and Laboratory Medicine; JCTLM, Joint Committee on Traceability in Laboratory Medicine; IQC, Internal Quality Control; EQA, External Quality Assessment.

- Post

Table 1 M… …nce of individual la…

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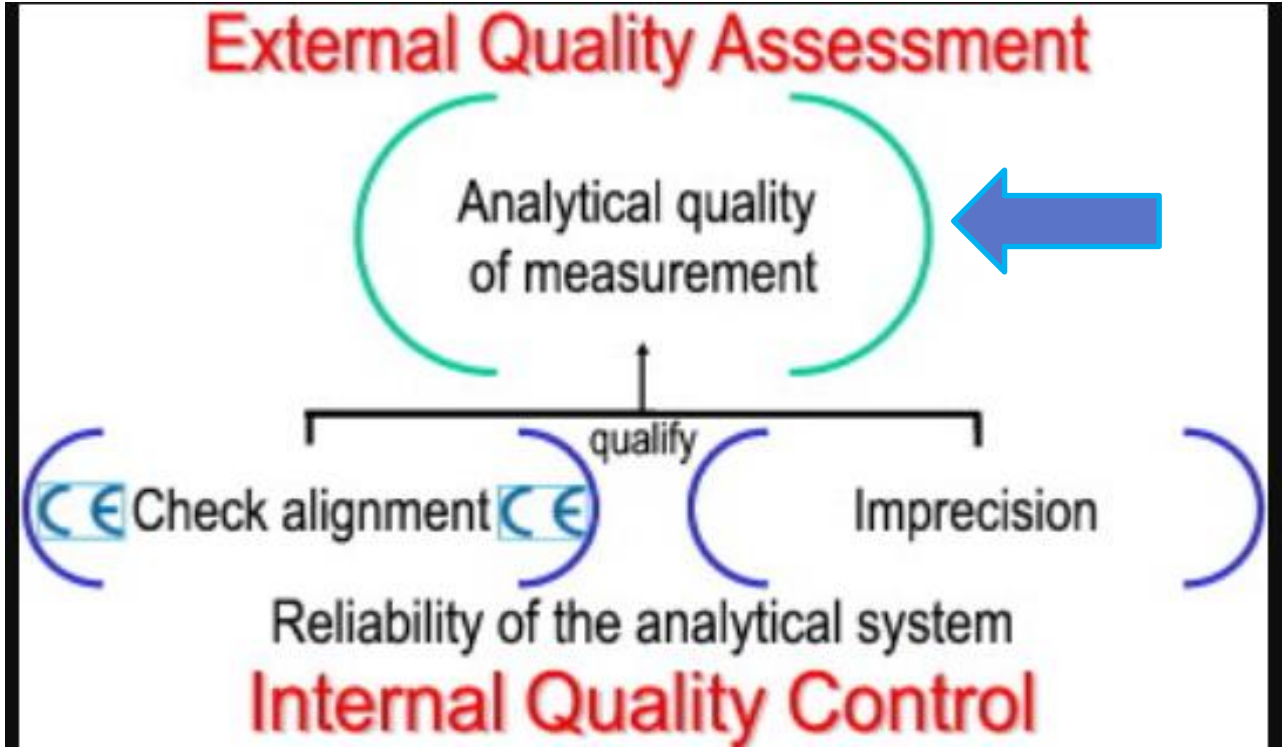

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Verification of in vitro medical diagnostics (IVD) metrological traceability: Responsibilities and strategies

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Clinica Chimica Acta 450 (2015) 125–126

ELSEVIER

Letter to the Edit

The calibrator value the Abbott enzymat inadequate for ensu serum measuremen

Table 1

Uncertainties for each contributing factor in determination of serum creatinine with Abbott enzymatic assay on Architect *c*16000 platform after calibration with two different lots of system calibrator. Data obtained by measurements of NIST SRM 967a reference material (certified value ± expanded uncertainty: L1, 0.847 mg/dL ± 0.018 mg/dL and L2, 3.877 mg/dL ± 0.082 mg/dL).

	SRM 967a level 1	SRM 967a level 2
Multigent Clin Chem Calibrator lot no. 40043Y600		
Imprecision (u_{Rw})	0.47%	0.40%
Bias (u_{bias})	3.57%	7.05%
Relative combined standard uncertainty [$u_c = (u_{bias}^2 + u_{Rw}^2)^{0.5}$]	3.60%	7.06%
Expanded uncertainty ($U = k \times u_c$)	7.20%	14.12%
Multigent Clin Chem Calibrator lot no. 40496Y600		
Imprecision (u_{Rw})	0.53%	0.42%
Bias (u_{bias})	4.02%	1.71%
Relative combined standard uncertainty [$u_c = (u_{bias}^2 + u_{Rw}^2)^{0.5}$]	4.05%	1.76%
Expanded uncertainty ($U = k \times u_c$)	8.10%	3.52%

Note that the measuring system as described perfectly fulfils analytical performance specifications (APS) for combined uncertainty of serum creatinine measurement on clinical samples. After the introduction of a new lot of calibrator, we observed, however, a constant overestimation (in average, +8%) of creatinine results during the participation in the regional external quality assessment (EQA) scheme. As the analytical imprecision of the method was optimal, we verified the trueness of the measuring system by using the NIST SRM 967a reference material. This confirmed the presence of significant positive bias when the measuring system was calibrated with the new lot of calibrator. Consequently, the combined uncertainty experimentally obtained using this calibrator lot on clinical samples was much higher than the desirable performance goal.

