State-of-the-art of Laboratory Quality Indicators
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
• Quality indicators (QIs): definition and aims
• QIs in laboratory medicine
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• QIs and state-of-the-art
• Take home messages
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)

<table>
<thead>
<tr>
<th>PRE-PRE-ANALYTICAL</th>
<th>PRE-ANALYTICAL</th>
<th>ANALYTICAL</th>
<th>POST-ANALYTICAL</th>
<th>POST-POST-ANALYTICAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Right test</td>
<td>• Right sample handling</td>
<td>• Right (accurate) results</td>
<td>• Right laboratory report</td>
<td>• Right physician acknowledgement, interpretation and utilization</td>
</tr>
</tbody>
</table>
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 -

Pre-pre-analytical, very high frequency, high risk

Pre-analytical, high frequency

Intra-analytical

Post-analytical, high frequency

Post-post-analytical, very high frequency, high risk

Frequency of occurrence

12%

2%

0.2%

2.2%

5.0%

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

<table>
<thead>
<tr>
<th>Clinical Setting</th>
<th>Incidence (%)</th>
<th>Position in the rank</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Internal Medicine</td>
<td>18</td>
<td>2°</td>
<td>Graber ML et al, Arch Int Med 2005</td>
</tr>
<tr>
<td>General and Medical Subspecialty Divisions</td>
<td>44</td>
<td>1°</td>
<td>Schiff GD et al, Arch Int Med 2009</td>
</tr>
<tr>
<td>Pediatrics</td>
<td>35</td>
<td>5°</td>
<td>Singh H et al, Pediatrics 2010</td>
</tr>
</tbody>
</table>
## Diagnostic Errors in Test Ordering and Interpretation

<table>
<thead>
<tr>
<th>Setting</th>
<th>Primary care</th>
<th>Internal medicine</th>
<th>ED</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to order an appropriate diagnostic test</td>
<td>55%</td>
<td>28%</td>
<td>58%</td>
</tr>
<tr>
<td><strong>Incorrect interpretation</strong></td>
<td>37%</td>
<td>38%</td>
<td>37%</td>
</tr>
</tbody>
</table>

Graber ML et al. Arch Int Med 2005
Mario Plebani*

Laboratory-associated and diagnostic errors: a neglected link

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

<table>
<thead>
<tr>
<th>years</th>
<th>1950–1990</th>
<th>1990s</th>
<th>2000s</th>
<th>Today</th>
</tr>
</thead>
<tbody>
<tr>
<td>Analytical errors</td>
<td>Errors in clinical laboratories</td>
<td>Errors in laboratory medicine (laboratory-associated errors)</td>
<td>Testing-related diagnostic errors</td>
<td></td>
</tr>
</tbody>
</table>
Outline of Talk

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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.
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”

― W. Edwards Deming
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.
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
14 laboratory quality indicators have been identified in the literature meeting the following criteria:

a) previously 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

<table>
<thead>
<tr>
<th>Stage</th>
<th>IOM Domains*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test ordering</td>
<td>Effectiveness, efficiency, timeliness</td>
</tr>
<tr>
<td>Test order appropriateness†</td>
<td></td>
</tr>
<tr>
<td>Patient identification/specimen collection</td>
<td></td>
</tr>
<tr>
<td>Inpatient wristband identification error</td>
<td>Safety</td>
</tr>
<tr>
<td>Patient satisfaction with phlebotomy</td>
<td>Patient-centeredness</td>
</tr>
<tr>
<td>Specimen identification, preparation, and transport</td>
<td></td>
</tr>
<tr>
<td>Specimen inadequacy/rejection</td>
<td>Effectiveness, efficiency, safety, timeliness</td>
</tr>
<tr>
<td>Blood culture contamination</td>
<td>Efficiency, safety</td>
</tr>
<tr>
<td>Specimen container information error</td>
<td>Efficiency, safety</td>
</tr>
<tr>
<td>Analysis</td>
<td></td>
</tr>
<tr>
<td>Proficiency testing performance</td>
<td>Safety</td>
</tr>
<tr>
<td>Gynecologic cytology-biopsy discrepancy</td>
<td>Effectiveness, efficiency, safety</td>
</tr>
<tr>
<td>Result reporting</td>
<td></td>
</tr>
<tr>
<td>Inpatient laboratory result availability</td>
<td>Patient-centeredness, timeliness</td>
</tr>
<tr>
<td>Corrected laboratory reports</td>
<td>Efficiency, safety</td>
</tr>
<tr>
<td>Critical values reporting</td>
<td>Safety, timeliness</td>
</tr>
<tr>
<td>Turnaround time</td>
<td>Timeliness</td>
</tr>
<tr>
<td>Clinician satisfaction with laboratory services</td>
<td>Effectiveness, timeliness</td>
</tr>
<tr>
<td>Result interpretation and ensuing action</td>
<td></td>
</tr>
<tr>
<td>Follow-up of abnormal cervical cytology results</td>
<td>Effectiveness, timeliness</td>
</tr>
</tbody>
</table>
### Table 2  Analytical

