Opinion Paper

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Defining a roadmap for harmonizing quality indicators in Laboratory Medicine: a consensus statement on behalf of the IFCC Working Group "Laboratory Error and Patient Safety" and EFLM Task and Finish Group "Performance specifications for the extra-analytical phases"

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Abstract: The improving quality of laboratory testing requires a deep understanding of the many vulnerable steps involved in the total examination process (TEP), along with the identification of a hierarchy of risks and challenges that need to be addressed. From this perspective, the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) is focusing its activity on implementation of an efficient tool for obtaining

meaningful information on the risk of errors developing throughout the TEP, and for establishing reliable information about error frequencies and their distribution. More recently, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has created the Task and Finish Group "Performance specifications for the extraanalytical phases" (TFG-PSEP) for defining performance specifications for extra-analytical phases. Both the IFCC and EFLM groups are working to provide laboratories with a system to evaluate their performances and recognize the critical aspects where improvement actions are needed. A Consensus Conference was organized in Padova, Italy, in 2016 in order to bring together all the experts and interested parties to achieve a consensus for effective harmonization of quality indicators (QIs). A general agreement was achieved and the main outcomes have been the release of a new version of model of quality indicators (MQI), the approval of a criterion for establishing performance specifications and the definition of the type of information that should be provided within the report to the clinical laboratories participating to the QIs project.

Keywords: extra-analytical phases; harmonization; patient safety; performance specifications; quality indicators; total testing process.

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Introduction

One of the leading missions of the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory

Medicine (IFCC) is to stimulate studies on the topic of errors in Laboratory Medicine, collect available data on this issue, and recommend strategies and procedures for improving patient safety in laboratory testing. A recent substantial body of evidence has demonstrated that most errors in Laboratory Medicine occur in the pre- and postanalytical phases of laboratory testing [1-5]. Therefore, improving the quality of laboratory testing requires a deep understanding of the many vulnerable steps involved in the total examination process (TEP), along with the identification of a hierarchy of risks and challenges that need to be addressed. From this perspective, the WG-LEPS is focusing its activity on implementation of an efficient tool for obtaining meaningful information on the risk of errors developing throughout the TEP, and for establishing reliable information about error frequencies and their distribution. The final purpose is to:

- improve the awareness of laboratory professionals regarding errors and patient safety;
- define performance specifications for the extra-analytical phases of the TEP, so providing laboratories with a benchmark for performance evaluation and increasing knowledge about the critical aspects needing improvement actions.

More recently, the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) has created the Task and Finish Group "Performance specifications for the extraanalytical phases" (TFG-PSEP) for defining performance specifications for extra-analytical phases [6]. Both the IFCC and EFLM groups are working to provide laboratories with a system to evaluate their performances and recognize the critical aspects where improvement actions are needed.

The WG-LEPS project, which commenced in 2008, aims to define a model of quality indicators (MQI), complying with harmonization criteria and requirements of the International Standard ISO 15189:2012 [7]. Specifically, the quality indicators (QIs) included in the MQI should be representative of all the critical activities comprised within the TEP and should also be measurable by most laboratories worldwide, and be designed to be independent of the health care context, laboratory testing's purpose and goals, number and types of patients tested, type of activities, sensitivity and training of staff, etc. [8–10].

A preliminary MQI has been initially developed and tested under actual conditions, by involving laboratories over a 5-year period (2008–2013). All the main findings that emerged during the experimentation phase were discussed in a Consensus Conference held in Padova in 2013 ("Harmonization of quality indicators: why, how and when?"). The 2013 Conference reached a preliminary

consensus on terms, rationale, criteria and purpose of each QI and its procedures for data collection [11].

A preliminary set of MQI, reviewed, approved and finally issued after the Consensus Conference, were used since 2014, when a second Consensus Conference was organized in Padova, on 26th October, 2016, entitled "Harmonization of quality indicators in Laboratory Medicine: 2 years later". The aim of the meeting was to bring together all experts and interested parties for:

- discussing experience previously accumulated in the past few years;
- establishing whether or not the list of QIs should be revised, modified or improved;
- better understanding the feasibility of data collection by clinical laboratories worldwide and identifying additional tools (e.g. based on information technology) which may be effective to further improve the ongoing program;
- streamlining all other potential improvements and the best way to achieve a broad consensus for effective QIs harmonization.

