HDMBLM Rijeka 2015.

8th Congress of the Croatian society of medical biochemistry and laboratory medicine with international participation

22 – 26 September 2015, Rijeka, Croatia

State-of-the-art of Laboratory Quality Indicators

Mario Plebani

University-Hospital of Padova, Italy

Outline of Talk

- Quality in laboratory medicine
- Quality indicators (QIs): definition and aims
- QIs in laboratory medicine
- QIs and state-of-the art
- QIs: harmonization and performance criteria
- QIs and state-of-the art
- Take home messages

Outline of Talk

- **Quality in laboratory medicine**
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- Take home messages

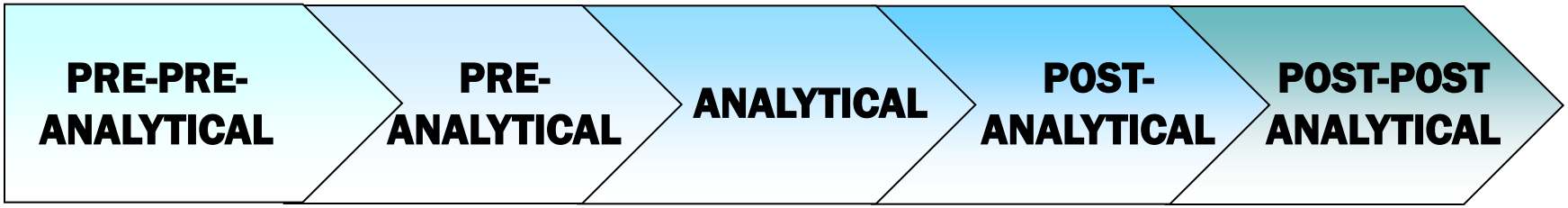
Quality in Laboratory Medicine

Quality in laboratory medicine should be defined as the guarantee that ***each*** and ***every step*** in the total testing process is ***correctly*** performed, thus ensuring ***valuable decision making*** and ***effective patient care***.

Plebani M. Clin Biochem Rev 2012

Ensuring Quality in Laboratory Services

(a patient-centered view)



- Right test
- Right patient
- Right specimen

- Right sample handling

- Right (accurate) results

- Right laboratory report

- Right physician acknowledgement, interpretation and utilization

Criteria for Quality Testing

- **Right** test, for the right patient
- **Right** time for specimen collection
- **Right** specimen and processing

Pre-analytical

- **Right** test result generated

Analytical

- **Right** test result reported, acknowledged and interpreted

Post-analytical

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

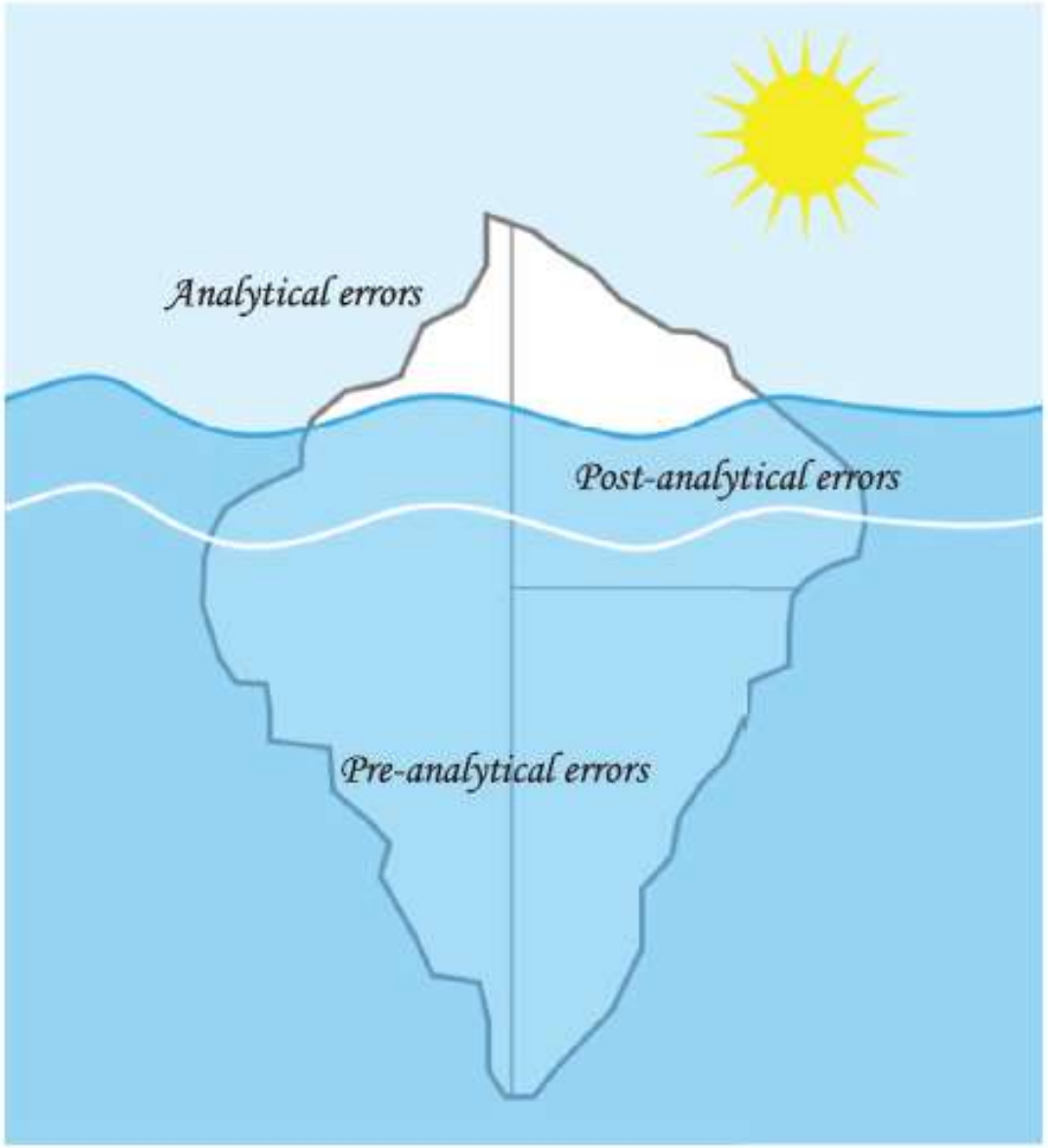
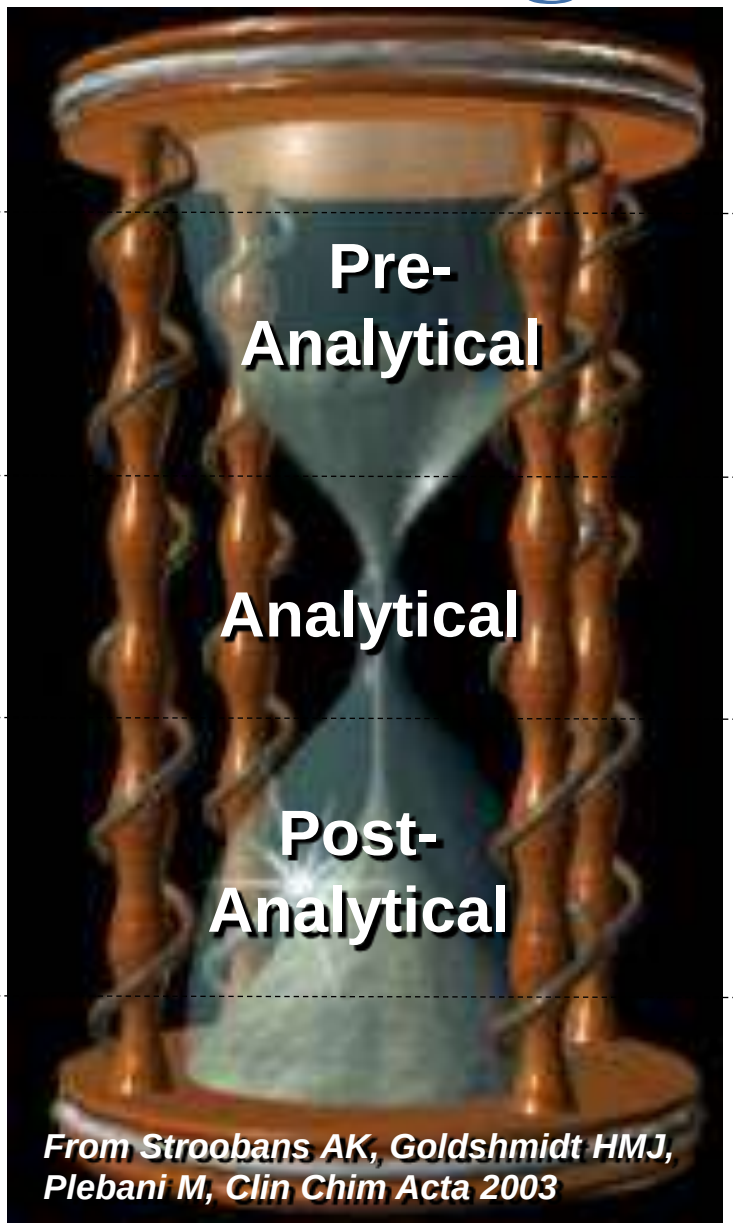


Figure 1 The iceberg of laboratory errors.

Errors in Laboratory Medicine - The hourglass model -



From Stroobans AK, Goldshmidt HMJ, Plebani M, Clin Chim Acta 2003

	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%

What is the link between
quality, ***errors*** and ***patient safety***
in laboratory medicine?

Missed or delayed diagnoses and failure to order appropriate diagnostic or laboratory tests

Clinical Setting	Incidence (%)	Position in the rank	References
Ambulatory	55	1°	Gandhi TK et al, Ann Int Med 2006
Emergency Depts	58	1°	Kachalia A et al, Ann Emerg Med 2007
Internal Medicine	18	2°	Graber ML et al, Arch Int Med 2005
General and Medical Subspecialty Divisions	44	1°	Schiff GD et al, Arch Int Med 2009
Pediatrics	35	5°	Singh H et al, Pediatrics 2010

DIAGNOSTIC ERRORS IN TEST ORDERING and INTERPRETATION

Setting	Primary care	Internal medicine	ED
Failure to order an appropriate diagnostic test	55%	28%	58%
Incorrect interpretation	37%	38%	37%

Gandhi TK et al. Ann Int Med 2006
Kachalia A. et al. Ann Emerg Med 2007
Graber ML et al. Arch Int Med 2005

DE GRUYTER DOI 10.1515/dx-2013-0030 — Diagnosis 2014; 1(1): 89–94

Mario Plebani*

Laboratory-associated and diagnostic errors: a neglected link

Table 1 The evolving concept of laboratory errors towards patient safety.

years			
1950–1990	**1990s**	**2000s**	**Today**
Analytical errors	Errors in clinical laboratories	Errors in laboratory medicine (laboratory-associated errors)	Testing-related diagnostic errors

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Quality Indicators

The **science of measuring health status** has improved, as has the evidence supporting "best practices" that have been proven to lead to improvements in health status.