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

### Table 3  Postanalytical

<table>
<thead>
<tr>
<th>Description</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is a process for demand management</td>
<td>43%</td>
</tr>
<tr>
<td>Laboratory provides help and advice in interpreting clinical laboratory data</td>
<td>80%</td>
</tr>
<tr>
<td>There is an audit of the effect of added interpretative comments</td>
<td>16%</td>
</tr>
<tr>
<td>There is a written critical limits (alert) list</td>
<td>58%</td>
</tr>
<tr>
<td>There is a record of the number of calls/emails/letters received for clinical advice</td>
<td>18%</td>
</tr>
<tr>
<td>Proportion of requests with additional tests added by laboratory response</td>
<td>13%</td>
</tr>
<tr>
<td>There are automatic reflex tests via reporting rules</td>
<td>57%</td>
</tr>
</tbody>
</table>
### 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 purpose of this Working Group is to stimulate studies on the topic of 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): 697-8).

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 monographs.
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 focusing on all steps of the laboratory total testing process (TTP), although the International Standard ISO 15189:2012 for Accreditation of Medical Laboratories require 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 (MIQ) 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 MIQ 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 data 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 MIQ 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 relevance 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 MIQ 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.foqc.org) which allows interested laboratories to require the password to eventually introduce the data from their laboratories. 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 MIQ 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 laboritories results, is periodically issued.
<table>
<thead>
<tr>
<th>ID</th>
<th>Code</th>
<th>Description</th>
<th>Notes</th>
<th>Actions</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>MQI-Pre</td>
<td>Quality Indicators of Pre-Analytical Phase</td>
<td>insert your data until December 2013</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>3</td>
<td>MQI-Intra</td>
<td>Quality Indicators of Intra-Analytical Phase</td>
<td>insert your data until December 2013</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>4</td>
<td>MQI-Post</td>
<td>Quality Indicators of Post-Analytical Phase</td>
<td>insert your data until December 2013</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>5</td>
<td>MQI-Supp</td>
<td>Quality Indicators of Support processes</td>
<td>insert your data until December 2013</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>8</td>
<td>MQI - 1</td>
<td>Key Processes Indicators - Priority 1</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>9</td>
<td>MQI - 2</td>
<td>Key Processes Indicators - Priority 2</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>10</td>
<td>MQI - 3</td>
<td>Key Processes Indicators - Priority 3</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>11</td>
<td>MQI - 4</td>
<td>Key Processes Indicators - Priority 4</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>12</td>
<td>MQI - Outcome</td>
<td>Outcome Measures</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
<tr>
<td>13</td>
<td>MQI - Support</td>
<td>Support processes Indicators</td>
<td>insert your data starting from January 2014</td>
<td>Edit, Repository</td>
</tr>
</tbody>
</table>
Quality Indicators

Key Processes

- Pre-analytical phase
- Intra-analytical phase
- Post-analytical phase

34
7
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 Bioquímica Clinica y Patología

BR

Health Minister

RCPA
KIMMS

New Zealand
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\textsuperscript{1}, Laura Sciacovelli\textsuperscript{1} and Giuseppe Lippi\textsuperscript{2}

\textsuperscript{1}Dipartimento di Medicina di Laboratorio, Università degli Studi di Padova, Padova; \textsuperscript{2}U.O. Diagnostica Ematochimica, Azienda Ospedaliero-Universitaria di Parma, Parma, Italy
CRITERIA FOR HARMONIZATION
HARMONIZATION OF QUALITY INDICATORS IN LABORATORY MEDICINE: WHY, HOW AND WHEN?

