EFLM
EUROPEAN FEDERATION OF CLINICAL CHEMISTRY AND LABORATORY MEDICINE

European Commission
Joint Research Centre
IRMM
Institute for Reference Materials and Measurements

CIRME

1st EFLM Strategic Conference

Defining analytical performance goals 15 years after the Stockholm Conference

8th CIRME International Scientific Meeting

14:00-14:30 Performance criteria and quality indicators for the pre-analytical phase
Mario Plebani (IT)

Mario Plebani

15 YEARS AFTER THE STOCKHOLM CONFERENCE

Nomen Omen:

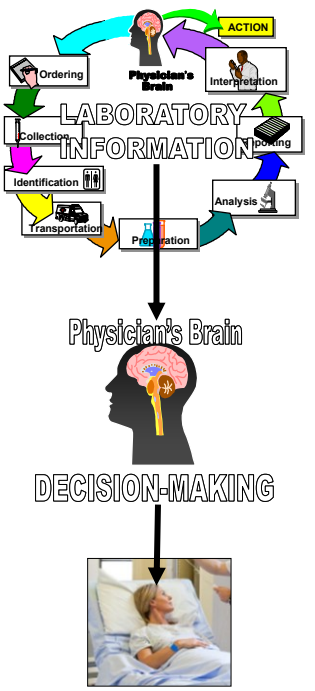
- Analytical performance goals
- Performance goals
- Performance criteria
- Quality specifications

QUALITY SPECIFICATIONS

- The ***level of performance*** required to ***facilitate*** ***clinical decision-making***.

Callum G Fraser

- may we add "to ***assure*** desirable ***clinical outcomes***"? As this is the final goal.



QUALITY SPECIFICATIONS and PREANALYTIC FACTORS

At the Stockholm Consensus Conference on Quality Specifications, Walter G. Guder delivered a lecture on " preanalytical factors and their influence on analytical quality specifications " underlining that " ***non-analytical errors*** explained more than **60%** of distrusted results, of which ***variables*** in the ***preanalytical phase*** contributed to more than half of the cases"