This evidence base has allowed for the development of numerous ***quality indicators***, which then have been tested for ***reliability***, ***validity***, ***ease of use***, and ***usefulness*** for improving quality.

Quality Indicators

Health care quality indicators provide an ***important tool for measuring the quality of care***. Indicators are based on evidence of "best practices" in health care that have been proven to lead to improvements in health status and thus can be used to assess, track, and monitor provider performance.

"More recent assessments using the indicators have been included in public reports intended to steer patients toward higher-quality care and drive providers to improve their scores in order to bolster their public reputation".

Patient Safety and Quality of Care

- It has been documented that ***performance and outcome measures*** can ***improve the quality*** of care.
- Such measures have supported ***accountability***, helped to make judgments and ***set priorities***, enabling comparison over time between providers and the ***effectiveness of interventions***.

Mainz J. 2004

Quality Indicators

- ***Quality indicators*** are explicitly defined and ***measurable*** items referring to the structures, processes or outcomes of care, namely laboratory services.
- They infer a ***judgment*** about the ***quality*** of care provided: they do not provide definitive answers but ***indicate potential problems*** or good quality of laboratory services.

Campbell SM et al. BMJ 2003
Plebani M et al. CCLM 2015

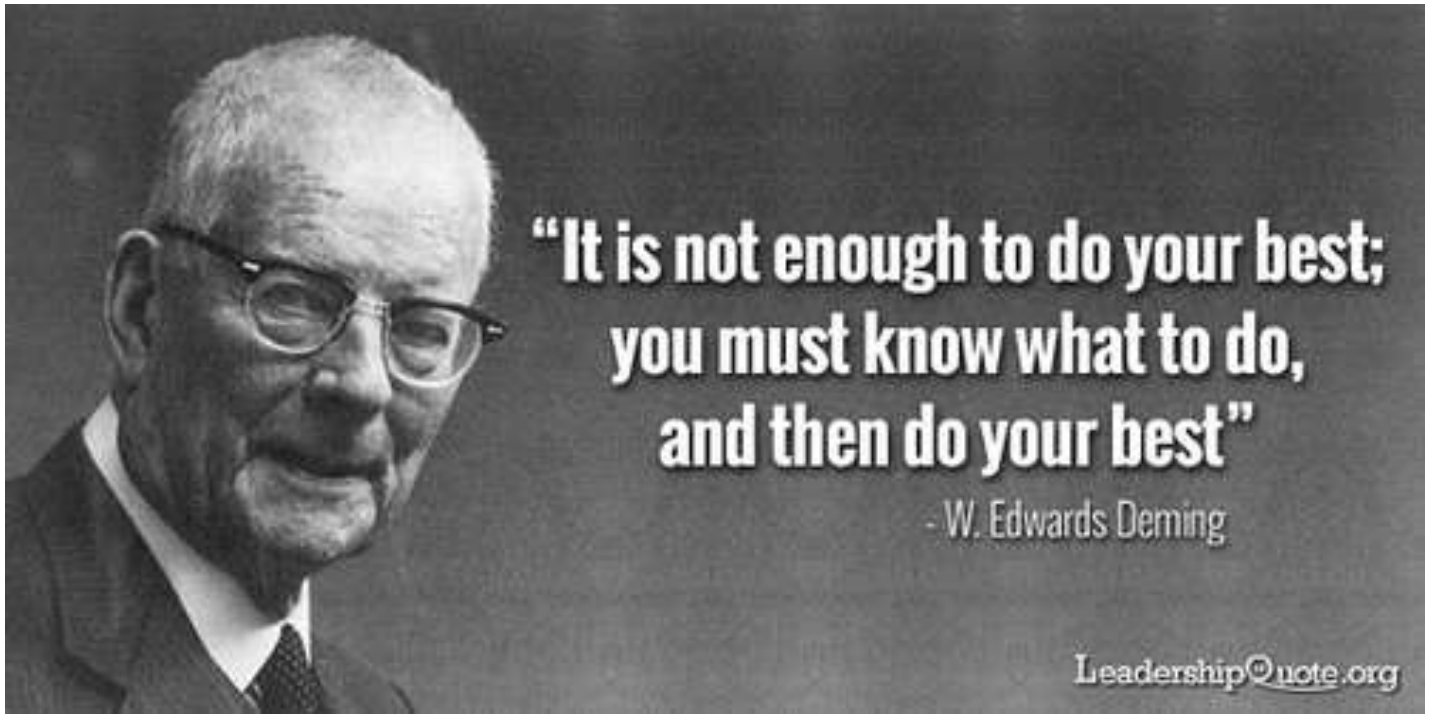
Quality Indicators

- The identification of reliable ***quality indicators*** (QIs) is a crucial step in enabling users to ***quantify*** the quality of a selected aspect of care by comparing it against a defined criterion (IOM).
- A quality indicator is thus “an ***objective measure*** that potentially evaluates all critical care domains as defined by the IOM (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficiency), that is based on ***evidence*** associated with those domains, and can be implemented in a consistent and comparable across settings and over time”.

Quality Indicators

The true rationale:

"you cannot manage what you cannot measure"



ERRORS
in the
Total Testing Process

Quality Indicators

Identification, Documentation, Corrective and Preventive actions

Risk Management
in the
Total Testing Process

Quality Improvement
and
Errors Reduction

Outline of Talk

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QUALITY INDICATORS IN LABORATORY MEDICINE: RATIONALE

- The definition of ***quality*** in laboratory medicine
- The ***nature of errors*** in laboratory medicine
- The need to avoid laboratory-related errors (a ***patient safety issue***)
- The need of tools enabling the laboratory to ***identify***, ***correct***, and ***monitor*** problems in all steps of the testing cycle
- The compliance with some specific ***requirements*** of the International Standard for Laboratory Accreditation (***ISO 15189***)

Quality Indicators in Laboratory Medicine

QI are about measuring our contribution to patient care

- **Patient safety**
- **Clinical effectiveness**
- **Patient-centred**
- **Timely**
- **Efficient**
- **Equitability**

Clinical QI are about doing the

"***the right test*** on the ***right person*** at the ***right time***, with a ***right analytical performance*** and ***interpreting*** that test correctly".

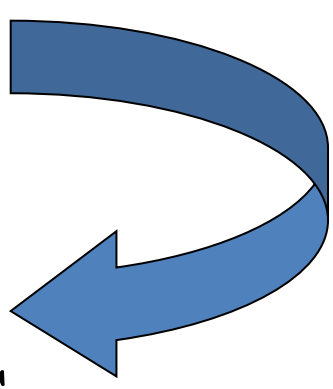
Why do we need Quality Indicators ?

Valuable source of information for:

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

PATIENT SAFETY and QUALITY INDICATORS

Quality Indicators

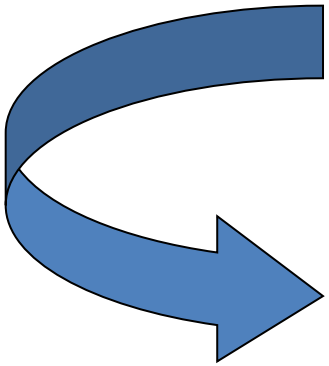


Process Measures

-Harmonization

-Metric

-Performance specifications



Outcome Measures

- Work in progress

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 aspects 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

BS EN ISO 15189:2012

BSI Standards Publication

Medical laboratories — Requirements for quality and competence (ISO 15189:2012)

PATIENT SAFETY and QUALITY INDICATORS

LABORATORY INDICATORS: WHAT IS OBVIOUS?

The most critical performance indicator for medical laboratories is the delivery of accurate test results.

Ravine D, Suthers G. J Clin Pathol 2012

Laboratory Medicine Quality Indicators

A Review of the Literature

Shahram Shahangian, PhD, MS, and Susan R. Snyder, PhD, MBA

14 laboratory quality indicators have been identified in the literature meeting the following criteria:

a) previousy used quantitative measure associated with laboratory testing or service;

b) measure potentially related to at least 1 IOM health care domain;

Laboratory Medicine Quality Indicators

A Review of the Literature

Shahram Shahangian, PhD, MS, and Susan R. Snyder, PhD, MBA

Table 1
Laboratory Medicine Quality Indicators by Stage of the Total Testing Process

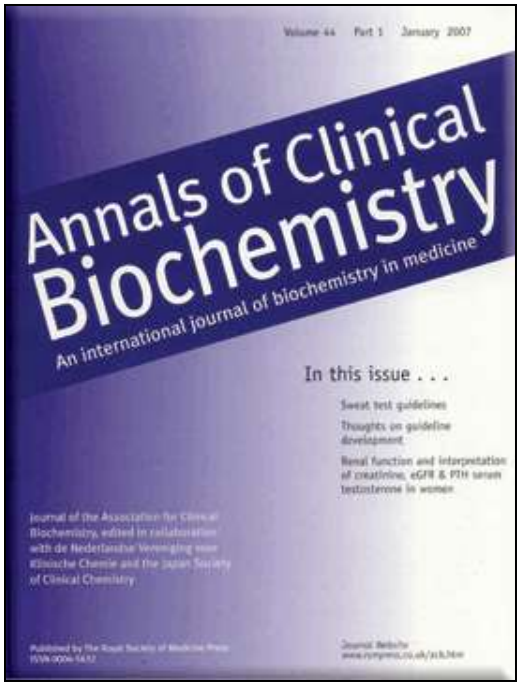
Stage	IOM Domains*
Test ordering	
Test order appropriateness†	Effectiveness, efficiency, timeliness
Patient identification/specimen collection	
Inpatient wristband identification error	Safety
Patient satisfaction with phlebotomy	Patient-centeredness
Specimen identification, preparation, and transport	
Specimen inadequacy/rejection	Effectiveness, efficiency, safety, timeliness
Blood culture contamination	Efficiency, safety
Specimen container information error	Efficiency, safety
Analysis	
Proficiency testing performance	Safety
Gynecologic cytology-biopsy discrepancy	Effectiveness, efficiency, safety
Result reporting	
Inpatient laboratory result availability	Patient-centeredness, timeliness
Corrected laboratory reports	Efficiency, safety
Critical values reporting	Safety, timeliness
Turnaround time	Timeliness
Clinician satisfaction with laboratory services	Effectiveness, timeliness
Result interpretation and ensuing action	
Follow-up of abnormal cervical cytology results	Effectiveness, timeliness

Table 2 Analytical

Turnaround times are discussed with your clinicians	75%
Internal evaluations of new methods made prior to implementation	84%
Assay precision determined at critical concentrations for any assays	55%
Reference ranges are determined in your laboratory on locally sourced samples	42%
There is a trust point-of-care committee	67%