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:

- **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.

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.
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

Key Processes

Priority

1  2  3  4

Pre-analytical phase

Intra-analytical phase

Post-analytical phase

22  2  2  2

5  0  1  0

8  0  0  3
Quality Indicators

Support Processes

<table>
<thead>
<tr>
<th>Priority</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
</tr>
</thead>
<tbody>
<tr>
<td>Employee competence</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Client relationship</td>
<td>0</td>
<td>2</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Efficiency of LIS</td>
<td>0</td>
<td>0</td>
<td>1</td>
<td>0</td>
</tr>
</tbody>
</table>
Quality Indicators

Outcome Measures

Priority

Sample recollection

Inaccurate results
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

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-OutpTN</td>
<td>Number of outpatients requests with erroneous data entry (test name)/ Total number of outpatients requests.</td>
</tr>
<tr>
<td>Pre-OutpMT</td>
<td>Number of outpatients requests with erroneous data entry (missed test)/ Total number of outpatients requests.</td>
</tr>
<tr>
<td>Pre-OutpAT</td>
<td>Number of outpatients requests with erroneous data entry (added test)/ Total number of outpatients requests.</td>
</tr>
<tr>
<td>Pre-InpTN</td>
<td>Number of inpatients requests with erroneous data entry (test name)/ Total number of inpatients requests.</td>
</tr>
<tr>
<td>Pre-InpMT</td>
<td>Number of inpatients requests with erroneous data entry (missed test)/ Total number of inpatients requests.</td>
</tr>
<tr>
<td>Pre-InpAT</td>
<td>Number of inpatients requests with erroneous data entry (added test)/ Total number of inpatients requests.</td>
</tr>
</tbody>
</table>
Requests with erroneous data entry (added test): error percentage

Number of patients requests with errors concerning input of tests (added)/ Total number of patients requests

- All Laboratories
- ITA001

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

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-NotRec</td>
<td>Number of samples not received/ Total number of samples.</td>
</tr>
<tr>
<td>Pre-NotSt</td>
<td>Number of samples not properly stored before analysis / Total number of samples.</td>
</tr>
<tr>
<td>Pre-DamS</td>
<td>Number of samples damaged during transportation/ Total number of samples.</td>
</tr>
<tr>
<td>Pre-InTem</td>
<td>Number of samples transported at inappropriate temperature/Total number of samples.</td>
</tr>
<tr>
<td>Pre-ExcTim</td>
<td>Number of samples with excessive transportation time/ Total number of samples.</td>
</tr>
</tbody>
</table>

### Contaminated samples

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-MicCon</td>
<td>Number of contaminated samples rejected/ Total number of microbiological samples.</td>
</tr>
</tbody>
</table>
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

Number of samples haemolyzed / Total number of samples

All Laboratories

ITA001
Haemolyzed sample: sigma values

Number of samples haemolyzed / Total number of samples
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.
<table>
<thead>
<tr>
<th>Issue</th>
<th>Range</th>
<th>Median</th>
<th>Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specimen not received</td>
<td>2.0 - 6.1</td>
<td>2.9</td>
<td>Optimum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>4.0 Desirable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>6.0 Minimum</td>
</tr>
<tr>
<td>Specimen insufficient</td>
<td>0.07 - 0.8</td>
<td>0.15</td>
<td>Optimum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.07 Desirable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.8 Minimum</td>
</tr>
<tr>
<td>Wrong container</td>
<td>0.02 - 0.2</td>
<td>0.03</td>
<td>Optimum</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.02 Desirable</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>0.2 Minimum</td>
</tr>
</tbody>
</table>
## Quality Indicators