Clinical Chemistry 57:12
1670–1680 (2011)

Reviews

Proficiency Testing/External Quality Assessment: Current Challenges and Future Directions

W. Greg Miller,[1*] Graham R.D. Jones,[2] Gary L. Horowitz,[3] and Cas Weykamp[4]

BACKGROUND: Proficiency testing (PT), or external quality assessment (EQA), is intended to verify on a recurring basis that laboratory results conform to expectations for the quality required for patient care.

or harmonization among different measurement procedures.

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Table 3. Evaluation capabilities of PT/EQA related to scheme design.

	Sample characteristics			Evaluation capability						
				Accuracy						
				Individual laboratory					Standardization or harmonization[b]	
					Relative to participant results		Reproducibility		Measurement procedure calibration traceability	
Category	Commutable	Value assigned with RMP[a] or CRM	Replicate samples in survey	Absolute vs RMP or CRM	Overall	Peer group	Individual laboratory intralab CV	Measurement procedure interlab CV	Absolute vs RMP or CRM	Relative to participant results
1	Yes	Yes	Yes	X	X	X	X	X	X	X
2	Yes	Yes	No	X	X	X		X	X	X
3	Yes	No	Yes		X	X	X	X		X
4	Yes	No	No		X	X		X		X
5	No	No	Yes			X	X	X		
6	No	No	No			X		X		

[a] RMP, reference measurement procedure; CRM, certified reference material.

[b] Standardization when patient results are equivalent between measurement procedures and calibration is traceable to SI by use of a reference measurement procedure; harmonization when patient results are equivalent between measurement procedures and calibration is not traceable to a reference measurement procedure.

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The role of external quality assessment in the verification of in vitro medical diagnostics in the traceability era

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- Quality of the EQA Target
- Commutability of the material
- APS for EQA

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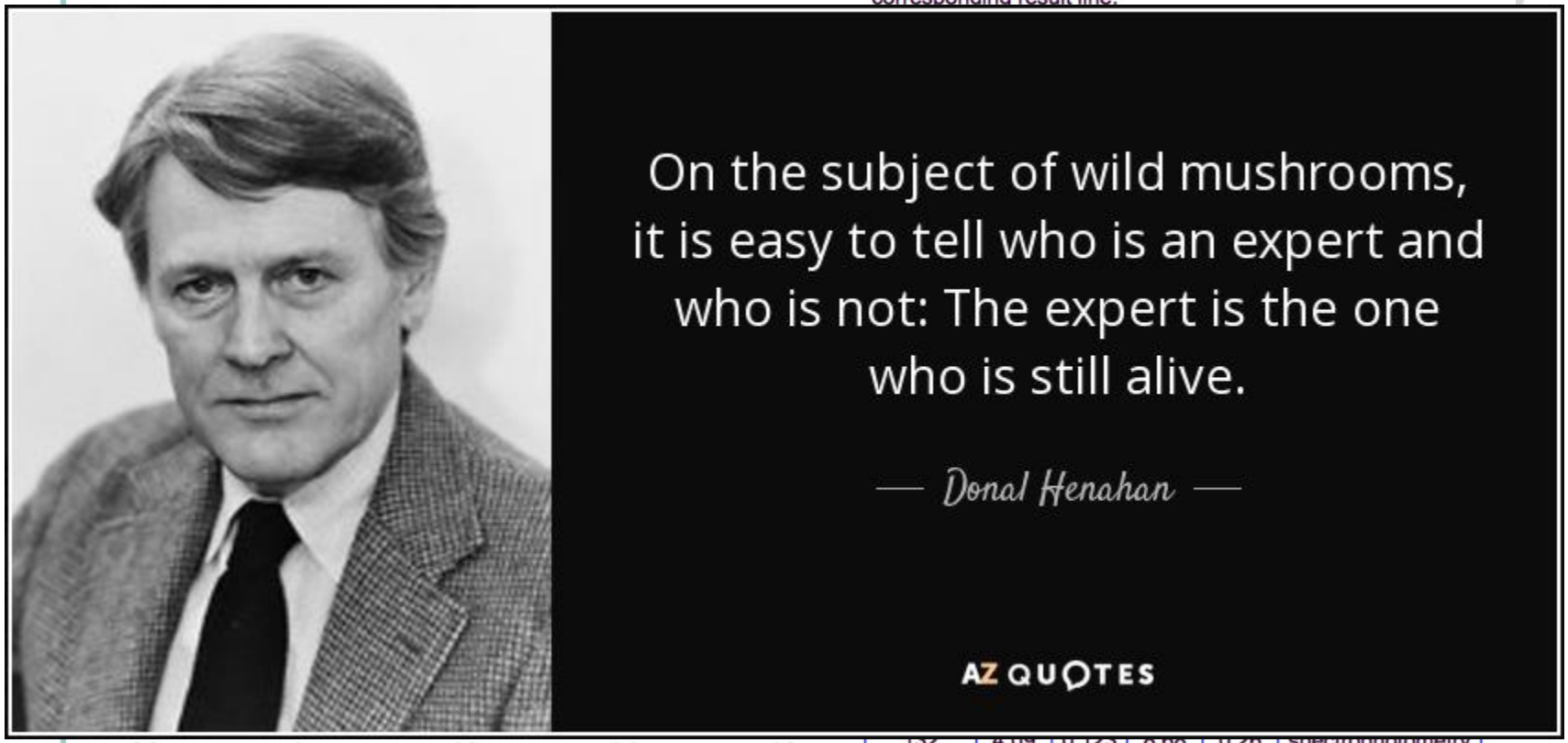
corresponding result line.