Conference

The 2016 Conference was very successful, hosting participants from 14 different Countries: Australia, Austria, Brazil, China, Croatia, Estonia, France, Hungary, India, Italy, Serbia, Spain, the UK and the USA. The meeting was also attended by representatives of the Executive Board and Education and Management Division Executive Committee of the IFCC; the EFLM Executive Board; the EFLM Working Groups on "Pre-analytical phase" (WG-PRE) and "Post-analytical phase" (WG-POST); Italian scientific societies of laboratory medicine; the Italian accreditation body (Accredia); in vitro diagnostic (IVD) manufacturers.

In summarizing what was reported, the purpose of the 2016 Conference was to achieve wide consensus on which QIs and performance specifications should be used in clinical laboratories worldwide, so complying with the ISO 15189:2012 requirements, monitoring the main critical activities and promoting minimization of error risk. The data collected and published in the past years were discussed by all participants [12–15].

All QIs included in the last MQI were revisited and discussed, in an effort to investigate to what extent each indicator may still be valid or should be modified, or whether more accurate explanations should be provided (as a note) for better understanding by the users (i.e. laboratory professionals). The discussion was continued after the conference with electronic correspondence exchange.

Despite the importance of using QIs as a quality assurance tool, it was also recognized that the number of participating laboratories applying QIs is not as large as it could and should be. The underlying reasons may be mainly attributable to time constraints and shortage of human resources for data collection, which may make it difficult to implement most QIs and to assure continuous participation over time. Moreover, some national surveys organized by national scientific societies or external quality assessment (EQA)/proficiency testing (PT) providers, using a limited number of QIs proposed by WG-LEPS, have potentially distracted the focus on the MQI project.

According to the consensus of the 2014 EFLM Strategic Conference "Defining analytical performance goals 15 years after the Stockholm Conference on Quality Specifications in Laboratory Medicine", for the definition of performance specifications the models based on the impact on clinical outcome and on the state-of-the-art have been discussed, as the biological variation model is not applicable to extra-analytical QIs [16]. In particular, it has been widely recognized that performance specifications based on a reliable state-of-the-art, defined on QIs' data, is the most feasible and attainable criterion to be immediately applicable because no data can be collected from clinicians' opinion. Participants' views have been exchanged regarding the opportunity to define one, two or even three limits for defining laboratory performance. In particular: one limit set at the 25th percentile to define the acceptable or unacceptable performance; two limits set at 10th-80th percentiles for high, medium and low performance; three limits set at 25th-50th-75th for high, medium, low, unacceptable performance, respectively [17].

Finally, considerations about the information in the reports currently generated for the single laboratories participating in the WG-LEPS project have been exchanged, in order to evaluate their completeness, adequacy and effectiveness. Importantly, all participants approved the reports without modifications, so judging them to be adequate and useful for identifying local laboratory performance and allowing benchmarking with other laboratories both in the same country and around the world.

Consensus statement

A general agreement was achieved. The main outcomes of the conference have been the release of a new version of MQI, the approval of a criterion for establishing performance specifications and the definition of the type of information that should be provided within the report to the clinical laboratories participating in the QIs project.

Model of quality indicators

The reviewed MQI are reported in Tables 1-3. A general agreement was achieved for all QIs included in the MQI. Several measurements (53) have been identified to monitor 27 QIs (Table 4) and some explanatory notes have been exploited for facilitating interpretation of measurable events.

The agreed MQI are now (2017) available from the dedicated WG-LEPS website (www.ifcc-mqi.com), as an External Quality Assurance Program (EQAP). The participating laboratories are not required to use all the QIs proposed in the MQI. They can, at least in the initial phase, select the most appropriate QIs for their specific setting (particularly from among those rated as "priority 1") and collect and report the corresponding data. Afterwards, they may eventually implement and use additional QIs.