**Pre-Analytical Processes**

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Performance Specifications on the basis of 25th - 50th - 75th percentile</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Misidentification errors</td>
<td></td>
</tr>
<tr>
<td>Percentage</td>
<td>0.040</td>
</tr>
<tr>
<td>Sigma</td>
<td>4.54</td>
</tr>
<tr>
<td>Test transcription Errors (added tests)</td>
<td></td>
</tr>
<tr>
<td>Percentage</td>
<td>0.240</td>
</tr>
<tr>
<td>Sigma</td>
<td>4.26</td>
</tr>
<tr>
<td>Sample haemolysed</td>
<td></td>
</tr>
<tr>
<td>Percentage</td>
<td>0.852</td>
</tr>
<tr>
<td>Sigma</td>
<td>3.84</td>
</tr>
</tbody>
</table>
POST-ANALYTICAL QIs
# Quality Indicators

## Post-Analytical Processes

### Quality of reports

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-Comm</td>
<td>Percentage of: Number of reports with Interpretative comments impacting positively on patient’s outcome/Total number of reports.</td>
</tr>
<tr>
<td>Post-IncRep</td>
<td>Percentage of: Number of incorrect reports issued by the laboratory / Total number of reports issued by the laboratory.</td>
</tr>
<tr>
<td>Post-OutTime</td>
<td>Percentage of: Number of reports delivered outside the specified time/ Total number of reports.</td>
</tr>
</tbody>
</table>
## Quality Indicators

### Post-Analytical Processes

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Performance Specifications</th>
<th>Minimum</th>
<th>Desirable</th>
<th>Optimum</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-Comm</strong></td>
<td><strong>Percentage</strong></td>
<td>0.12</td>
<td>32.2</td>
<td>62.5</td>
</tr>
<tr>
<td></td>
<td><strong>Sigma</strong></td>
<td>1.699</td>
<td>1.967</td>
<td>4.429</td>
</tr>
<tr>
<td><strong>Post-IncRep</strong></td>
<td><strong>Percentage</strong></td>
<td>0.035</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td><strong>Sigma</strong></td>
<td>4.621</td>
<td>4.791</td>
<td>4.932</td>
</tr>
<tr>
<td><strong>Post-OutTime</strong></td>
<td><strong>Percentage</strong></td>
<td>0.13</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td><strong>Sigma</strong></td>
<td>3.782</td>
<td>4.508</td>
<td>4.793</td>
</tr>
</tbody>
</table>
# Quality Indicators

## Post-Analytical Processes

### Turn-Around-Time

<table>
<thead>
<tr>
<th>Indicator</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-INRTAT</td>
<td>Turn Around Time (minutes) of International Normalized Ratio (INR) value at 90th percentile (STAT).</td>
</tr>
<tr>
<td><strong>Priority 1</strong></td>
<td></td>
</tr>
<tr>
<td>Post-PotTAT</td>
<td>Turn Around Time (minutes) of Potassium (K) at 90th percentile (STAT).</td>
</tr>
<tr>
<td><strong>Priority 1</strong></td>
<td></td>
</tr>
<tr>
<td>Post-TnTAT</td>
<td>Turn Around Time (minutes) of Troponin I (TnI) or Troponin T (TnT) at 90th percentile (STAT).</td>
</tr>
<tr>
<td><strong>Priority 1</strong></td>
<td></td>
</tr>
<tr>
<td>Post-WBCTAT</td>
<td>Turn Around Time (minutes) of White Blood Cell Count (WBC) at 90th percentile (STAT).</td>
</tr>
<tr>
<td><strong>Priority 1</strong></td>
<td></td>
</tr>
<tr>
<td>Quality Indicators</td>
<td>Performance Specifications on the basis of 25th -50th – 75th percentile</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Turn Around Time</strong> (minutes) of International Normalized Ratio (INR) value at 90th percentile (STAT).</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Time</strong></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Turn Around Time</strong> (minutes) of Potassium (K) at 90th percentile (STAT).</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Time</strong></td>
</tr>
<tr>
<td><strong>Turn Around Time</strong> (minutes) of Troponin I (TnI) or Troponin T (TnT) at 90th percentile (STAT).</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Time</strong></td>
</tr>
<tr>
<td><strong>Turn Around Time</strong> (minutes) of White Blood Cell Count (WBC) at 90th percentile (STAT).</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>Time</strong></td>
</tr>
</tbody>
</table>
# Quality Indicators