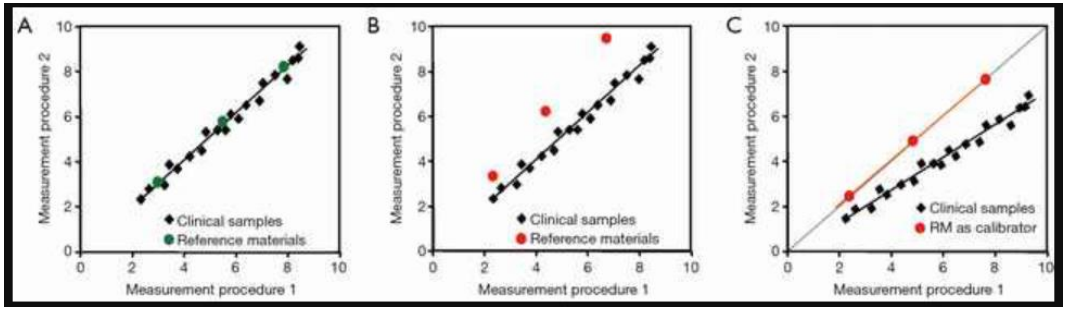


3,8 4 4,2 4,4 4,6
A [mmol/l]

145	4.148	0.15	8.876	0.322	spectrophotometry

Other issues with Target assignment

- Reference method/SRM availability
- Cost
- Range of concentrations
- Time to get a result



Clinical Chemistry 64:3
447–454 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 1: General Experimental Design

W. Greg Miller,[1*] Heinz Schimmel,[2] Robert Rej,[3] Neil Greenberg,[4] Ferruccio Ceriotti,[5] Chris Burns,[6] Jeffrey R. Budd,[7] Cas Weykamp,[8] Vincent Delatour,[9] Göran Nilsson,[10] Finlay MacKenzie,[11] Mauro Panteghini,[12] Thomas Keller,[13] Johanna E. Camara,[14] Ingrid Zegers,[2] and Hubert W. Vesper,[15] for the IFCC Working Group on Commutability

Clinical Chemistry 64:3
455–464 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 2: Using the Difference in Bias between a Reference Material and Clinical Samples

Göran Nilsson,[1] Jeffrey R. Budd,[2] Neil Greenberg,[3] Vincent Delatour,[4] Robert Rej,[5] Mauro Panteghini,[6] Ferruccio Ceriotti,[7] Heinz Schimmel,[8] Cas Weykamp,[9] Thomas Keller,[10] Johanna E. Camara,[11] Chris Burns,[12] Hubert W. Vesper,[13] Finlay MacKenzie,[14] and W. Greg Miller,[15*] for the IFCC Working Group on Commutability

Clinical Chemistry 64:3
465–474 (2018)

Special Reports

IFCC Working Group Recommendations for Assessing Commutability Part 3: Using the Calibration Effectiveness of a Reference Material

Jeffrey R. Budd,[1] Cas Weykamp,[2] Robert Rej,[3] Finlay MacKenzie,[4] Ferruccio Ceriotti,[5] Neil Greenberg,[6] Johanna E. Camara,[7] Heinz Schimmel,[8] Hubert W. Vesper,[9] Thomas Keller,[10] Vincent Delatour,[11] Mauro Panteghini,[12] Chris Burns,[13] and W. Greg Miller,[14*] for the IFCC Working Group on Commutability

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Table 2: Example of summary description of analytical performance specifications (APS) based on the RCPAQAP General Serum Chemistry External Quality Assurance (EQA) Scheme.