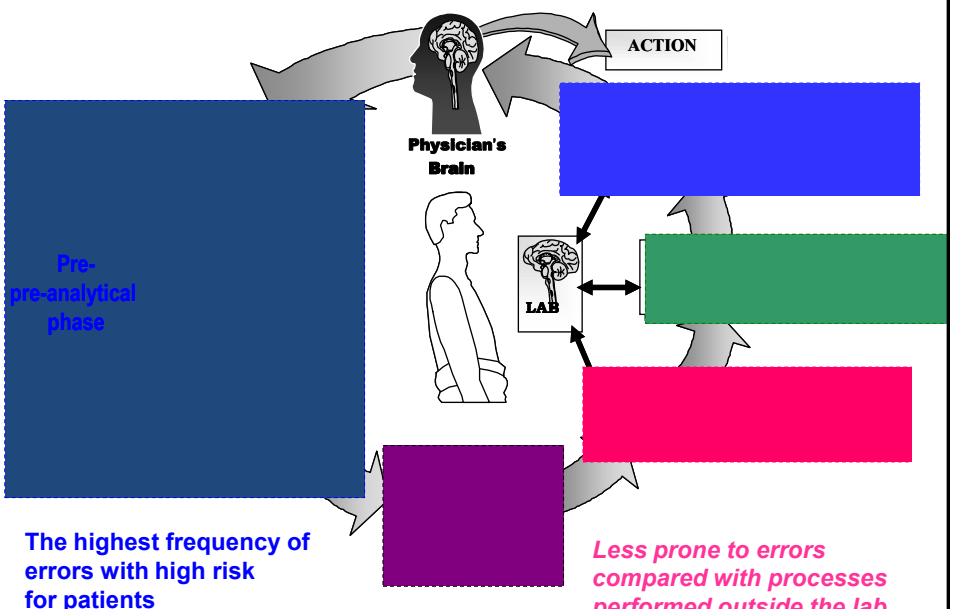
Stockholm 1999

AFTER THE STOCKHOLM CONFERENCE

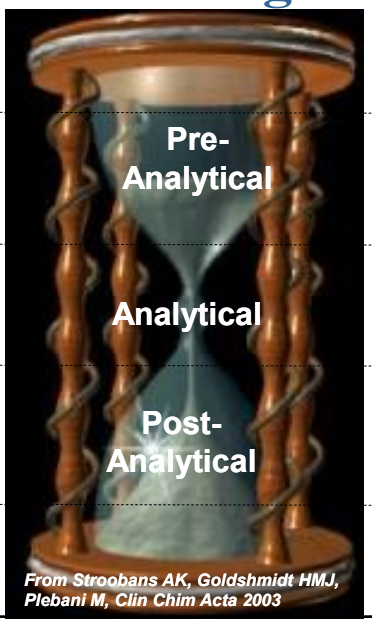
- Evidence has been collected on the **frequency** and **stratification** of ***errors*** in laboratory medicine.
- The **vulnerability** of the **pre-analytical phase**, which accounts for approximately 70% of laboratory errors, has been highlighted leading with the need to subdivide it into two main phases, the pre-preanalytic and the "true" pre-analytic one.
- Consensually defined criteria for setting **extra-analytical quality indicators** have been developed and data collected.
- This in turn, should provide the way to define reliable **performance criteria** in the pre-analytic phase.

PRE-ANALYTICAL PHASE: THE DARK SIDE OF THE MOON

- The preanalytical phase consists of pre-preanalytical phase and "true" preanalytical phase
- ***Pre-preanalytical***: the processes of selecting appropriate tests, ordering, collecting, identifying and labeling, handling, and transporting biological samples.
- ***Pre-analytical***: the process of accepting samples by the laboratory, centrifuging, aliquoting, diluting, and sorting the biological samples.



Errors in Laboratory Medicine - The hourglass model -



	Frequency of occurrence
Pre-pre-analytical, very high frequency, high risk	12%
Pre-analytical, high frequency	2%
Intra-analytical	0.2%
Post-analytical, high frequency	2.2%
Post-post-analytical, very high frequency, high risk	5.0%

Criteria for Quality Testing

*"Wrongs" anywhere compromise test result **quality** and **patients' safety**!*

Performance criteria

	Analytical Phase	Pre-Analytical Phase
Hierarchy of criteria	***Well defined***	***Not defined*** Possibly based on the State-of-the-Art and on Outcome Measures
Quality Specifications	***Well defined*** Bias and Reproducibility	***Under development***
Metrics	***Well defined***	***Proposed*** - Percentage - Parts per million (ppm) - Six sigma
Tools of measures	***Well defined*** - Internal Quality Control (IQC) - External Quality Assessment (EQA)	***Recently defined*** Quality indicators (QI)

AFTER THE STOCKHOLM CONFERENCE

- Evidence has been collected on the frequency and stratification of errors in laboratory medicine.
- The vulnerability of the pre-analytical phase, which accounts for approximately 70% of laboratory errors, has been highlighted leading with the need to subdivide it into two main phases, the pre-preanalytic and the "true" pre-analytic one.
- ***Consensually defined criteria for setting extra-analytical quality indicators have been developed and data collected.***
- This in turn, should provide the way to define reliable performance criteria in the pre-analytic phase.

WHY DO WE NEED QUALITY INDICATORS ?

Valuable source of information for:

- In-house quality improvement program;
- Benchmarking;
- External quality assurance schemes;
- Stakeholders (both patients and administrators).

QUALITY INDICATORS: A DEFINITION

ISO 15189:2012

Measure of the degree to which a set of inherent characteristics fulfils requirements

Note 1. Measure can be expressed, for example, as % yield (% within specified requirements), % defects (% outside specified requirements), defects per million occasions (DPMO) or on the Six Sigma scale.

Note 2. Quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes.

Implementing QI is a must

for each ISO 15189 accredited laboratory

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

Example: number of unacceptable samples, number of errors at registration and/or accession, number of corrected reports