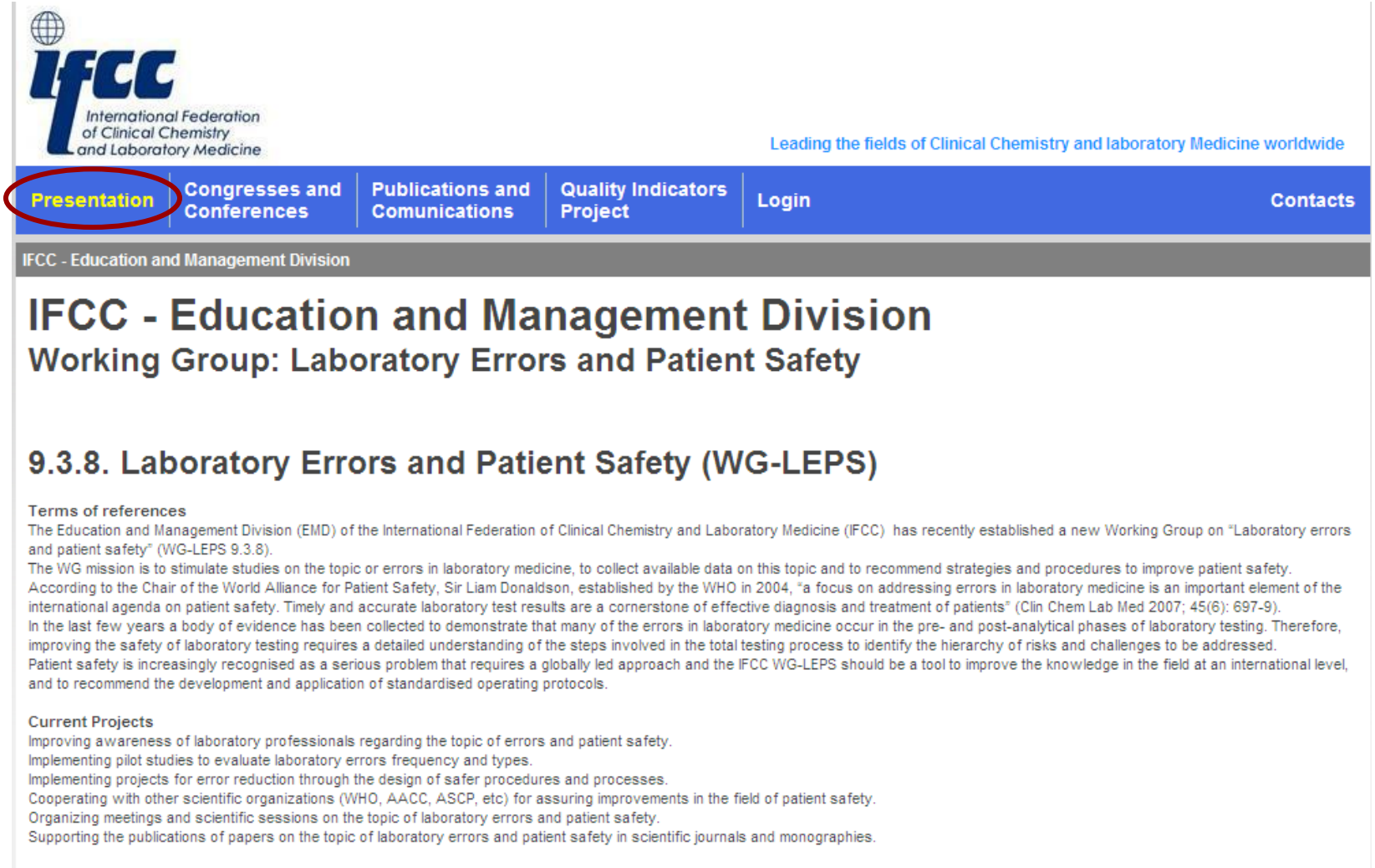
Table 3 Postanalytical

There is a process for demand management	43%
Laboratory provides help and advice in interpreting clinical laboratory data	80%
There is an audit of the effect of added interpretative comments	16%
There is a written critical limits (alert) list	58%
There is a record of the number of calls/emails/letters received for clinical advice	18%
Proportion of requests with additional tests added by laboratory	13% response
There are automatic reflex tests via reporting rules	57%



Ann Clin Biochem 2011: 48: 238-40

www.ifcc-mqi.com



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IFCC - Education and Management Division

IFCC - Education and Management Division
Working Group: Laboratory Errors and Patient Safety

9.3.8. Laboratory Errors and Patient Safety (WG-LEPS)

Terms of references

The Education and Management Division (EMD) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has recently established a new Working Group on "Laboratory errors and patient safety" (WG-LEPS 9.3.8).

The WG mission is to stimulate studies on the topic or errors in laboratory medicine, to collect available data on this topic and to recommend strategies and procedures to improve patient safety.

According to the Chair of the World Alliance for Patient Safety, Sir Liam Donaldson, established by the WHO in 2004, "a focus on addressing errors in laboratory medicine is an important element of the international agenda on patient safety. Timely and accurate laboratory test results are a cornerstone of effective diagnosis and treatment of patients" (Clin Chem Lab Med 2007; 45(6): 697-9).

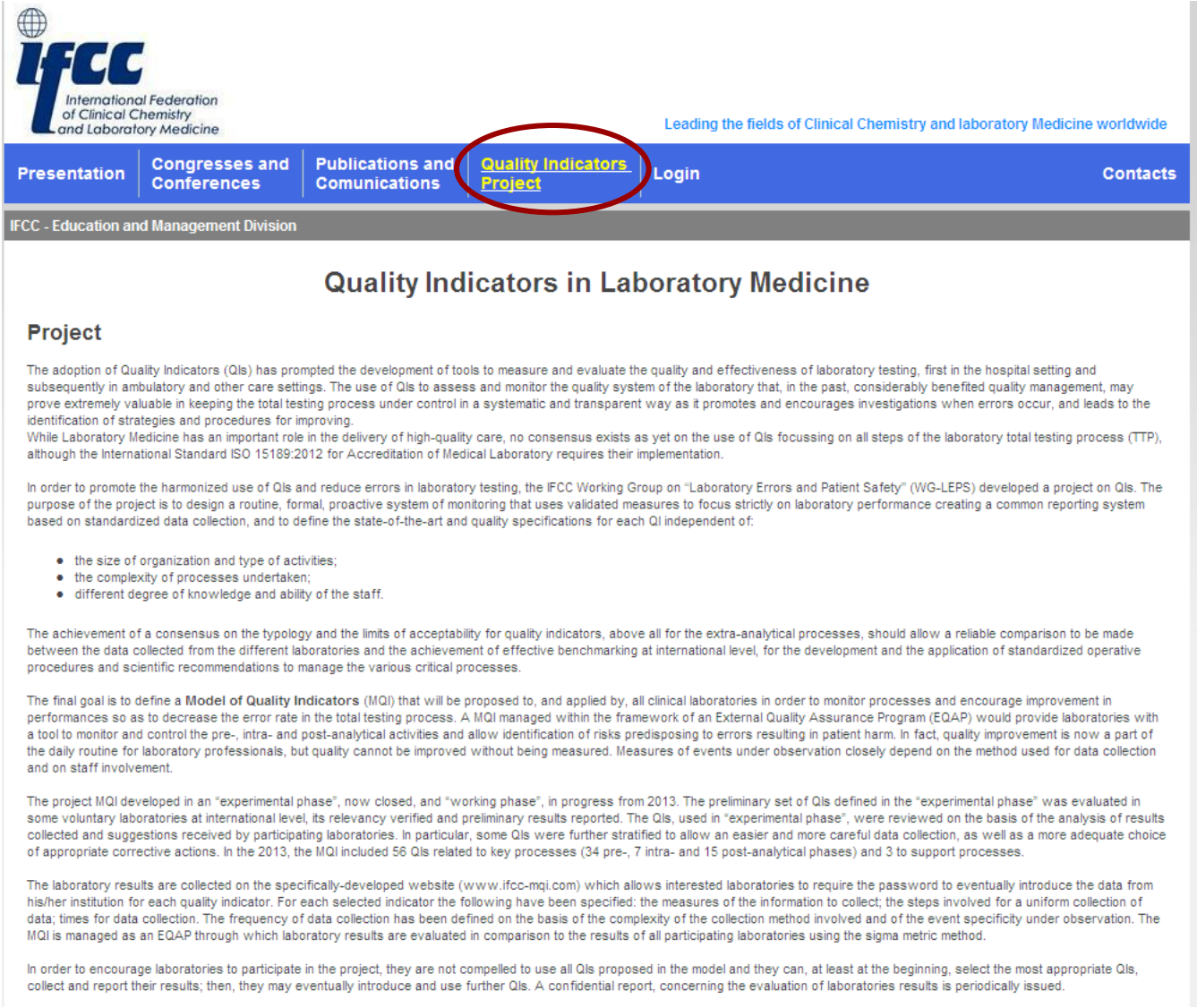
In the last few years a body of evidence has been collected to demonstrate that many of the errors in laboratory medicine occur in the pre- and post-analytical phases of laboratory testing. Therefore, improving the safety of laboratory testing requires a detailed understanding of the steps involved in the total testing process to identify the hierarchy of risks and challenges to be addressed.

Patient safety is increasingly recognised as a serious problem that requires a globally led approach and the IFCC WG-LEPS should be a tool to improve the knowledge in the field at an international level, and to recommend the development and application of standardised operating protocols.

Current Projects

Improving awareness of laboratory professionals regarding the topic of errors and patient safety.
Implementing pilot studies to evaluate laboratory errors frequency and types.
Implementing projects for error reduction through the design of safer procedures and processes.
Cooperating with other scientific organizations (WHO, AACC, ASCP, etc) for assuring improvements in the field of patient safety.
Organizing meetings and scientific sessions on the topic of laboratory errors and patient safety.
Supporting the publications of papers on the topic of laboratory errors and patient safety in scientific journals and monographies.

www.ifcc-mqi.com



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Quality Indicators in Laboratory Medicine

Project

The adoption of Quality Indicators (QIs) has prompted the development of tools to measure and evaluate the quality and effectiveness of laboratory testing, first in the hospital setting and subsequently in ambulatory and other care settings. The use of QIs to assess and monitor the quality system of the laboratory that, in the past, considerably benefited quality management, may prove extremely valuable in keeping the total testing process under control in a systematic and transparent way as it promotes and encourages investigations when errors occur, and leads to the identification of strategies and procedures for improving.
While Laboratory Medicine has an important role in the delivery of high-quality care, no consensus exists as yet on the use of QIs focussing on all steps of the laboratory total testing process (TTP), although the International Standard ISO 15189:2012 for Accreditation of Medical Laboratory requires their implementation.