1. The EQA material is not validated as commutable
2. The overall target-setting method for each measurand is shown below. In addition, method, instrument, reagent manufacturer-based consensus targets are provided based on returned results
3. The APS are to be applied to each individual measurement result
4. The APS are applied for assessment of total error (i.e. the effects of imprecision and bias combined)
5. The rationale for the APS is 'Aspirational' (to improve performance) where this is required. The response of the laboratory to 'out of range' results should be to review performance and seek improvement
6. The APS are established based on biological variation and state of the art (levels 2 and 3 from Milan conference). The components of biological variation and the level (optimal, desirable, or minimal) are shown below

Further details on the RCPAQAP process used to establish these APS are available [9, 15]

Measurand	Assignment of target	Analytical performance specifications	Employed component(s) of biological variation	Quality level
S/P-ALT	IFCC reference procedure in a JCTLM-listed reference laboratory	±5 U/L up to 40 U/L; ±12% >40 U/L	Within-individual (imprecision)	Optimal
S/P-Bicarbonate	Selected well-controlled commercial measuring system by an ISO 15189 accredited clinical laboratories	±2.0 mmol/L up to 20.0 mmol/L; ±10% >20.0 mmol/L	Within- and between-individual (total error)	Minimal
S-Transferrin	Median of laboratories participating in EQA	±0.20 g/L up to 2.50 g/L; ±8% >2.50 g/L	Within- and between-individual (total error)	Minimal

Challenges

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The role of external quality assessment in the verification of in vitro medical diagnostics in the traceability era

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Table 2

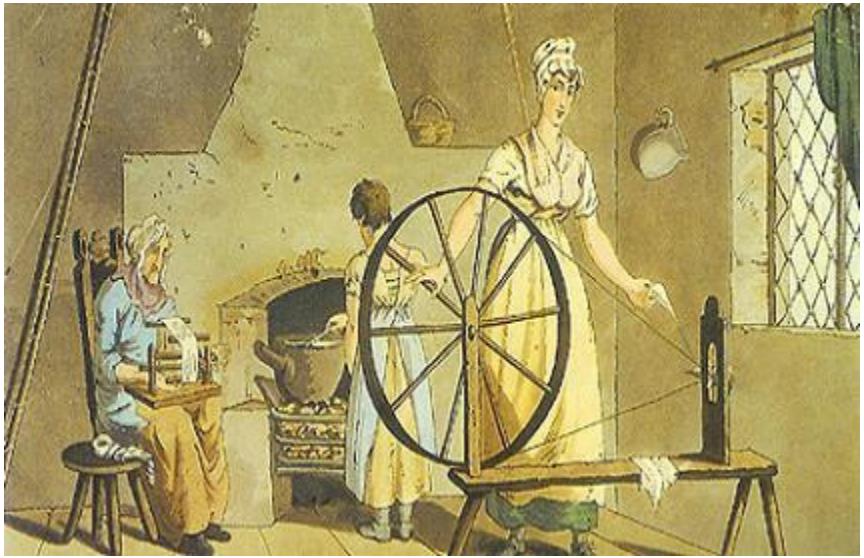
Constraints limiting the introduction of External Quality Assessment (EQA) schemes that meet metrological criteria. Adapted from ref. 20.

- Technical aspects: lack of certified control materials or difficulties to prepare commutable samples
- Practical considerations: complicated logistics of distribution of frozen samples
- Educational limitations: lack of awareness of which quality factors make an EQA important
- Economic concerns: higher costs

EQALM associate members	Country	Link
Oneworld Accuracy, Vancouver	Canada	Web site
Labquality, Helsinki	Finland	Web site
Bio Group Medical System, Rimini	Italy	Web site
Oneworld Accuracy Italia, Bologna	Italy	Web site
Randox International Quality Assessment Scheme, Crumlin	United Kingdom	Web site
Bio-Rad Laboratories - EQAS Programs, Irvine	United States	Web site
[illegible]	[illegible]	[illegible]
WEQAS, Cardiff	United Kingdom	Web site
EQALM non-European members	Country	Link
The Royal College of Pathologists of Australasia Quality Assurance Programs (RCPAQAP)	Australia	Web site
Programa Nacional de Controle de Qualidade - PNCQ, Rio de Janeiro	Brasil	Web site
Clinical Microbiology Proficiency Testing (CMPT), Vancouver	Canada	Web site
Institute for Quality Management in Healthcare, Toronto	Canada	Web site
CMCEQAS – (Haemostasis & Transfusion Medicine), CMC, Vellore	India	Web site
Preventive Medicine Foundation, Taipei	Taiwan	Web site
Equalis, Uppsala	Sweden	Web site

EQA Providers

- Not for profit – limitation on R&D
- Volunteers/passionate
- Parochial - loyalty
- Limited resources – time, money
- Proud
- Role of commercial EQA providers?



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What is the role of EQA?