Data of participating laboratories will be collected through the dedicated website and each participant will have a confidential username and password for assuring confidentiality.

Performance specifications

The limits for evaluation of laboratory performance are fixed at the 25th and 75th percentile according to the QIs data collected during the previous year. The performance is then classified as follows:

- individual results <25th percentile of value distribution = performance of high quality;
- individual results between 25th and 75th percentile of value distribution = performance of medium quality;
- individual results >75th percentile of value distribution = performance of low quality.

At the end of each year of data collection, QIs data from participating laboratories will be processed and analyzed, so allowing the calculating of the 25th and 75th percentiles to be used as performance limits for the following year (for 2017, 2016). The new performance specifications will be introduced only if the state-of-the art is improving, otherwise previous quality specifications should be active. This criterion, based on the state-of-the-art, allows aligning performance specifications to the path of general laboratory improvement and, at the same time, laboratories will

Table 1: Quality Indicators concerning the key processes.

Key processes				
Quality indicator	Code	Measurements	Priority order	Explanatory note
Pre-analytical phase Misidentification errors	Pre-MisR	Percentage of: Number of misidentified requests/Total number of	1	
	Pre-MisS	requests Percentage of: Number of misidentified samples/Total number of	1	
Inappropriate test	Pre-OffQue	samples Percentage of: Number of requests without clinical question	2	Offside patients = not hospitalized patients
requests	Pre-OffReq	(offside patients)/Total number of requests (offside patients) Percentage of: Number of inappropriate requests, with respect to clinical question (offside patients)/Number of requests reporting	4	Offside patients = not hospitalized patients
	Pre-InsReq	cunical question (oriside patients) Percentage of: Number of inappropriate requests, with respect to clinical question (inside patients)/Number of requests reporting clinical question (inside patients)	4	Inside patients=hospitalized patients
Test transcription errors	Pre-LabTDE	Percentage of: Number of requests with erroneous data entered by laboratory personnel/Total number of requests entered by	1	Laboratory personnel = personnel that are under the laboratory control
	Pre-OffTDE	Percentage of: Number of requests with erroneous data entered by offside personnel/Total number of requests entered by offside	4	Offside personnel = personnel that are not under the laboratory control
Unintelligible requests	Pre-OffUn	personner Percentage of: Number of unintelligible offside patients requests/ Total number of offside patients requests	М	Offside patients = not hospitalized patients
	Pre-InsUn	Percentage of: Number of unintelligible inside patients requests/ Total number of inside natients requests	9	Inside patients = hospitalized patients
Incorrect sample type	Pre-WroTy	Percentage of: Number of samples of wrong or inappropriate sample matrix (e.g. whole blood instead of plasma)/Total number of samples	₩ ,	
	Pre-WroCo	Percentage of: Number of samples collected in wrong container/ Total number of samples		
Incorrect fill level	Pre-InsV	Percentage of: Number of samples with insufficient sample volume/Total number of samples	П	Insufficient = when the sample volume is less than that requested independently of the possibility to perform the test. It has to measure the incorrect collection (volume inferior than defined), independently of collected volume (50% or 80 % or 90%)
	Pre-SaAnt	Percentage of: Number of samples with inappropriate sample- anticoagulant volume ratio/Total number of samples with anticoagulant	1	Samples of pediatric patients have to be excluded

Table 1 (continued)