In order to promote the harmonized use of QIs and reduce errors in laboratory testing, the IFCC Working Group on "Laboratory Errors and Patient Safety" (WG-LEPS) developed a project on QIs. The purpose of the project is to design a routine, formal, proactive system of monitoring that uses validated measures to focus strictly on laboratory performance creating a common reporting system based on standardized data collection, and to define the state-of-the-art and quality specifications for each QI independent of:

- the size of organization and type of activities;
- the complexity of processes undertaken;
- different degree of knowledge and ability of the staff.

The achievement of a consensus on the typology and the limits of acceptability for quality indicators, above all for the extra-analytical processes, should allow a reliable comparison to be made between the data collected from the different laboratories and the achievement of effective benchmarking at international level, for the development and the application of standardized operative procedures and scientific recommendations to manage the various critical processes.

The final goal is to define a **Model of Quality Indicators** (MQI) that will be proposed to, and applied by, all clinical laboratories in order to monitor processes and encourage improvement in performances so as to decrease the error rate in the total testing process. A MQI managed within the framework of an External Quality Assurance Program (EQAP) would provide laboratories with a tool to monitor and control the pre-, intra- and post-analytical activities and allow identification of risks predisposing to errors resulting in patient harm. In fact, quality improvement is now a part of the daily routine for laboratory professionals, but quality cannot be improved without being measured. Measures of events under observation closely depend on the method used for data collection and on staff involvement.

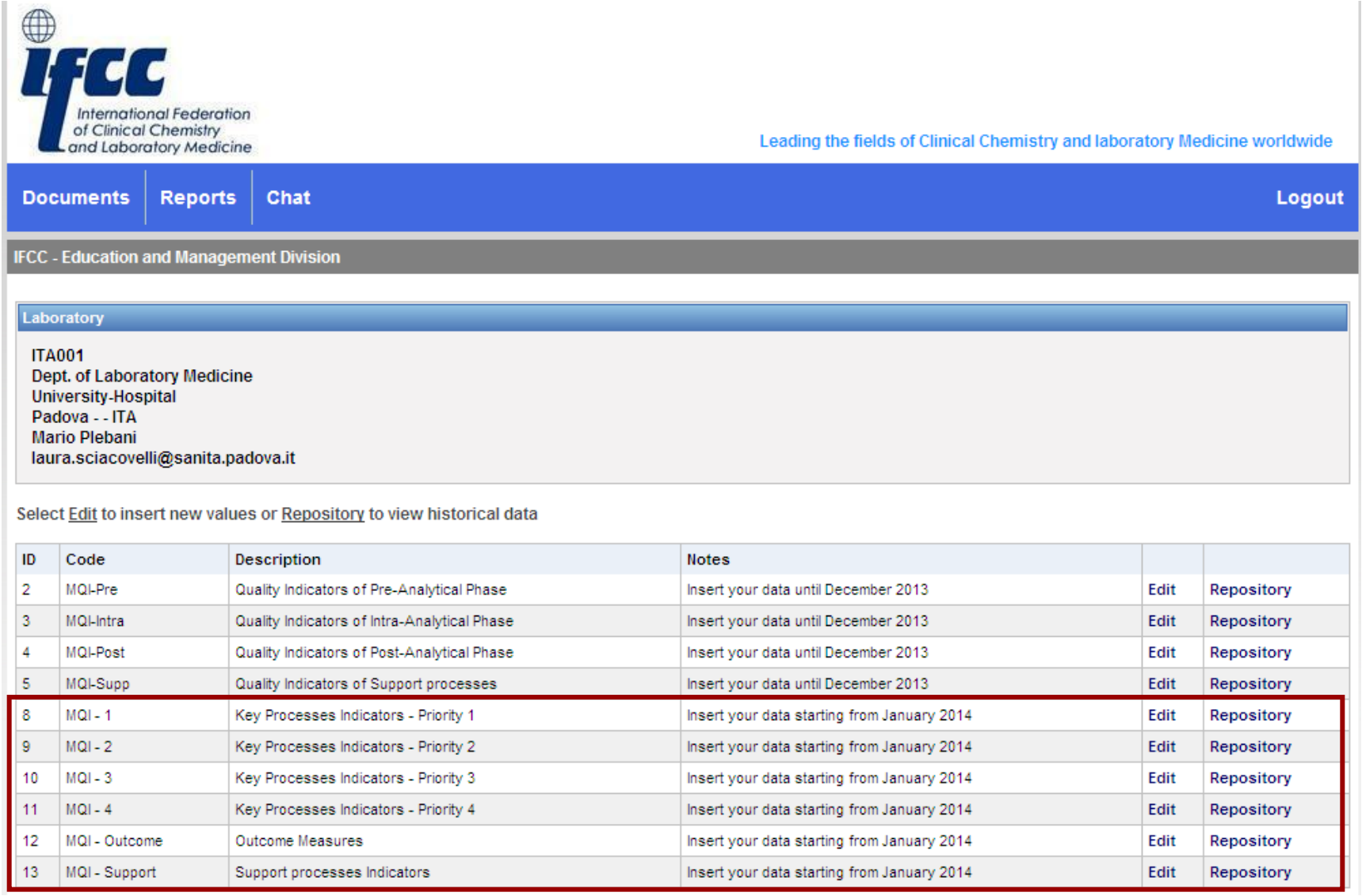
The project MQI developed in an "experimental phase", now closed, and "working phase", in progress from 2013. The preliminary set of QIs defined in the "experimental phase" was evaluated in some voluntary laboratories at international level, its relevancy verified and preliminary results reported. The QIs, used in "experimental phase", were reviewed on the basis of the analysis of results collected and suggestions received by participating laboratories. In particular, some QIs were further stratified to allow an easier and more careful data collection, as well as a more adequate choice of appropriate corrective actions. In the 2013, the MQI included 56 QIs related to key processes (34 pre-, 7 intra- and 15 post-analytical phases) and 3 to support processes.

The laboratory results are collected on the specifically-developed website (www.ifcc-mqi.com) which allows interested laboratories to require the password to eventually introduce the data from his/her institution for each quality indicator. For each selected indicator the following have been specified: the measures of the information to collect; the steps involved for a uniform collection of data; times for data collection. The frequency of data collection has been defined on the basis of the complexity of the collection method involved and of the event specificity under observation. The MQI is managed as an EQAP through which laboratory results are evaluated in comparison to the results of all participating laboratories using the sigma metric method.

In order to encourage laboratories to participate in the project, they are not compelled to use all QIs proposed in the model and they can, at least at the beginning, select the most appropriate QIs, collect and report their results; then, they may eventually introduce and use further QIs. A confidential report, concerning the evaluation of laboratories results is periodically issued.

www.ifcc-mqi.com

www.ifcc-mqi.com



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Laboratory

ITA001
Dept. of Laboratory Medicine
University-Hospital
Padova - - ITA
Mario Plebani
laura.sciacovelli@sanita.padova.it

Select Edit to insert new values or Repository to view historical data

ID	Code	Description	Notes		
2	MQI-Pre	Quality Indicators of Pre-Analytical Phase	Insert your data until December 2013	Edit	Repository
3	MQI-Intra	Quality Indicators of Intra-Analytical Phase	Insert your data until December 2013	Edit	Repository
4	MQI-Post	Quality Indicators of Post-Analytical Phase	Insert your data until December 2013	Edit	Repository
5	MQI-Supp	Quality Indicators of Support processes	Insert your data until December 2013	Edit	Repository
8	MQI - 1	Key Processes Indicators - Priority 1	Insert your data starting from January 2014	Edit	Repository
9	MQI - 2	Key Processes Indicators - Priority 2	Insert your data starting from January 2014	Edit	Repository
10	MQI - 3	Key Processes Indicators - Priority 3	Insert your data starting from January 2014	Edit	Repository
11	MQI - 4	Key Processes Indicators - Priority 4	Insert your data starting from January 2014	Edit	Repository
12	MQI - Outcome	Outcome Measures	Insert your data starting from January 2014	Edit	Repository
13	MQI - Support	Support processes Indicators	Insert your data starting from January 2014	Edit	Repository

Quality Indicators

Key Processes

Pre-analytical phase	→	34
Intra-analytical phase	→	7
Post-analytical phase	→	15

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Laboratory Quality Indicators Around the World

Association for Clinical Biochemistry

CDC
AHRQ

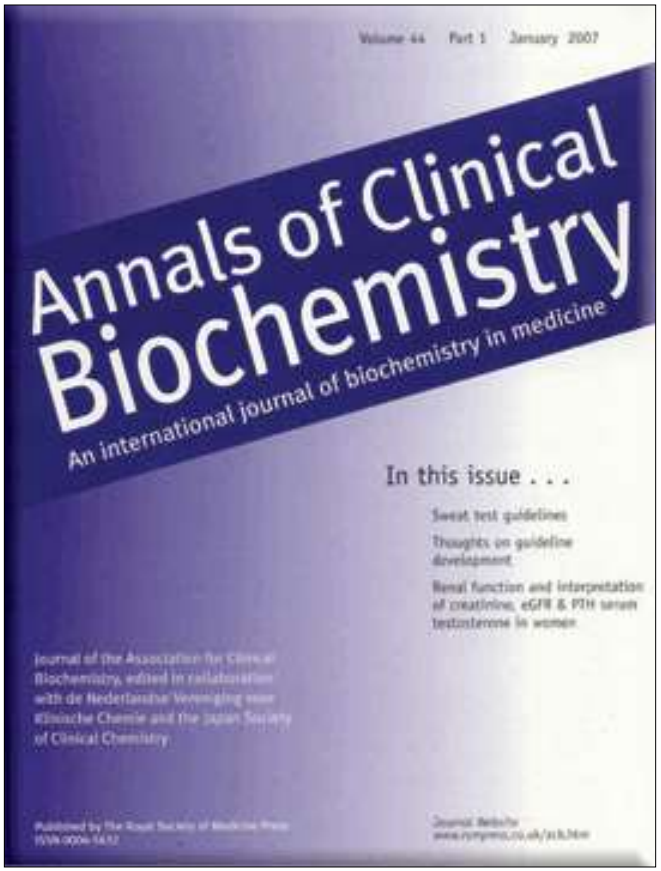
Survey on extra-analytical phase

Sociedad Espagnola de Bioquìmica Clinica y Patologia

Health Minister

BR

RCPA
KIMMS



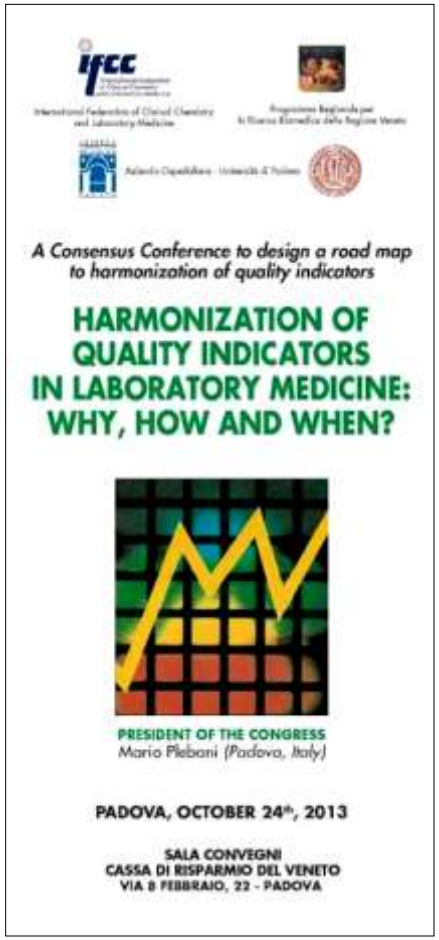
Quality indicators for laboratory diagnostics: consensus is needed

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

CRITERIA FOR HARMONIZATION



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

A quality indicator needs to have:

- A ***title***
- ***Definition***: what exactly are we measuring?
- ***Rationale***: why we are measuring it?
- ***Goal***: what performance do we expect?
- ***Classification***: what can be it used to evaluate?
- ***Methodology***: how do we measure it and what are the limitations of the measurement?
- ***Data presentation***: how do we communicate the information?