- **Regulatory**
  - Police role
  - APS
  - Cost
- **Aspirational**
  - Cost
- **Frequency of challenge**
  - Cost
  - Sample size
  - Profit!
- **Sharing results**
  - Classification
  - privacy

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A category 1 EQA scheme for comparison of laboratory performance and method performance: An international pilot study in the framework of the Calibration 2000 project

Rob Jansen [a,*], Nuthar Jassam [b], Annette Thomas [c], Carmen Perich [d], Pilar Fernandez-Calle [d], Ana Paula Faria [e], Helena Correia [e], Julian H. Barth [f], Cas Weykamp [a], Christa Cobbaert [g], Marc Thelen [h], Carmen Ricós [d]

[a] Dutch Foundation for Quality Assessment in Medical Laboratories (SKML), Nijmegen, The Netherlands
[b] Department of Clinical Biochemistry, Harrogate District Foundation Trust, Harrogate, UK
[c] WEQAS Quality Laboratory, Cardiff and Vale University Health Board, Cardiff, UK
[d] Spanish Society of Clinical Chemistry and Molecular Pathology (SEQC), Analytical Quality Commission, Spain
[e] Instituto Nacional de Saude, Portugal
[f] Blood Sciences, Old Medical School, Leeds Teaching Hospitals Trust, Leeds, UK
[g] Department of Clinical Chemistry, Leiden University Medical Center, Leiden, The Netherlands
[h] Department of Clinical Chemistry and Hematology, Amphia Hospital, Breda, The Netherlands

Table 2b
Analytes tested with commutable EQA materials and values assigned by reference method not obtaining comparable results.

Analyte	Reference method and laboratory	Routine method (number of labs)	Routine calibrator traceability
ALT AST	IFCC (TRIS buffer with pyridoxal phosphate, 37 °C) Haga Hospital, The Hague	IFCC, with pyridoxal phosphate (4) IFCC without pyridoxal phosphate (8)	IFCC Absorptivity
α-Amylase	IFCC (Maltoheptaoside with p-nitrophenol and ethylidene, 37 °C) Haga Hospital, The Hague	Maltoheptaoside-p-nitro phenol and ethylidene (5) Maltotrioside with 2 chloro-p-nitrophenol (3)	IRMM/IFCC 456[@@] "Masterlot" IFCC Absorptivity
Calcium	Atomic absorption spectrometry INSTAND, Düsseldorf	Arsenazo (7) O-cresolphthalein (5)	NIST-SRM 915[*] NIST-SRM 909b[**] NIST-SRM 956[***]
Creatinine eGFR	GC–IDMS DGKL, Hanover	Enzymatic (1) Jaffé kinetic (5) Jaffé kinetic compensated (7)	NIST-SRM 914[*] NIST-SRM 909b[**] NIST-SRM 967[****] IDMS[&]
GGT	IFCC (gamma-glutamyl-3-carboxy-4-nitroanilide > 4 mmol/L, 37 °C) Haga Hospital, The Hague	IFCC (12)	ERM/IFCC 452[&&]
LDH	IFCC (lactate to pyruvate, 37 °C) Haga Hospital, The Hague	Lactate to pyruvate (7) Pyruvate to lactate (5)	IRMM 453[@@]
Magnesium	Atomic absorption spectrometry INSTAND, Düsseldorf	Arsenazo (1) Xylidyl blue (3) Chlorophosphonazo (1)	NIST-SRM 929[*] NIST-SRM 909b[**]
Sodium	Flame emission spectrometry INSTAND, Düsseldorf	Indirect potentiometry (12)	NIST-SRM 909b[**] NIST-SRM 956[***]

eGFR, estimated glomerular filtration rate.
* Aqueous solution, pure substance.
** Lyophilized human serum with unproven commutability.
*** Frozen human serum with unproven commutability.
**** Frozen human serum with proven commutability.
& Animal tissue, commutable.
&& Animal tissue l, not commutable.
@@ Human tissue, commutability not proved.