Quality indicator Code Measurements Unsuitable samples for transportation and storage problems Pre-NotSt percentage of: Number canalysis/Total number of analysis/Total number of pre-DamS percentage of: Number of transportation/Total number of transportation pre-Heml Pre-ExcTim percentage of: Number of transportation/Total number of transportation pre-Heml Pre-HemV percentage of: Number of transportation pre-Heml Percentage of: Number of transportation of sample collection Number of samples for hen percentage of: Number of samples with an anticoal sample collection Percentage of: Number of sample collect	Number of samples not received/Total number of number of samples not properly stored before number of samples damaged during Yotal number of samples transported at inappropriate otal number of samples transported at inappropriate otal number of samples with excessive transportation ber of samples	Priority order 1 1 1	Explanatory note This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
age Pre-NotSt Pre-DamS Pre-InTem Pre-MicCon Pre-HemV Pre-HemN Pre-HemR Pre-HemR Pre-InTime	ntage of: Number of samples not received/Total number of less ntage of: Number of samples not properly stored before sis/Total number of samples amaged during portation/Total number of transported samples ntage of: Number of samples transported at inappropriate erature/Total number of samples ntage of: Number of samples with excessive transportation total number of samples with excessive transportation for the samples of samples with excessive transportation total number of samples		This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-NotSt Pre-DamS Pre-InTem Pre-MicCon Pre-HemV Pre-HemN Pre-HemN Pre-HemR Pre-InTime	ntage of: Number of samples not properly stored before sis/Total number of samples antage of: Number of samples damaged during portation/Total number of transported samples antage of: Number of samples transported at inappropriate erature/Total number of samples with excessive transportation Total number of samples		This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-InTem Pre-ExcTim Pre-Cont Pre-HemV Pre-HemR Pre-HemR Pre-InTime	ntage of: Number of samples damaged during portation/Total number of transported samples amples of: Number of samples transported at inappropriate erature/Total number of samples ntage of: Number of samples with excessive transportation total number of samples		This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-InTem Pre-ExcTim Pre-Cont Pre-HemV Pre-HemR Pre-HemR Pre-InTime	portation/Total number of transported samples ntage of: Number of samples transported at inappropriate erature/Total number of samples ntage of: Number of samples with excessive transportation Total number of samples		This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-InTem Pre-ExcTim Pre-Cont Pre-HemI Pre-HemR Pre-Clot Pre-InTime	ntage of: Number of samples transported at inappropriate erature/Total number of samples ntage of: Number of samples with excessive transportation Total number of samples	П	This QI has to be collected if the transportation temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-ExcTim Pre-MicCon Pre-HemV Pre-HemR Pre-HemR Pre-InTime	erature/Total number of samples ntage of: Number of samples with excessive transportation Total number of samples	₽	temperature is measured through appropriate measuring device or a procedure that guarantees the detection of the temperature. This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-ExcTim Pre-MicCon Pre-HemV Pre-HemR Pre-HemR Pre-InTime	ntage of: Number of samples with excessive transportation Total number of samples	1	detection of the temperature This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-ExcTim Pre-MicCon Pre-HemV Pre-HemR Pre-HemR Pre-InTime	ntage of: Number of samples with excessive transportation Total number of samples	1	This QI has to be collected if the transportation time is measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-Cont Pre-HemV Pre-HemR Pre-HemR Pre-InTime	Total number of samples		measured through appropriate measuring devices or a procedure that guarantees the detection of the times Microbiological samples: blood culture, urine, sputum, pharvngeal, etc.
Pre-MicCon Pre-HemV Pre-HemR Pre-HemR Pre-Clot Pre-InTime	ather of Number of microbiological contaminated camples		Microbiological samples: blood culture, urine, sputum. pharvngeal, etc.
Pre-Cont Pre-HemV Pre-HemR Pre-InTime	ntage of: Nambel of inferoblotogical containmated samples	1	sputum. pharyngeal, etc.
Pre-Cont Pre-HemV Pre-HemR Pre-Clot	rejected/Total number of microbiological samples		
Pre-Heml Pre-HemR Pre-Clot	Percentage of: Number of contaminated samples rejected/Total	1	Contaminated samples = samples which are
Pre-Heml Pre-HemR Pre-Clot	number of not microbiological samples		contaminated by infusion, drugs, anticoagulants
Pre-Heml Pre-HemR Pre-Clot			(EDTA, citrate), parenteral nutrition, X-ray contrast
Pre-Heml Pre-HemR Pre-Clot			material, etc.
Pre-Heml Pre-Clot Pre-InTime	Percentage of: Number of samples with free hemoglobin (Hb)	1	Checked samples = all samples verified for
Pre-HemR Pre-Clot Pre-InTime	>0.5 g/L detected by visual inspection/Total number of checked		hemolysis have to be included (clinical chemistry,
Pre-HemR Pre-Clot Pre-InTime	les for hemolysis		immunochemistry, coagulation, etc.)
Pre-HemR Pre-Clot Pre-InTime	Percentage of: Number of samples with free hemoglobin (Hb)	1	Checked samples = all samples verified for
Pre-HemR Pre-Clot Pre-InTime	>0.5 g/L detected by automated hemolytic index/Total number of		hemolysis have to be included (clinical chemistry,
Pre-HemR Pre-Clot Pre-InTime	checked samples for hemolysis		immunochemistry, coagulation, etc.)
Pre-Clot Pre-InTime	Percentage of: Number of samples rejected due to hemolysis/Total	1	Checked samples = all samples verified for
Pre-Clot Pre-InTime	number of checked samples for hemolysis		hemolysis have to be included (clinical chemistry,
Pre-Llot Pre-InTime		•	Immunocnemistry, coagulation, etc.).
Pre-InTime	reicentage of: Number of Samples clotted/Total number of	-	checked samples = all samples vermed for clots have
Pre-InTime	samples with an anticoagulant checked for clots		to be included (hematology, coagulation clinical chemistry, etc.)
	Percentage of: Number of samples collected at inappropriate time	2	This QI has to be collected if time of sample collection
	of sample collection/Total number of samples requiring a specified time for data collection		is required (e.g. cortisol)
Intra-analytical phase			
Test uncovered by an IQC Intra-IQC Percentage of: Number or in the menu	Percentage of: Number of tests without IQC/Total number of tests in the menu	1	IQC: internal quality control
Unacceptable Intra-UnIQC Percentage of: Number or performances in IQC nesults	Percentage of: Number of IQC results outside defined limits/Total number of IQC results	П	IQC: internal quality control