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

Quality Indicators 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**)

Laboratory Error

Failure of a planned action to be completed as intended, or use of a wrong plan to achieve an aim, occurring at ***any part of the laboratory cycle, from ordering examinations*** to reporting results and appropriately interpreting and reacting to them.


TECHNICAL SPECIFICATION

ISO/TS 22367

Medical laboratories — Reduction of error through risk management and continual improvement

ISO

ISO/TS 22367: 2008

Quality Indicators in Laboratory Medicine: Criteria for Harmonization

In addition, the process of harmonization of QIs includes **two** compulsory steps:

1. Identification of **common QIs**
2. **Standardization of the reporting** system.

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

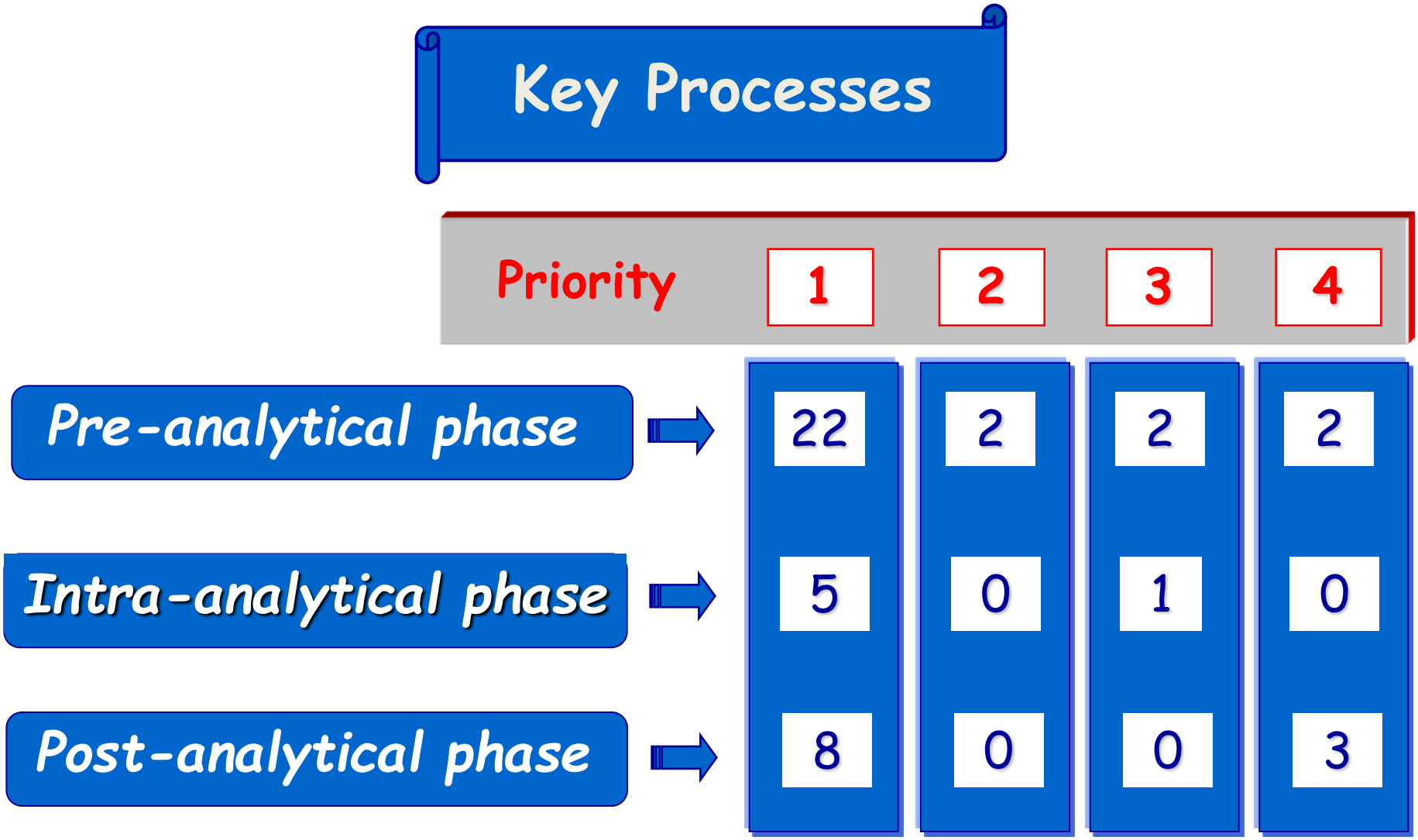
Opinion paper

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

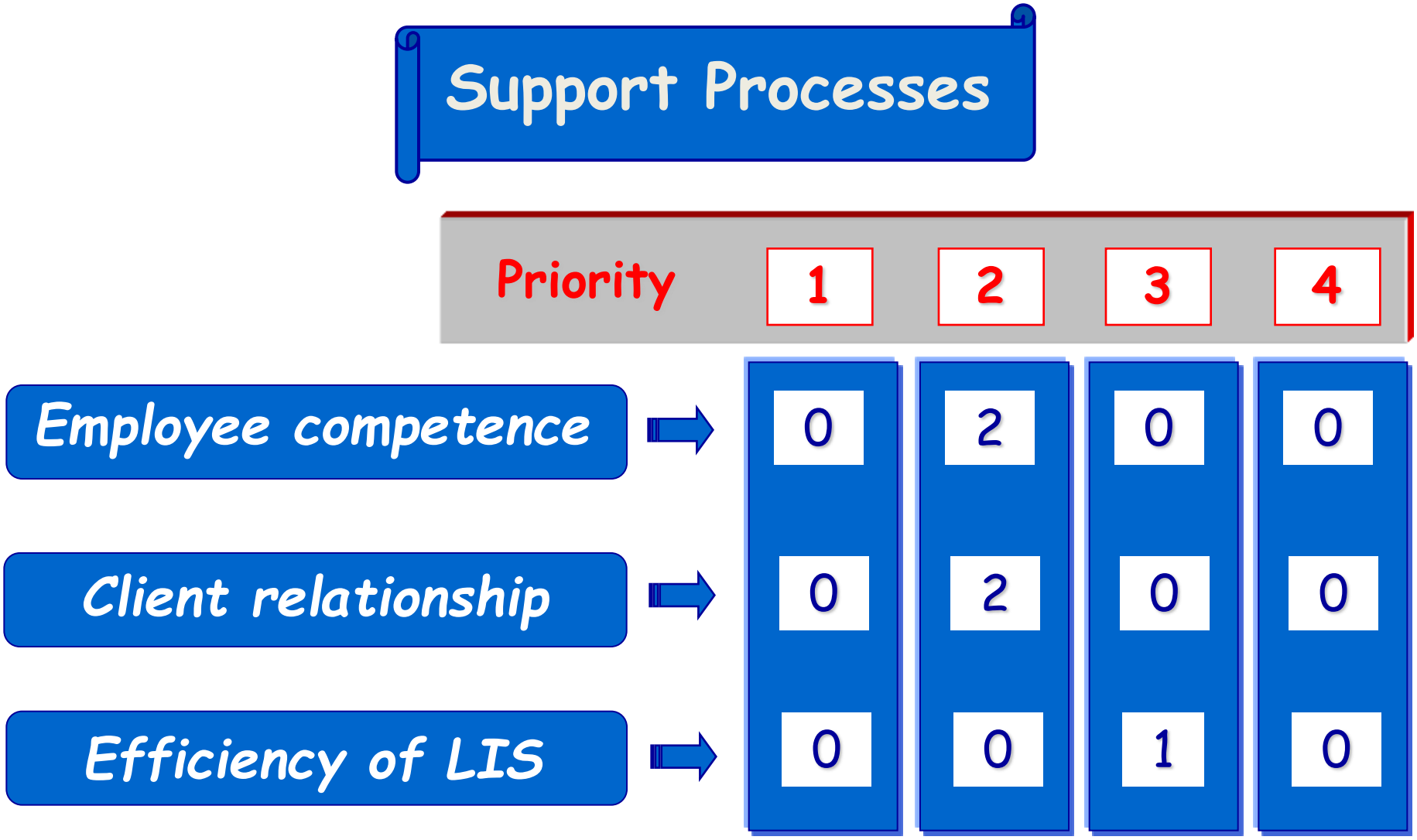
Harmonization of quality indicators in laboratory medicine. A preliminary consensus

mario.plebani@unipd.it

Quality Indicators



Quality Indicators



Quality Indicators

Outcome Measures

Priority 1

Sample recollection → 2

Inaccurate results → 1

PRE-ANALYTICAL QIs

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.