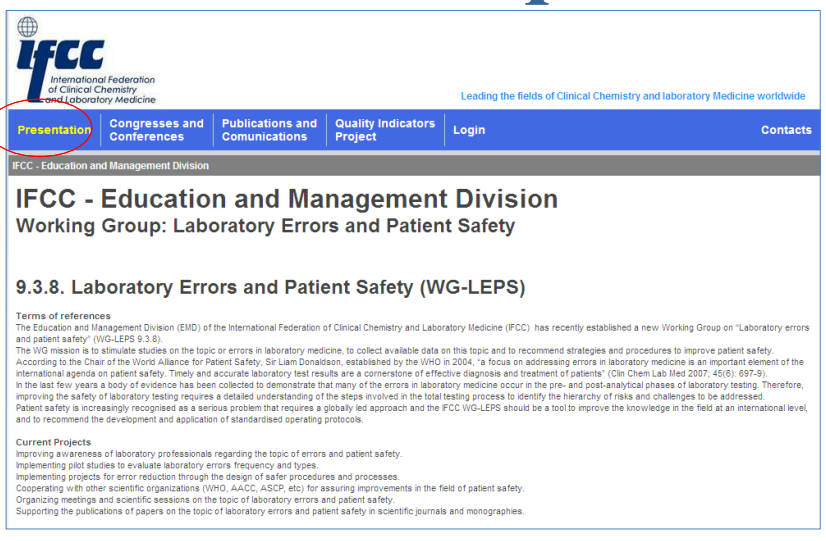
Implementing QI is a must

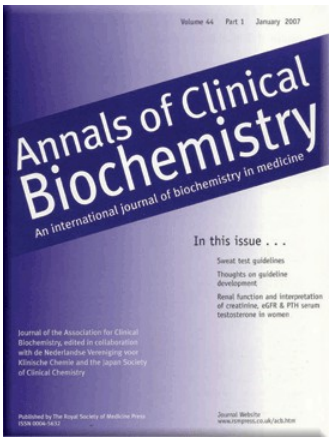
for each ISO 15189 accredited laboratory

4.14.7. the process of monitoring quality indicators shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement.

The indicators shall be periodically reviewed, to ensure their continued appropriateness

www.ifcc-mqi.com





Quality indicators for laboratory diagnostics: consensus is needed

There is now a compelling need to reorganize and possibly unify these ongoing projects, as well as establish an international consensus for producing joint recommendations focused on the adoption of universal quality indicators and common terminology. This is supported by a

Mario Plebani [1], Laura Sciacovelli [1] and Giuseppe Lippi [2]

[1]Dipartimento di Medicina di Laboratorio, Università degli Studi di Padova, Padova; [2]U.O. Diagnostica Ematochimica, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy

International Federation of Clinical Chemistry and Laboratory Medicine

Programma Regionale per la Ricerca Biomedica della Regione Veneto

Azienda Ospedaliera - Università di Padova

A Consensus Conference to design a road map to harmonization of quality indicators

HARMONIZATION OF QUALITY INDICATORS IN LABORATORY MEDICINE: WHY, HOW AND WHEN?

PRESIDENT OF THE CONGRESS
Mario Plebani *(Padova, Italy)*

PADOVA, OCTOBER 24th, 2013

SALA CONVEGNI
CASSA DI RISPARMIO DEL VENETO
VIA 8 FEBBRAIO, 22 - PADOVA

Consensus Conference Program

Chairpersons: ***Greg Miller*** *(USA)*
Mario Plebani *(Italy)*

9.00 **State-of-the-art and criteria for harmonization**
Mario Plebani

9.20 **Quality Indicators and clinical effectiveness**
Julian H. Barth

9.40 **Pre-analytical phase indicators**
Ana-Maria Simundic

10.00 **Neglected post-analytic quality metrics and their use in improving patient safety**
Michael Astion

10.20 **Quality Indicators for efficiency and effectiveness**
Wilson Shcolnik

Coffee Break.

11.10 **Indicators for strategic and support processes**
Mercedes Ibarz Escuer

11.30 **Quality Indicators: how to measure the quality improvement**
Penny Petinos

12.00 **The IFCC project on Quality Indicators**
Laura Sciacovelli (IFCC)

14.00 ***ROUND TABLE***
Discussion and search for a consensus

QUALITY INDICATORS IN LABORATORY MEDICINE: CRITERIA FOR HARMONIZATION

- ***Importance*** and ***applicability*** to a wide range of clinical laboratories at an international level;
- ***Scientific soundness*** with a focus on areas of great importance for quality in laboratory medicine;
- ***Feasibility***, both regarding data availability and the definition of thresholds for acceptable performance;
- ***Timeliness*** and possible utilization as a measure of **laboratory improvement**.