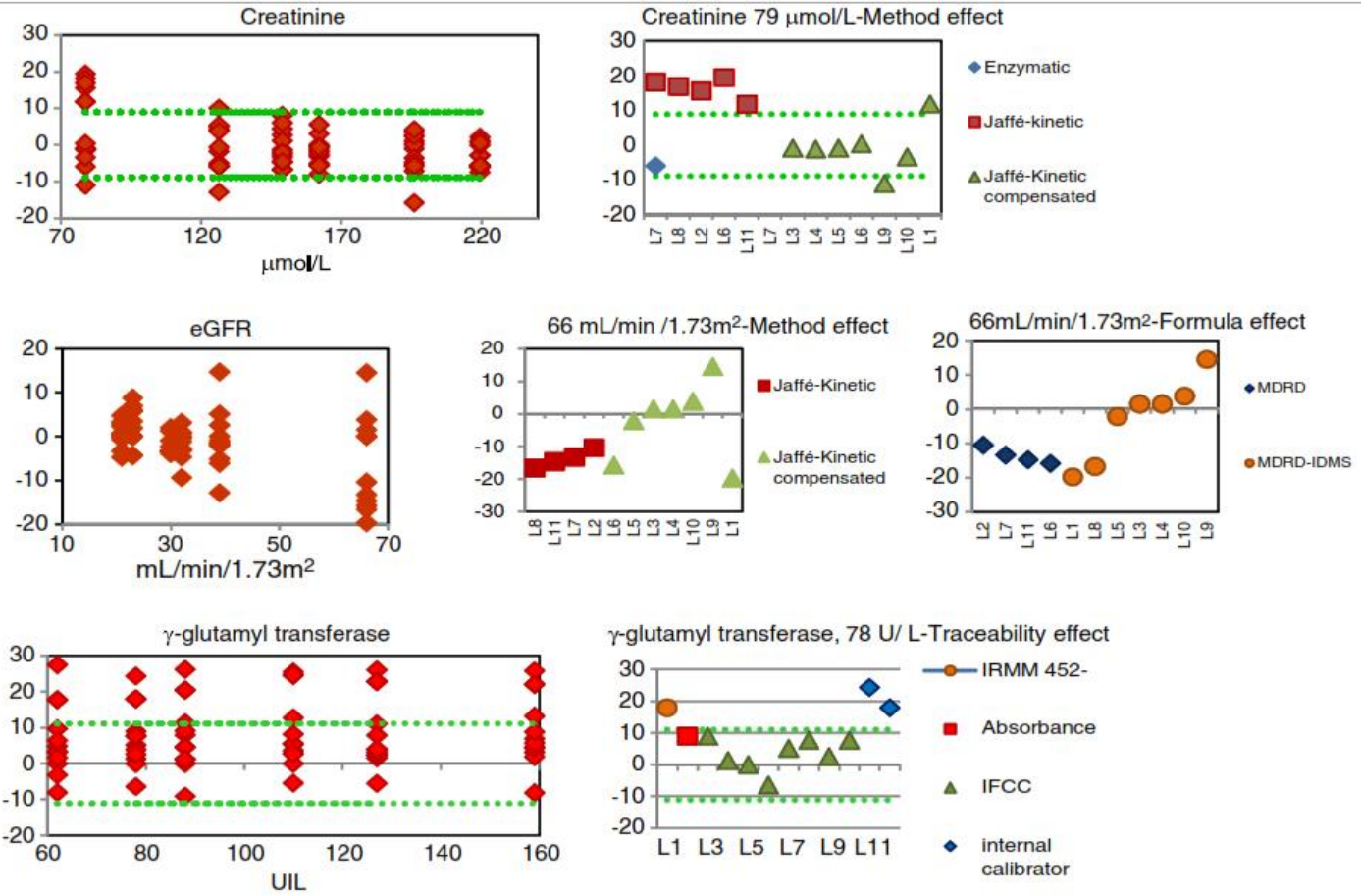

Fig. 2. Analytes tested with commutable EQA materials and values assigned by reference method not obtaining comparable results. Y-axis: Percentage deviation compared with the reference method value. X-axis in all figures except creatinine at 79 µmol/L, eGFR at 66 mL/min/1.72 m^2 and GGT at 78 U/L: reference method value for the six EQA-samples (creatinine:79, 126, 149, 162, 196, 219 µmol/L; eGFR: 21, 23, 30, 32, 39, 66 mL/min/1.72 m^2; GGT: 62, 78, 88, 110, 127, 159 U/L); Laboratory-procedures 1 to 12; dashed lines represent acceptability limits derived from biological variation (desirable for creatinine, optimum for GGT).

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The role of External Quality Assessment Schemes in Monitoring and Improving the Standardization Process

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ABSTRACT

This paper examines the evolution of External Quality Assessment Schemes (EQAS), focusing on the need for target values based on reference methods and control material commutability. Although the key role of EQAS in the standardization process has been clear from the start, it has never been totally implemented, mainly due to the lack of commutable materials. Costs, the difficulty to assign reference method values, and the non-availability of field methods able to provide results traceable to the reference measurement system have also

I will conclude by quoting and commenting on Graham Jones's personal observations [53]:

- If labs can do it differently, they will — setting standards is necessary as well as verifying their application
- Unless EQAS can show labs are the same, assume they are not — without adequate EQAS no further progress is possible
- If EQAS shows lab differences, it will not fix itself — EQAS organizers, as well as manufacturers and laboratorians have to take corrective action: only with category 1 or 2 EQAS corrective actions could be easily and correctly defined
- Action requires people talking, setting standards and doing
- Action should be local, national and international — no single organization can be successful alone.

Harmonization is a generalization of the concept of standardization that means achieving equivalent results, within medically meaningful limits, among different MPs using a scientifically sound approach.

Clinical Chemistry 63:7
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Editorials

Harmonization: Its Time Has Come

W. Greg Miller[1*]

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The Royal College of Pathologists of Australasia
Quality Assurance Programs

DE GRUYTER Clin Chem Lab Med 2018; 56(10): 1667–1672

Opinion Paper

Gary L. Myers and W. Greg Miller*

The roadmap for harmonization: status of the International Consortium for Harmonization of Clinical Laboratory Results