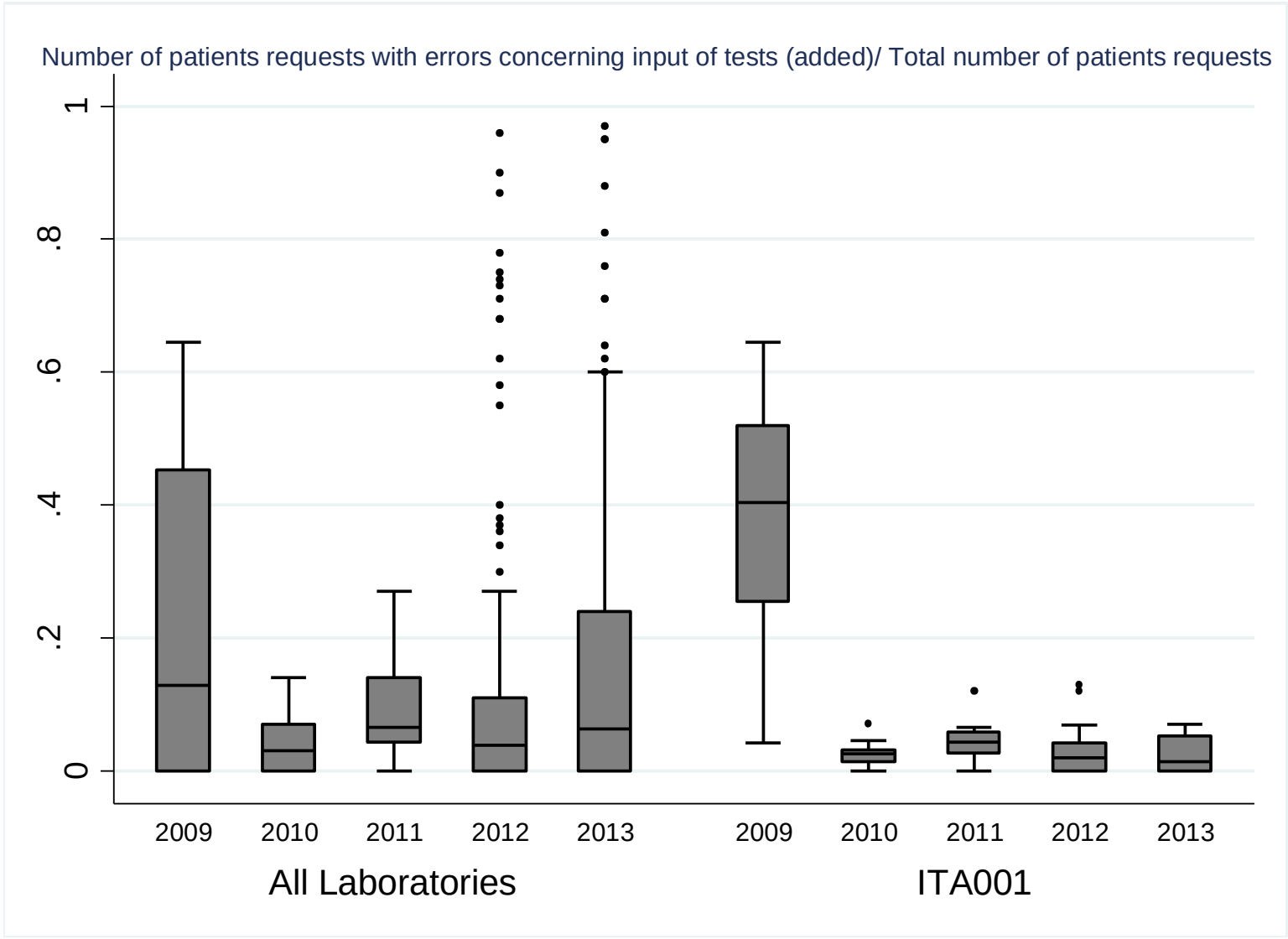
Quality Indicators

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.

Requests with erroneous data entry (added test): error percentage



Quality Indicators

Pre-Analytical Processes: Priority 1

Incorrect sample type

Pre-WroTy	Number of samples of wrong or inappropriate type (i.e. whole blood instead of plasma)/ Total number of samples.
Pre-WroCo	Number of samples collected in wrong container/ Total number of samples.

Incorrect fill level

Pre-InsV	Number of samples with insufficient sample volume/ Total number of samples.
Pre-SaAnt	Number of samples with inappropriate sample-anticoagulant volume ratio/ Total number of samples with anticoagulant.

Quality Indicators

Pre-Analytical Processes: Priority 1

Unsuitable samples for transportation and storage problems

Pre-NotRec	Number of samples not received/ Total number of samples.
Pre-NotSt	Number of samples not properly stored before analysis / Total number of samples.
Pre-DamS	Number of samples damaged during transportation/ Total number of samples.
Pre-InTem	Number of samples transported at inappropriate temperature/Total number of samples.
Pre-ExcTim	Number of samples with excessive transportation time/ Total number of samples.

Contaminated samples

Pre-MicCon	Number of contaminated samples rejected/ Total number of microbiological samples.

Quality Indicators

Pre-Analytical Processes: Priority 1

Sample haemolysed

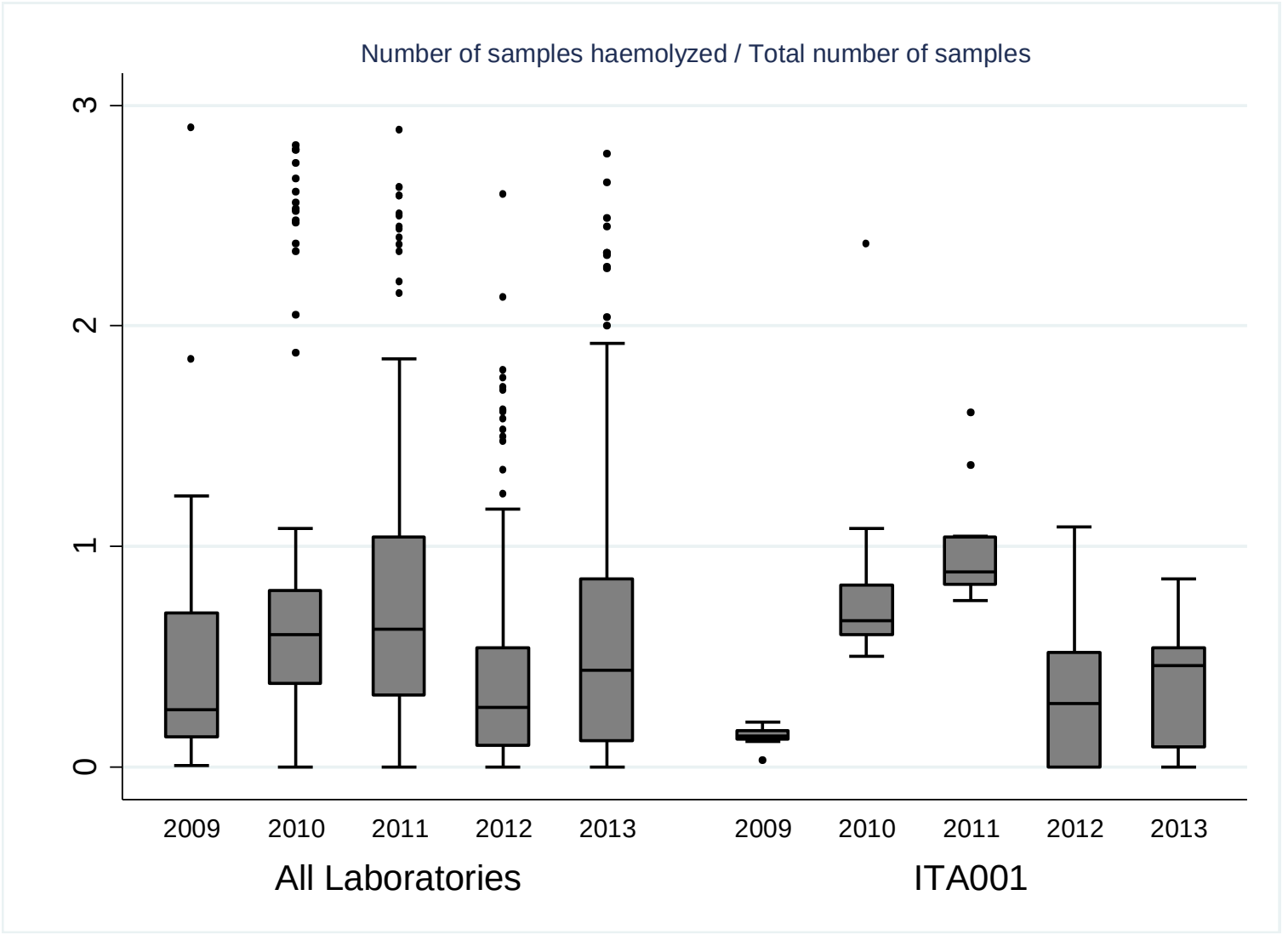
Pre-Hem	Number of samples with free Hb>0.5 g/L (clinical chemistry)/ Total number of samples (clinical chemistry)*