## Post-Analytical Processes

### Notification of Critical Values

<table>
<thead>
<tr>
<th>Category</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Post-OutCV</td>
<td>Percentage of: Number of critical values of outpatients notified after a consensually agreed time /Total number of critical values of outpatients to communicate.</td>
</tr>
<tr>
<td>Post-InpCV</td>
<td>Percentage of: Number of critical values of inpatients notified after a consensually agreed time /Total number of critical values of inpatients to communicate.</td>
</tr>
<tr>
<td>Post-OutCVT</td>
<td>Time (from result validation to result communication to the clinician) to communicate critical values of outpatient (minutes).</td>
</tr>
<tr>
<td>Post-InCVT</td>
<td>Time (from result validation to result communication to the clinician) to communicate critical values of inpatients (minutes).</td>
</tr>
</tbody>
</table>
# Quality Indicators

## Post-Analytical Processes

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Performance Specifications</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>on the basis of 25th -50° th - 75° th percentile</em></td>
</tr>
<tr>
<td></td>
<td>Minimum</td>
</tr>
<tr>
<td>Percentage of: Number of critical values of outpatients notified after a</td>
<td>Percentage</td>
</tr>
<tr>
<td>consensually agreed time (from result validation to result communication to</td>
<td>Sigma</td>
</tr>
<tr>
<td>the clinician) /Total number of critical values of outpatients to communicate.</td>
<td></td>
</tr>
<tr>
<td>(Post-OutCV)</td>
<td>Percentage</td>
</tr>
<tr>
<td></td>
<td>Sigma</td>
</tr>
<tr>
<td>Percentage of: Number of critical values of inpatients notified after a</td>
<td>Time</td>
</tr>
<tr>
<td>consensually agreed time (from result validation to result communication to the</td>
<td>Time</td>
</tr>
<tr>
<td>clinician) /Total number of critical values of inpatients to communicate.</td>
<td></td>
</tr>
<tr>
<td>(Post-InpCV)</td>
<td></td>
</tr>
</tbody>
</table>

**Post-Analytical Processes**
## OUTCOME MEASURES

### pre-analytical phase

<table>
<thead>
<tr>
<th>Measure</th>
<th>Causes</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Causes</th>
</tr>
</thead>
</table>
| 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

<table>
<thead>
<tr>
<th>Measure</th>
<th>Causes</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Outpatients called back for procedures</td>
<td>- Suspected patient/sample misidentification wrong</td>
</tr>
<tr>
<td></td>
<td>- Unsuitable samples</td>
</tr>
<tr>
<td></td>
<td>- Incorrect results</td>
</tr>
<tr>
<td></td>
<td>- Suspected interference</td>
</tr>
</tbody>
</table>
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.
## Outcome Measures

### Quality Indicators

<table>
<thead>
<tr>
<th>Quality Indicators</th>
<th>Minimum</th>
<th>Desirable</th>
<th>Optimum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percentage of: Number of inaccurate results released/Total number of results released <strong>(Out-InacR)</strong></td>
<td>Percentage</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sigma</td>
<td>4.363</td>
<td>4.562</td>
</tr>
<tr>
<td>Percentage of: Number of inpatients with recollected samples for laboratory errors/ Total number of inpatients <strong>(Out-RecInp)</strong></td>
<td>Percentage</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sigma</td>
<td>4.59</td>
<td>4.932</td>
</tr>
<tr>
<td>Percentage of: Number of outpatients with recollected samples for laboratory errors/ Total number of outpatients <strong>(Out-RecOutp)</strong></td>
<td>Percentage</td>
<td>0.06</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>Sigma</td>
<td>4.314</td>
<td>4.415</td>
</tr>
</tbody>
</table>

**Quality Specifications**

*on the basis of 25th - 50th – 75th percentile*
Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety

Mario Plebani a,*, Laura Sciakovelli a, Mariela Marinova a, Jessica Marcuccitti a, Maria Laura Chiozza b

Towards harmonization of quality indicators in laboratory medicine

Mario Plebani*, Maria Laura Chiozza and Laura Sciakovelli
Performance criteria and quality indicators for the pre-analytical phase

Laboratory critical values: Automated notification supports effective clinical decision making
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*
Pre-Analytical markers currently monitored in the UK

Pre-Analytical Marker

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
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!