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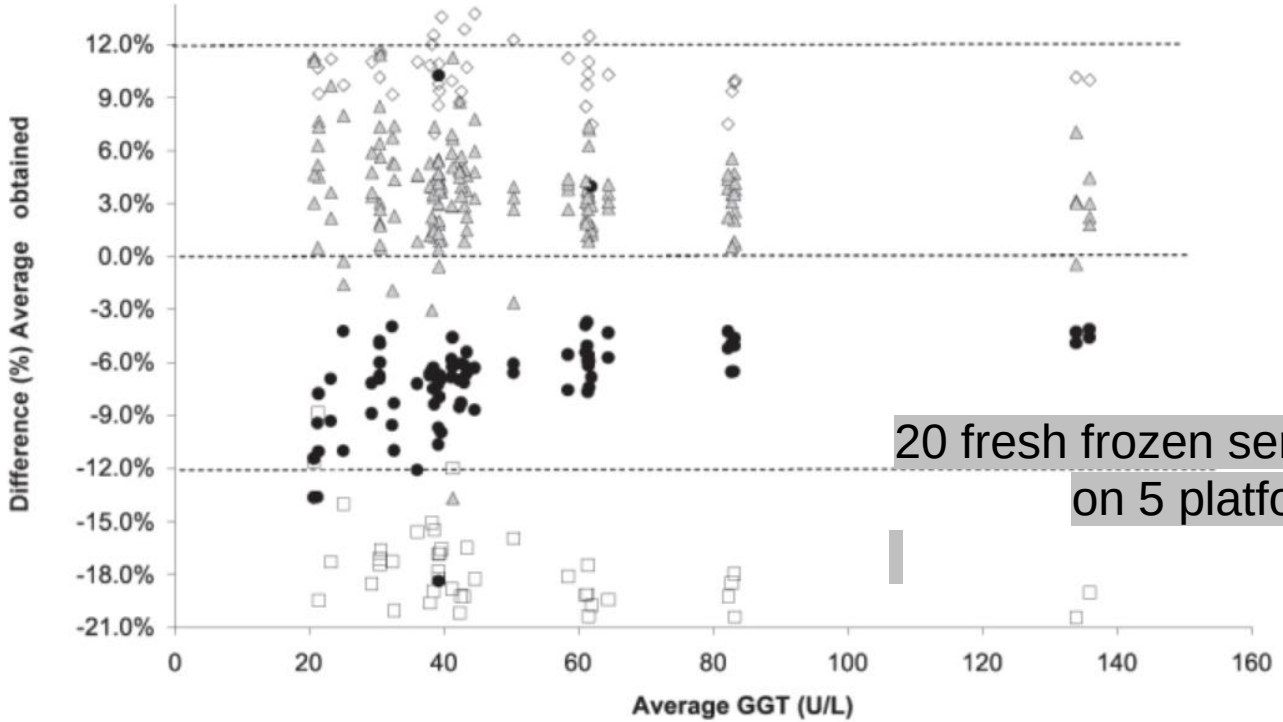

20 fresh frozen serum samples on 5 platforms

Figure 6. Analysis of method differences for GGT compared with average activities of all method and RCPAQAP Allowable limits of performance (ALE).

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Frequency of EQA

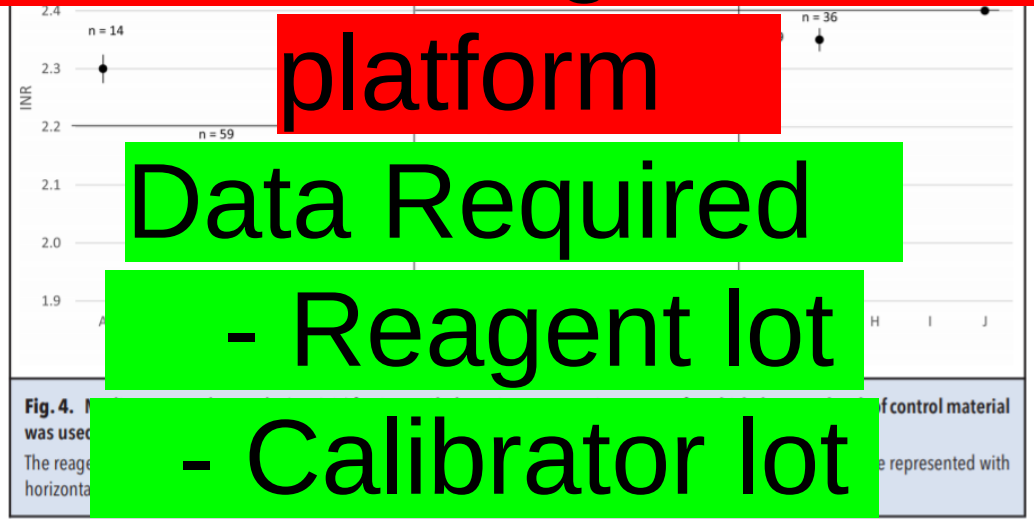
Challenges?