**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.*

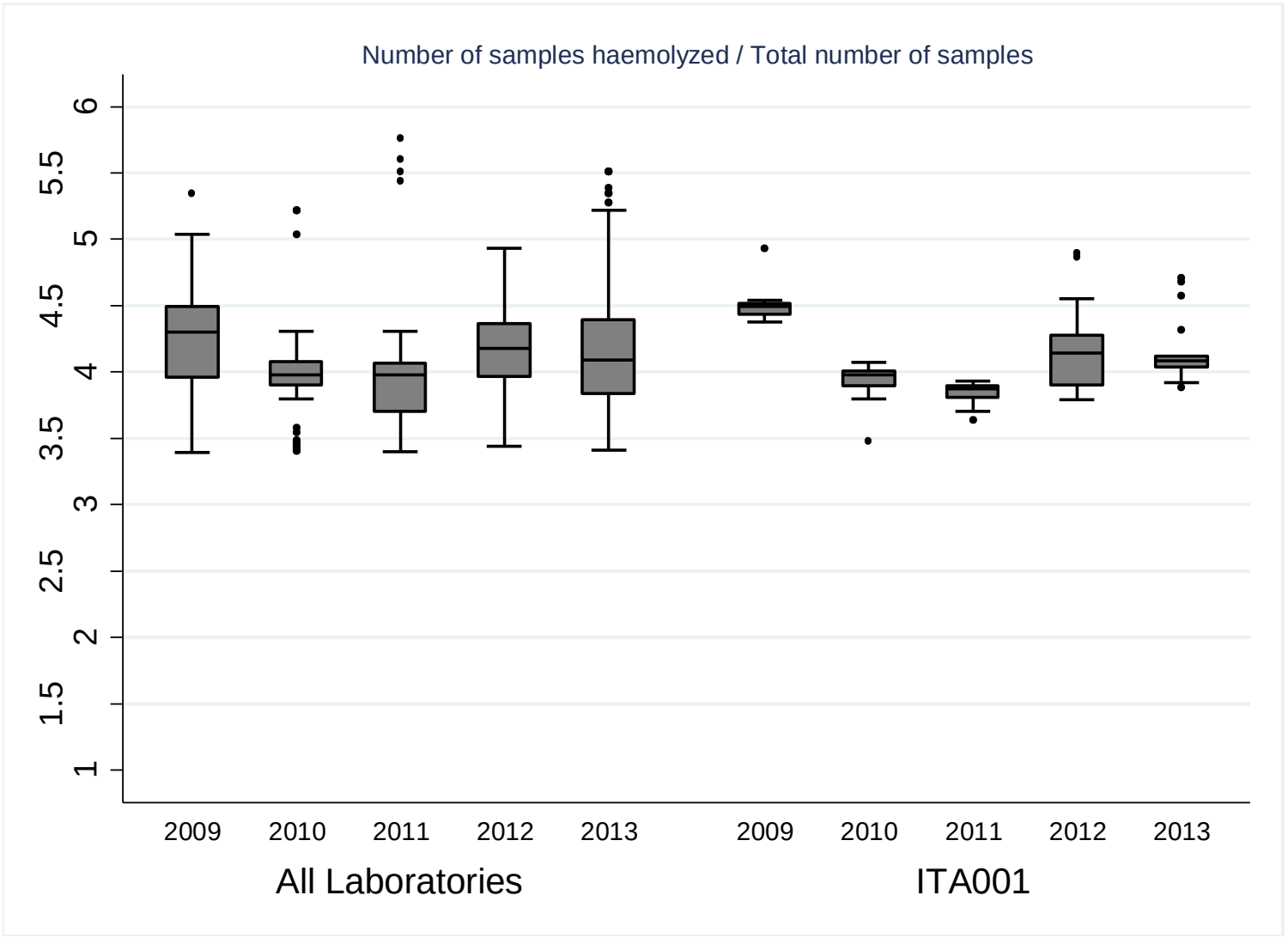
Samples clotted

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

Haemolyzed sample: error percentage

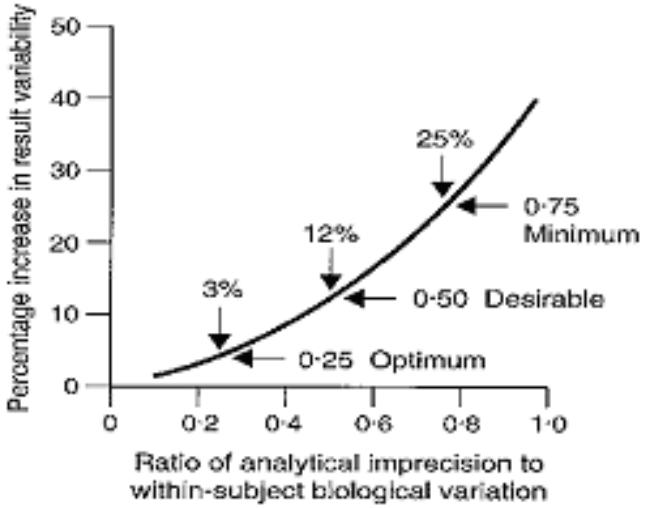


Haemolyzed sample: sigma values



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.



Quality Specifications

	Range	*Median*	*Specifications*	
Specimen not received	**2.0 - 6.1**	**2.9**	**2.0**	**Optimum**
			4.0	**Desirable**
			6.0	**Minimum**
Specimen insufficient	**0.07 - 0.8**	**0.15**	**0.07**	**Optimum**
			0.44	**Desirable**
			0.8	**Minimum**
Wrong container	**0.02 - 0.2**	**0.03**	**0.02**	**Optimum**
			0.11	**Desirable**
			0.2	**Minimum**

Quality Indicators

Pre-Analytical Processes

Quality Indicators		Performance Specifications *on the basis of 25th - 50th - 75th percentile*		
		Minimum	**Desirable**	**Optimum**
Misidentification errors	*Percentage*	0.040	0.010	0
	Sigma	4.54	5.04	5.25
Test transcription Errors (added tests)	*Percentage*	0.240	0.070	0
	Sigma	4.26	4.59	4.74
Sample haemolysed	*Percentage*	0.852	0.440	0.120
	Sigma	3.84	4.09	4.39

POST-ANALYTICAL QIs

Quality Indicators

Post-Analytical Processes

Quality of reports

Post-Comm ***-Priority 4-***	Percentage of: Number of reports with Interpretative comments impacting positively on patient's outcome/Total number of reports.
Post-IncRep ***-Priority 1-***	Percentage of: Number of incorrect reports issued by the laboratory / Total number of reports issued by the laboratory.
Post-OutTime ***-Priority 1-***	Percentage of: Number of reports delivered outside the specified time/ Total number of reports.

Quality Indicators

Post-Analytical Processes

Quality Indicators		Performance Specifications *on the basis of 25th-50th – 75th percentile*		
		Minimum	**Desirable**	**Optimum**
Percentage of: Number of reports with interpretative comments impacting positively on patient's outcome/ Total number of reports with interpretative comments **(Post-Comm)**	*Percentage*	0.12	32.2	62.5
	Sigma	1.699	1.967	4.429
Percentage of: Number of incorrect reports issued by the laboratory / Total number of reports issued by the laboratory **(Post-IncRep)**	*Percentage*	0.035	0	0
	Sigma	4.621	4.791	4.932
Percentage of: Number of reports delivered outside the specified time/ Total number of reports.**(Post-OutTime)**	*Percentage*	0.13	0	0
	Sigma	3.782	4.508	4.793

Quality Indicators

Post-Analytical Processes

Turn-Around-Time

Post-INRTAT ***-Priority 1-***	Turn Around Time (minutes) of International Normalized Ratio (INR) value at 90th percentile (STAT).
Post-PotTAT ***-Priority 1-***	Turn Around Time (minutes) of Potassium (K) at 90th percentile (STAT).
Post-TnTAT ***-Priority 1-***	Turn Around Time (minutes) of Troponin I (TnI) or Troponin T (TnT) at 90th percentile (STAT).
Post-WBCTAT ***-Priority 1-***	Turn Around Time (minutes) of White Blood Cell Count (WBC) at 90th percentile (STAT).

Quality Indicators

Post-Analytical Processes

Quality Indicators		Performance Specifications *on the basis of 25th -50th – 75th percentile*		
		Minimum	**Desirable**	**Optimum**
Turn Around Time (minutes) of International Normalized Ratio (INR) value at 90th percentile (STAT).	*Time*	61	54	39
Turn Around Time (minutes) of Potassium (K) at 90th percentile (STAT).	*Time*	65.5	56.0	38.5
Turn Around Time (minutes) of Troponin I (TnI) or Troponin T (TnT) at 90th percentile (STAT).	*Time*	78.0	66.0	49.0
Turn Around Time (minutes) of White Blood Cell Count (WBC) at 90th percentile (STAT).	*Time*	47.40	26.0	18.95

Quality Indicators

Post-Analytical Processes

Notification of Critical Values

Post-OutCV ***-Priority 1-***	Percentage of: Number of critical values of outpatients notified after a consensually agreed time (from result validation to result communication to the clinician) /Total number of critical values of outpatients to communicate.
Post-InpCV ***-Priority 1-***	Percentage of: Number of critical values of inpatients notified after a consensually agreed time (from result validation to result communication to the clinician) /Total number of critical values of inpatients to communicate**.**
Post-OutCVT ***-Priority 4-***	Time (from result validation to result communication to the clinician) to communicate critical values of outpatient (minutes).
Post-InCVT ***-Priority 4-***	Time (from result validation to result communication to the clinician) to communicate critical values of inpatients (minutes).

Quality Indicators

Post-Analytical Processes

Quality Indicators		Performance Specifications on the basis of 25th -50° th- 75° th percentile		
		Minimum	**Desirable**	**Optimum**
Percentage of: Number of **critical values** of outpatients notified after a consensually agreed time (from result validation to result communication to the clinician) /Total number of critical values of outpatients to communicate. **(Post-OutCV)**	*Percentage*	0	0	36.86
	Sigma	1.069	2.175	2.952
Percentage of: Number of critical values of inpatients notified after a consensually agreed time (from result validation to result communication to the clinician) /Total number of critical values of inpatients to communicate**. (Post-InpCV)**	*Percentage*	0	1.265	32.48
	Sigma	1.667	2.529	3.435
Time (from result validation to result communication to the clinician) to communicate critical values of outpatient (minutes) . **(Post-OutCVT)**	*Time*	60.0	6.5	2.7
Time (from result validation to result communication to the clinician) to communicate critical values of inpatients (minutes) . **(Post-InCVT)**	*Time*	6.0	5.0	3.5

OUTCOME MEASURES
pre-analytical phase

Measure	*Causes*
1) **Inappropriate test ordered**	- Cognitive problem - Defensive medicine issues - Misspelt test name - Misunderstanding of physician's request
2) **Appropriate test not ordered**	- Cognitive problem - Misspelt test name - Misunderstanding of physician's request - Test lost in translation (from physician's request to electronic or hard copy)

OUTCOME MEASURES post-analytical phase

Measure	*Causes*
▪ **Appropriate test ordered, but delay in TTP occurs**	- Delayed sample collection or transportation - Delayed analytical performance - Delayed transmission of results - Delayed acknowledgement by care operators/ physicians
▪ **Appropriate test result misapplied**	- Cognitive failure of clinicians - Available information incomplete - Wrong reference ranges or decision levels - No interpretative comment

OUTCOME MEASURES
post-analytical phase

Measure	*Causes*
• **Outpatients called back for procedures**	- Suspected patient/sample misidentification wrong - Unsuitable samples - Incorrect results - Suspected interference

Quality Indicators

Outcome Measures

Patient Safety

Out-InacR ***-Priority 1-***	Percentage of: Number of inaccurate results released/Total number of results released.
Out-RecInp ***-Priority 1-***	Percentage of: Number of inpatients with recollected samples for laboratory errors/ Total number of inpatients.
Out-RecOutp ***-Priority 1-***	Percentage of: Number of outpatients with recollected samples for laboratory errors/ Total number of outpatients**.**

Quality Indicators

Outcome Measures

Quality Indicators		Quality Specifications *on the basis of 25th -50th – 75th percentile*		
		Minimum	**Desirable**	**Optimum**
Percentage of: Number of inaccurate results released/Total number of results released **(Out-InacR)**	*Percentage*	0	0	0
	Sigma	4.363	4.562	5.04
Percentage of: Number of inpatients with recollected samples for laboratory errors/ Total number of inpatients **(Out-RecInp)**	*Percentage*	0	0	0
	Sigma	4.59	4.932	5.04
Percentage of: Number of outpatients with recollected samples for laboratory errors/ Total number of outpatients **(Out-RecOutp)**	*Percentage*	0.06	0	0
	Sigma	4.314	4.415	4.68

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

DE GRUYTER

Clin Chem Lab Med 2015; aop

Review

Mario Plebani*, Laura Sciacovelli, Ada Aita, Michela Pelloso and Maria Laura Chiozza

Performance criteria and quality indicators for the pre-analytical phase

Clinical Biochemistry 47 (2014) 1163–1168

Contents lists available at ScienceDirect

Clinical Biochemistry

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

Laboratory critical values: Automated notification supports effective clinical decision making

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

Department of Laboratory Medicine, Padua University School of Medicine, Padua, Italy

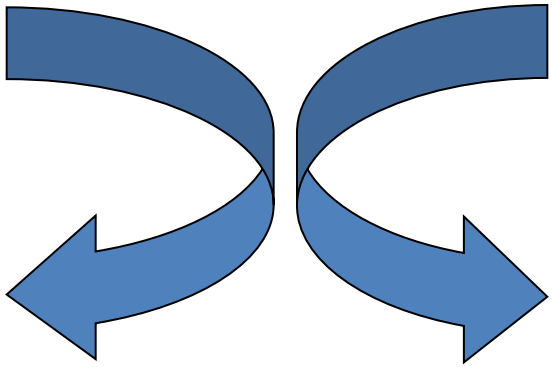
Outline of Talk

- Diagnostic errors and laboratory-associated errors
- Quality in laboratory medicine
- Quality indicators (QIs): definition and aims
- QIs in laboratory medicine
- QIs: harmonization and performance criteria
- **QIs and state-of-the-art**
- Take home messages