QUALITY INDICATORS IN LABORATORY MEDICINE: CRITERIA FOR HARMONIZATION

QIs must:

1) Be ***patient-centered***,
2) Be ***consistent*** with the requirements of the International Standard for medical laboratories accreditation (***ISO 15189: 2012***),
3) Have to address ***all stages*** of the Total Testing Process (***TTP***), as required by the definition of "laboratory error" (**ISO/TS 22367: 2008**)

DE GRUYTER DOI 10.1515/cclm-2014-0142 — Clin Chem Lab Med 2014; aop

Opinion paper

Mario Plebani*, Michael L. Astion, Julian H. Barth, Wenxiang Chen, César A. de Oliveira Galoro, Mercedes Ibarz Escuer, Agnes Ivanov, Warren G. Miller, Penny Petinos, Laura Sciacovelli, Wilson Shcolnik, Ana-Maria Simundic and Zorica Sumarac

Harmonization of quality indicators in laboratory medicine. A preliminary consensus

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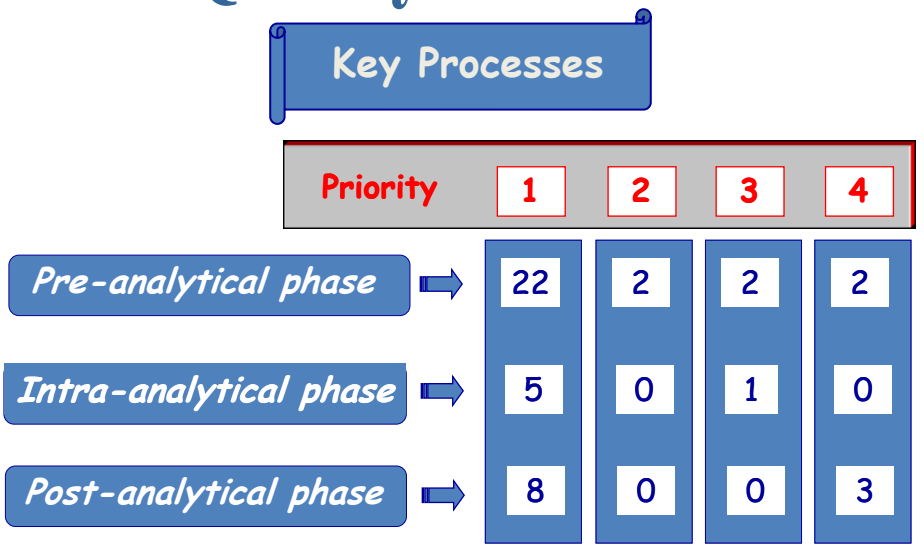
Quality Indicators