Risk points – change in calibrator, reagent lot or platform

Data Required

- Reagent lot

- Calibrator lot



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Comparison		
	IQC	EQA
Results	Known	Unknown
Results Available	Immediately	Later
Decision purpose	Release or repeat analysis	Quality Improvement
Frequency	Minimum daily, per batch, per shift	Periodically eg 1 / 4weeks 2 / 4 weeks 5 x 3 / year
Concentrations*	Normal, abnormal	Multiple concentrations, eg 6-8
Assesses	Bias	Accuracy & imprecision
Comparison*	Your lab only	Your lab to all labs & other labs using your method

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Results: *We observed significant variation and unexpected similarities in practice across laboratories, including QC frequency, cutoffs, number of levels analyzed, and other features.*

Conclusions: *This variation in practice indicates an opportunity exists to establish an evidence-based approach to QC that can be generalized across institutions.*

DOI: 10.1093/ajcp/aqy033

Clinical Chemistry 65:8
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Special Report

Patient-Based Real-Time Quality Control: Review and Recommendations

Tony Badrick,[1*] Andreas Bietenbeck,[2] Mark A. Cervinski,[3,4] Alex Katayev,[5] Huub H. van Rossum,[6,7] and Tze Ping Loh,[8] on behalf of the International Federation of Clinical Chemistry, and Laboratory Medicine Committee on Analytical Quality

The Percentiler and Flagger Programs

Modern quality assurance tools –

web-based monitoring of performance and test stability in relation to the flagging rate as surrogate medical decision

www.noklus.no

Norwegian Quality Improvement of Laboratory Examinations

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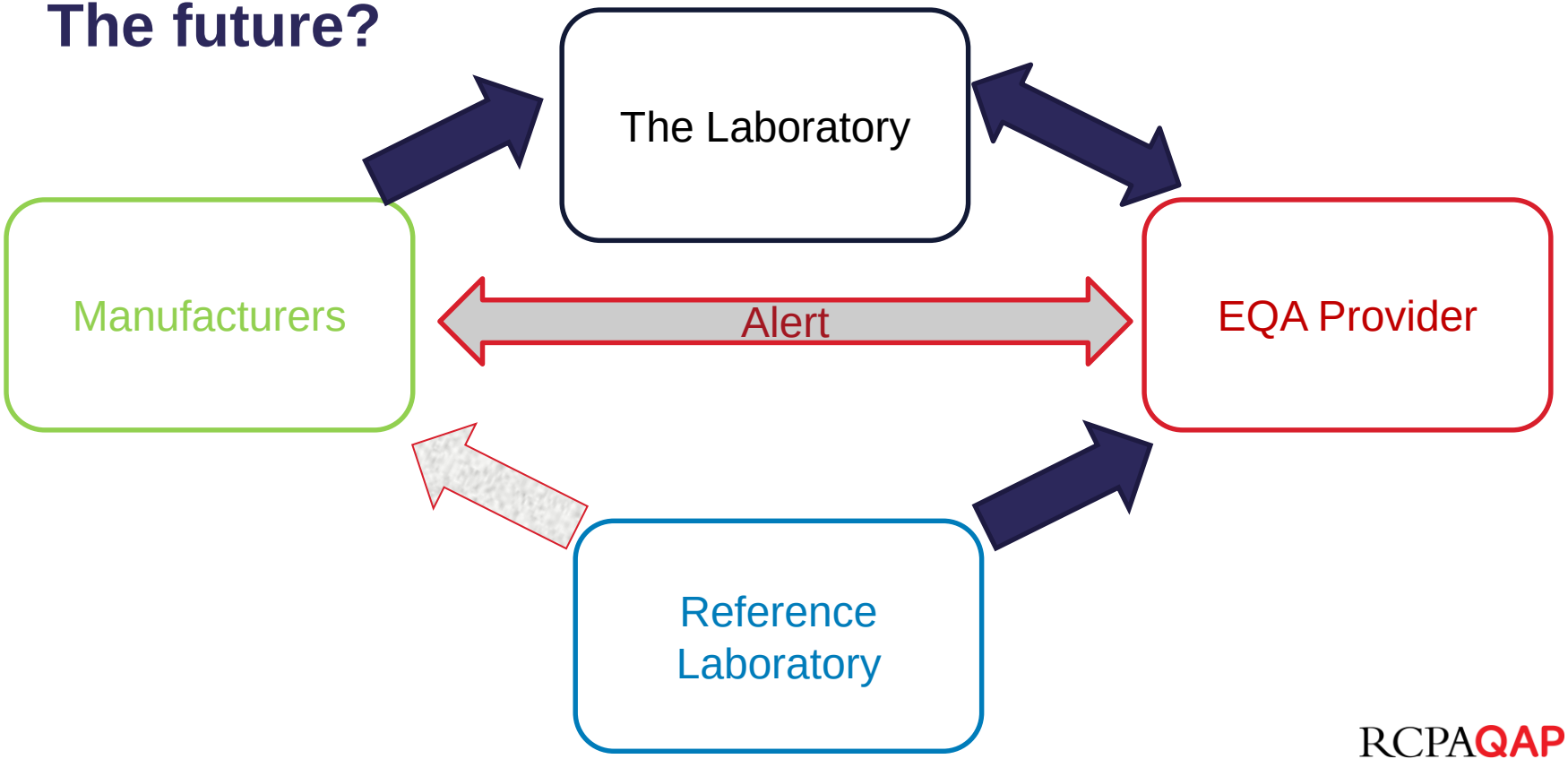
The future?



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Summary

- We are challenging the value of *conventional* EQA programs
- Key factors are commutability, target setting, APS, method (sub)classification
- EQA schemes need to harmonise
- Different form of EQA needed – real time and more data needed from participants
- Who tells the manufacturer?

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