QIs and state-of-the-art

- ***Increasing interest*** by laboratory professionals and participation to scientific events dealing with this topic (at an international level)
- Increasing number of available papers and documents
- ***Initiatives*** promoted by the International Federations (IFCC and EFLM)
- A list of ***harmonized QIs*** and a specific website are available (www.ifcc-mqi.com)
- Few clinical laboratories collecting ***regular*** and ***comprehensive data*** on QIs

THE QUALITY INDICATORS PARADOX

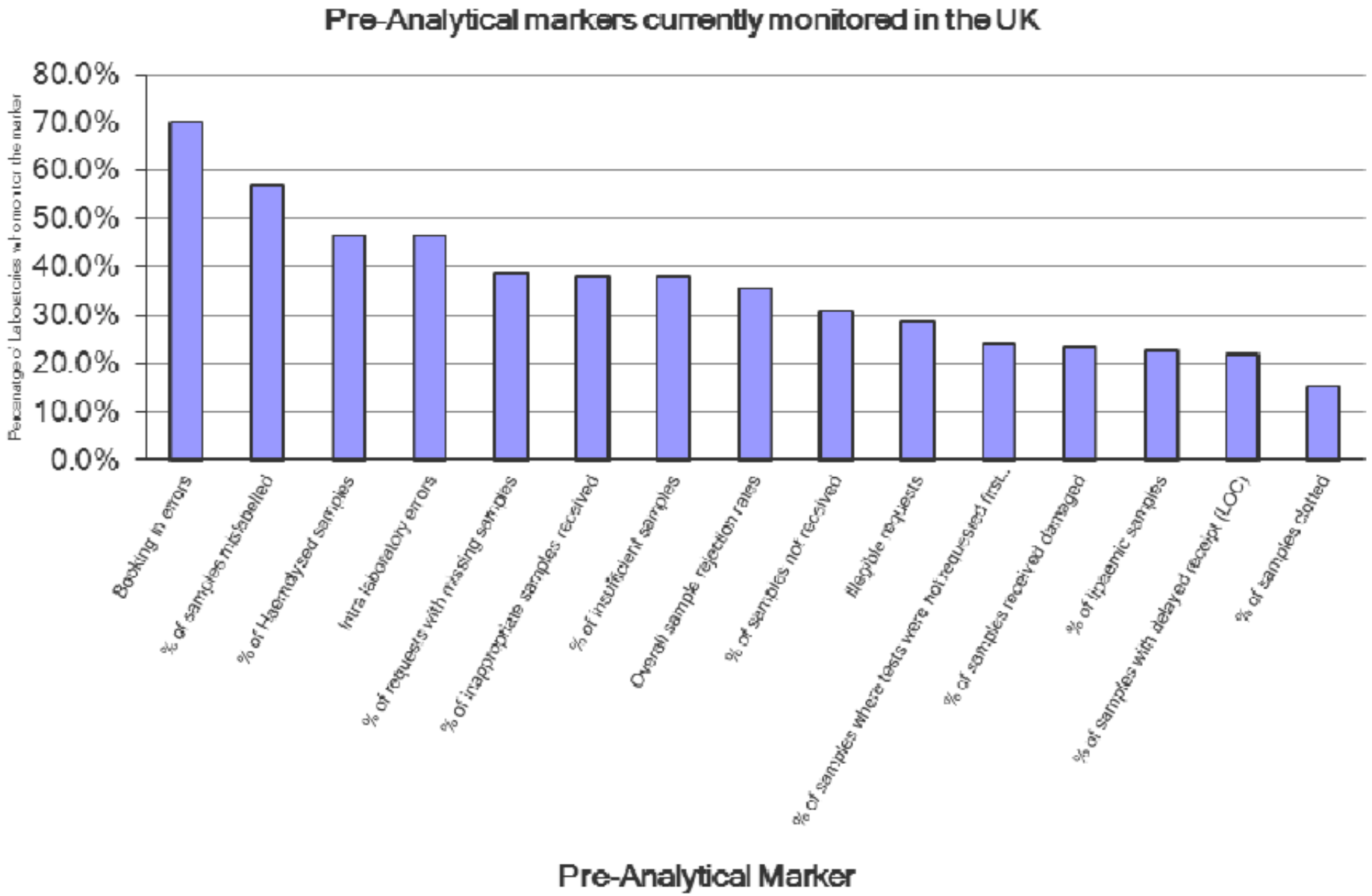


- **Increasing interest**
- **Available list of harmonized QIs and a specifically developed website**

- **Few laboratories are collecting regular and comprehensive data**

CURRENT DRAWBACKS

- Difficulties in ***defining*** and ***implementing policies*** and procedures to identify and monitor QIs on a regular base
- Difficulties in collecting data (manual versus information management)
- Difficulties in ***monitoring QIs over time*** (too many dropout)
- Adoption of only "***conventional QIs"*** (eg haemolyzed, clotted and insufficient samples)
- ***Lack of EQA schemes*** for the extra-analytical phases of laboratory testing (KIMMS)
- Poor awareness of the need of harmonized QIs and related performance criteria by ***national accreditation bodies***



Cornes M et al. Ann Clin Biochem 2015

CHANGING THE PARADOX

- New efforts for achieving ***better harmonization*** in the field of QIs (not only the identification of valuable QIs, but also data collection and reporting systems)
- More ***involvement*** of national societies and national "champions", spreading the leadership in this field
- ***Free exchange*** of criticisms, ideas and creative suggestions

CHANGING THE PARADOX

- A ***questionnaire*** to better understand the professional viewpoint and to receive some inputs (developed by the EFLM TFG-PSEP)
- Organization of a ***second consensus conference*** on QIs harmonization
- ……send me ***your own suggestions***, please

mario.plebani@unipd.it

LET ME PERSUADE YOU !

Ways to Persuade

Nagging

Coercion

WHY YOU HAVE TO ATTEND THE MQI PROJECT ?

- It's based on a list of ***consensually harmonized QIs***
- It's ***managed by the profession*** (under the IFCC umbrella)
- It's ***for free***
- The data are treated ***confidentially***
- It's a ***benchmark*** (EQA ?)between laboratories of your own Country and different Countries

Outline of Talk

- Quality in laboratory medicine
- Quality indicators (QIs): definition and aims
- QIs in laboratory medicine
- QIs: harmonization and performance criteria
- QIs and state-of-the-art
- Take home messages

Take home messages

Quality in laboratory testing includes all aspects of the so-called **"Brain-to-brain loop",**

from

- the "pre-pre-analytical" phase ("**Right test choice at the Right time on the Right patient**")

through

- analytical steps ("**Right results in the Right forms**")

to the

- "post-post-analytical" phase ("***Right interpretation, at the Right time with the Right advice as to what to do next with the result***").

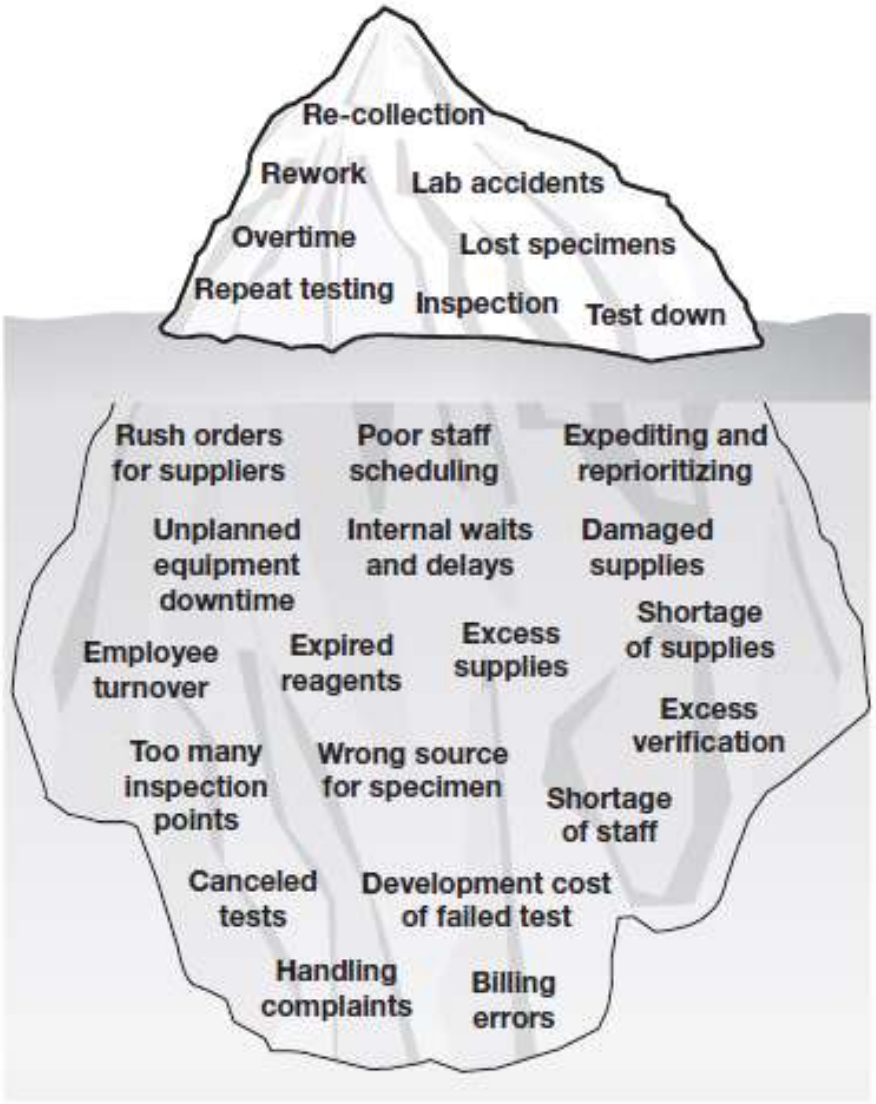
Take home messages

- Quality indicators represent a ***valuable tool*** for identifying, documenting and ***reducing errors*** in the total testing process
- Harmonized quality indicators may allow improvements in ***"in-house"*** quality, as well as a ***benchmark*** with other laboratories at an international level
- Quality indicators allow the identification and setting of ***performance criteria*** for the extra-analytical phases of laboratory testing

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

TANGO as a paradigm of joint efforts for improving PATIENT SAFETY

The Croatian Society of Medical Biochemistry and Laboratory Medicine, is a Champion in the field of quality and safety in Laboratory Medicine!