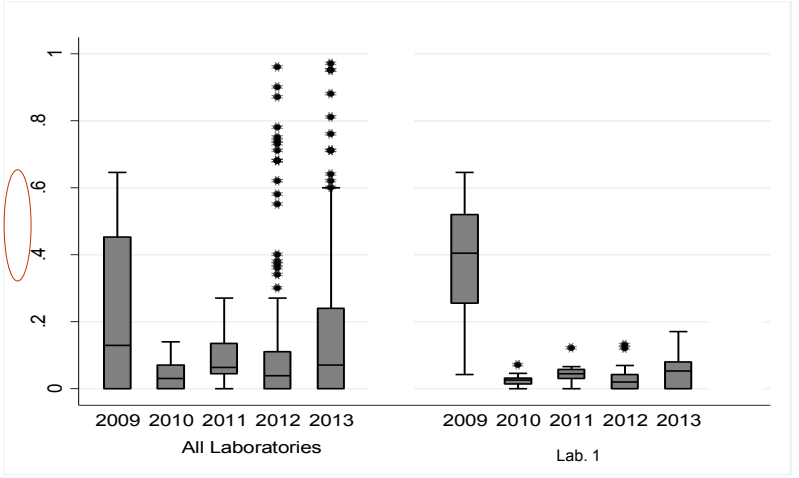
Quality Indicators

Pre-Analytical Processes: Priority 1

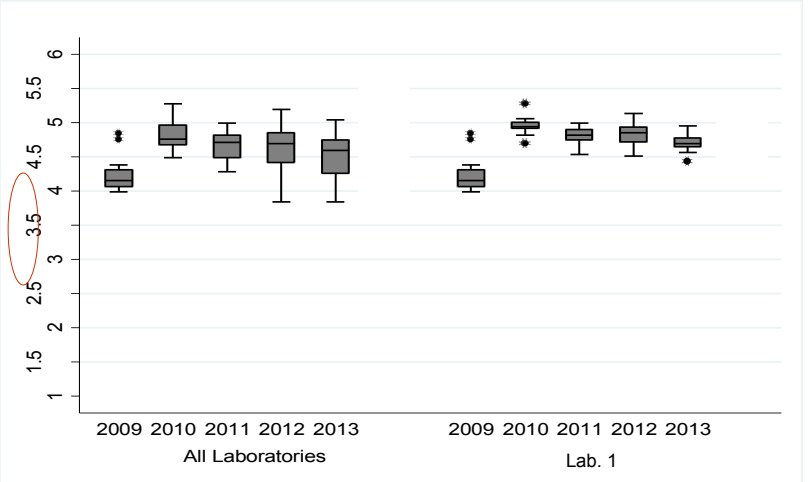
Test transcription errors

Pre-OutpTN	Number of outpatients requests with erroneous data entry (test name)/ Total number of outpatients requests.
Pre-OutpMT	Number of outpatients requests with erroneous data entry (missed test)/ Total number of outpatients requests.
Pre-OutpAT	Number of outpatients requests with erroneous data entry (added test)/ Total number of outpatients requests.
Pre-InpTN	Number of inpatients requests with erroneous data entry (test name)/ Total number of inpatients requests.
Pre-InpMT	Number of inpatients requests with erroneous data entry (missed test)/ Total number of inpatients requests.
Pre-InpAT	Number of inpatients requests with erroneous data entry (added test)/ Total number of inpatients requests.

Request with erroneous data entry
- Added tests -



Request with erroneous data entry
- Added tests -



Quality Indicators

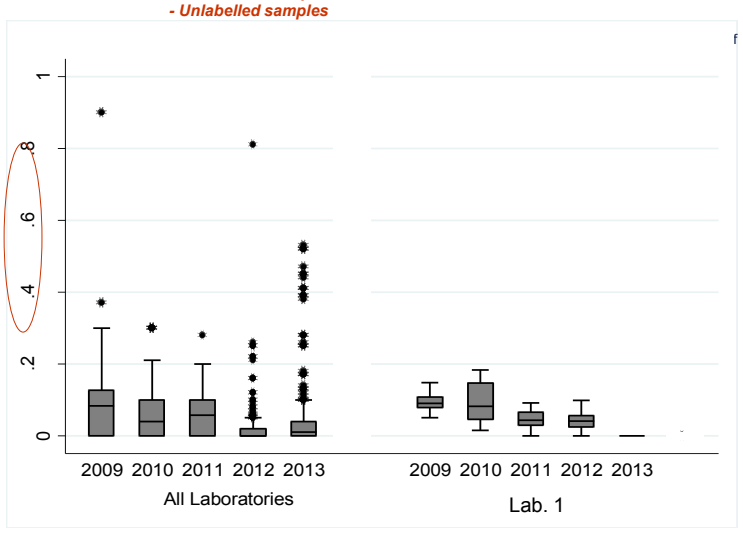
Pre-Analytical Processes: Priority 1

Misidentification errors

Pre-MisR	**Number of misidentified requests/ Total number of requests.**
Pre-MisS	**Number of misidentified samples/ Total number of samples.**
Pre-Iden	**Number of samples with fewer than 2 identifiers initially supplied/ Total number of samples.**
Pre-UnlS	**Number of unlabelled samples/ Total number of samples.**

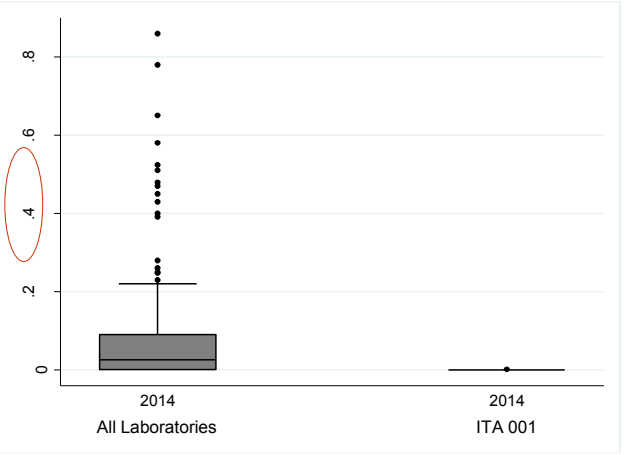
Patient Identification

- *Error concerning the requests*
- *Misidentified samples*
- *Misidentified requests*
- *Unlabelled samples*