laboratory in which the critical result has to be effectively reported to the clinical ward Inside patients = hospitalized patients

Table 1 (continued)

Key processes				
Quality indicator	Code	Measurements	Priority order	Explanatory note
Test uncovered by an EQA-PT control	Intra-EQA	Percentage of: Number of tests without EQA-PT control/Total number of tests in the menu	1	EQA: external quality assessment; PT: proficiency testing
Unacceptable performances in EQA-PT	Intra-Unac	Percentage of: Number of unacceptable performances in EQAS-PT Schemes, per year/Total number of performances in EQA Schemes,	П	EQA: external quality assessment; PT: proficiency testing
schemes Data transcription errors	Intra-ErrTran	per year Percentage of: Number of incorrect results for erroneous	1	
	Intra-FailLIS	manual transcription/ lotal number of results that need manual transcription Percentage of: Number of incorrect results for information system problems/Total number of results	1	
Post-analytical phase Inappropriate turnaround	Post-OutTime	Percentage of: Number of reports delivered outside the specified time /Total number of reports	1	Specified time = this concerns the reports (not results)
	Post-PotTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of potassium (K) at the 90th percentile (STAT)	1	
	Post-INRTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of the international normalized ratio (INR) value	П	
	Post-WBCTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of white blood cell (WBC) count at the 90th	₽	
	Post-TnTAT	Turnaround time (minutes), from sample reception in laboratory to release of result, of cardiac troponin (Tnl or TnT) at the 90th	1	
	Post-TATPotH	Percentage of: Number of potassium results (K) released after 1 h/Total number of potassium results (STAT)	1	
Incorrect laboratory reports	Post-RectRep	Percentage of: Number of rectified reports by laboratory after the release/Total number of released reports	₽	For example: Reports could be rectified for erroneous results or inappropriate/missed interpretative comments or wrong patient's details, etc.
Notification of critical results	Post-InsCR	Percentage of: Number of critical results of inside patients notified after a consensually agreed time (from result validation to result	1	Critical results = results that are so "extremely" abnormal and are considered life threatening because
		communication to the clinical ward)/Total number of critical results of inside patients to communicate		they may be associated with a significant dangerous event unless a medical action is promptly established. Consensually agreed time = time established by