Patient Identification

- Misidentified samples



Quality Indicators

Pre-Analytical Processes: Priority 1

Sample haemolysed

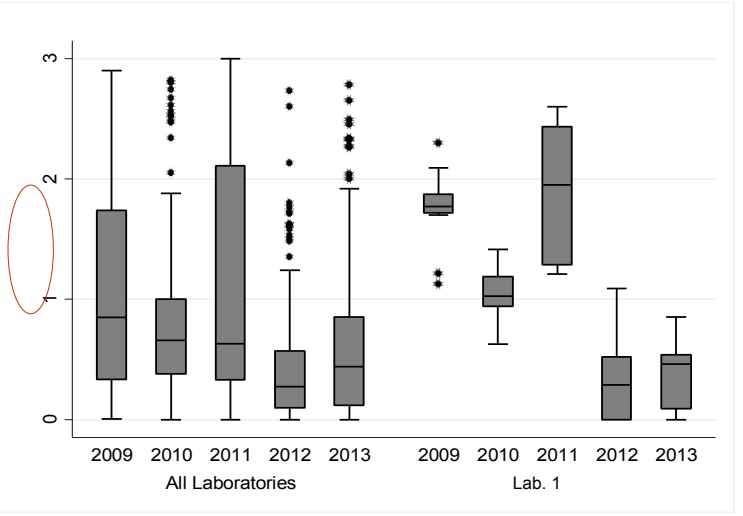
Pre-Hem — Number of samples with free Hb>0.5 g/L (clinical chemistry)/ Total number of samples (clinical chemistry)*

**clinical chemistry: i.e. all samples which are analysed on the chemistry analyser which is used for detection of HIL indices. If laboratories are detecting hemolysis visually, they count all samples with visible hemolysis. We suggest that a colour chart is provided for this purpose.*

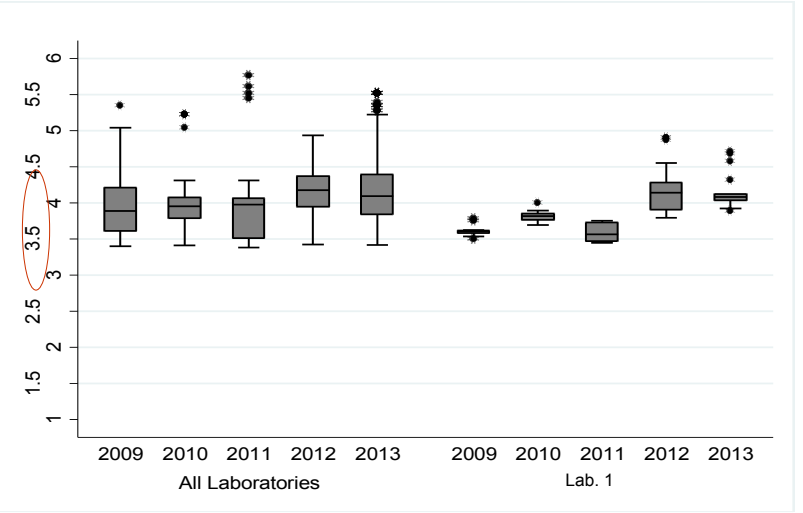
Samples clotted

Pre-Clot — Number of samples clotted/ Total number of samples with an anticoagulant.

Haemolysed samples



Haemolysed samples

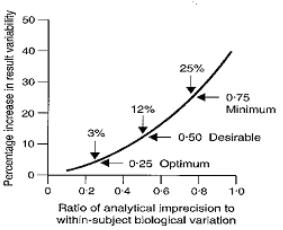


Quality Indicators	Year	Results, % (median)	Sigma Value (median)
Misidentification errors	2009	0.083	4.576
-errors concerning patient identification	2010	0.040	4.739
-misidentified samples	2011	0.057	4.656
-misidentified patients	2012	0	5.040
-unlabelled samples	2013	0.010	5.040
Test transcription errors	2009	0.220	4.248
-added tests	2010	0.140	4.429
-misinterpreted tests	2011	0.130	4.512
-missing tests	2012	0.050	4.536
	2013	0.101	4.411
Incorrect sample type	2009	0.050	4.791
-collected in inappropriate container	2010	0.040	4.853
-collected with inappropriate sample type	2011	0.020	5.027
	2012	0.020	4.932
	2013	0.038	4.860

Quality Indicators	Year	Results, % (median)	Sigma Value (median)
Unsuitable sample for transportation and storage problems	2009	0.010	5.054
-damage in transport	2010	0.013	5.015
-under inappropriate temperature condition or/and time	2011	0.010	4.338
-lost-not received	2012	0.010	4.966
-improperly stored	2013	0.020	4.500
Contaminated sample	2013	0	3.258
	2014	0.150	4.429
Sample haemolyzed	2009	0.850	3.887
-haematology/coagulation	2010	0.660	3.949
-chemistry	2011	0.630	3.975
-immunology	2012	0.270	4.175
	2013	0.440	4.093
Samples clotted	2009	0.206	4.293
-haematology/coagulation	2010	0.050	4.739
-chemistry	2011	0.060	4.739
-immunology	2012	0.090	4.429
	2013	0.179	4.378

THE PROPOSAL

To set quality specifications for pre-analytical variables according to the proposal by Fraser CG et al. (Ann Clin Biochem 1997) to classify them into ***three levels***: optimum, desirable and minimum.



	Percentage			
Quality Indicators	25th percentile	Median	75th percentile	Quality Specifications
Misidentification errors	0	0.010	0.040	Optimum = 0 Desirable = 0.010 Minimum = 0.040
Test transcription errors (added tests)	0	0.070	0.240	Optimum = 0 Desirable = 0.070 Minimum = 0.240
Sample haemolyzed	0.120	0.440	0.852	Optimum = 0.120 Desirable = 0.440 Minimum = 0.852

Contents lists available at SciVerse ScienceDirect

Clinical Biochemistry

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

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

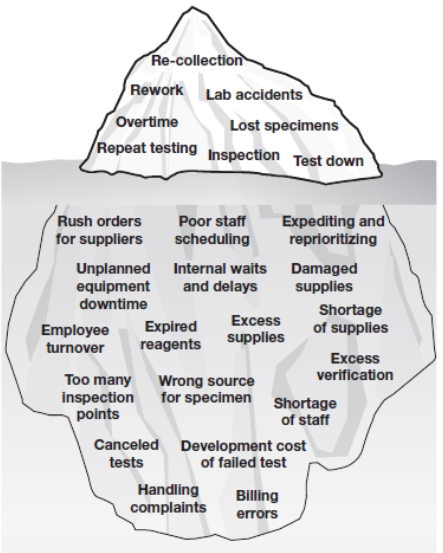
Mario Plebani*, Maria Laura Chiozza and Laura Sciacovelli

Towards harmonization of quality indicators in laboratory medicine

Errors and patient safety

The ***quality of laboratory testing*** may greatly ***affect*** the ***quality and affordability of patient care***.

Any defects or ***errors have consequences*** in the care of the patient as well as the costs to the health care



The iceberg as a metaphor of poor quality

"TAKE HOME MESSAGE" NUMBER 1

- The concept of ***quality*** in medicine and in laboratory medicine is strictly related to ***patient outcomes***.
- ***Patient safety*** is an important subset of quality.
- Quality and safety in laboratory medicine include all aspects of the ***total testing process***.

"TAKE HOME MESSAGE" NUMBER 2

- **Quality indicators (QIs)** are essential tools for quality measurement and improvement in the total testing process.
- The **implementation** and **monitoring** of QIs is a fundamental requirement for the accreditation of medical laboratories according to the **ISO 15189: 2012.**
- The consensually harmonized list of QIs represents a key issue for collecting data and setting **quality specifications** in the **pre-analytical phase**.

SEARCHING FOR CANADIAN CHAMPIONS

TANGO as a paradigm of joint efforts for improving PATIENT SAFETY

SEARCHING FOR CHAMPIONS

See you in Rio in 2015…….