Table 1 (continued)

Key processes				
Quality indicator	Code	Measurements	Priority order	Explanatory note
	Post-OffCR	Percentage of: Number of critical results of offside patients notified after a consensually agreed time (from result validation to result communication to the general practitioner)/Total number of critical results of offside patients to communicate	1	Critical results = results that are so "extremely" abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established. Consensually agreed time = time established by laboratory in which the critical result has to be effectively reported to the general practitioner. Offside patients = not hospitalized patients followed
	Post-InsCRT	Median value of time (from result validation to result	7	by general practitioner Critical results = results that are so "extremely"
		communication to the clinical ward) to communicate critical results of inside patients (minutes)		abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is the promptly established.
	Post-OffCRT	Median value of time (from result validation to result	4	nistice patients – nospitatized patients Critical results = results that are so "extremely"
		communication to the general practitioner) to communicate critical results of offside patients (minutes)		abnormal and are considered life threatening because they may be associated with a significant dangerous event unless a medical action is promptly established Offside patients = not hospitalized patients
Interpretative comments	Post-Comm	Percentage of: Number of reports with interpretative comments impacting positively on patient's outcome/Total number of reports with interpretative comments	4	

Table 2: Quality indicators concerning the support processes.

Support processes				
Quality indicator	Code	Measurements	Priority order	Explanatory note
Employee competence	Supp-Train	Number of training events organized for all staff, per year	2	
	Supp-CME	Percentage of: Number of employees that obtained all credits required in a year/Total number of employees	2	Credits are referred to continuing medical education (CME) in order to maintain the competence of medical professionals. Many Countries require professionals a specified number of credits (for examples, 50 credits in a year) for practicing
Client relationships	Supp-Phys	Percentage of: Sum of point given in the enquiry to the question of global satisfaction of the physician/Multiplication of the maximum point defined in the enquiries by the number of enquiries	2	
	Supp-Pat	Percentage of: Sum of point given in the enquiry to the question of global satisfaction of the patient/Multiplication of the maximum point defined in the enquiries by the number of enquiries	2	
Efficiency of laboratory information system	Supp-FailLIS	Number of laboratory information system unplanned downtime episodes, per year	3	

Table 3: Quality indicators concerning the outcome measures.

Outcome measures	5			
Quality indicator	Code	Measurements	Priority order	Explanatory note
Sample recollection	Out-RecLab	Percentage of: Number of patients with recollected samples for errors due to laboratory staff/Total number of patients	1	Examples of error: erroneous data collection; wrong result, etc.
	Out-RecOff	Percentage of: Number of patients with recollected samples for errors not due to the laboratory staff/Total number of patients	1	Examples of error: erroneous data collection; wrong result, etc.
Amended results	Out-InacR	Percentage of: Number of amended results/Total number of released results	1	
Safety	Out-Adv	Number of incident/adverse events occurred in laboratory concerning the health and safety of laboratory staff	1	
	Out-Inj	Number of needlestick injury/Total number of venipunctures	1	

not be discouraged from reaching unattainable limits, but will still acknowledge that achieving better performance is possible.

Notably, when the QIs data were used to measure the desirable events (Post-Comm, Supp-Train, Supp-Cred, Supp-Phys, Supp-Pat), the high and low levels of performance corresponded to the 75th and 25th percentiles, respectively. When the percentile values were equal, the use of a single value was feasible.

Table 5 reports, as an example, quality specifications concerning some QIs based on results collected in the 2016 year.

Data reporting for laboratories

The participants' reports to the EQAP should include the following information.

Table 4: Number of QIs and measurements included in the model of quality indicators issued in the Consensus Conference in 2016.

	Quality indicators	Meas	surements
Key processes	21	43	
– Pre-analytical	11	25	Priority 1 = 19
			Priority 2 = 2
			Priority 3 = 2
			Priority 4 = 2
– Intra-analytical	5	6	Priority 1 = 6
– Post-analytical	5	12	Priority 1 = 9
			Priority 4 = 3
Support processes	3	5	Priority 2 = 4
			Priority 3 = 1
Outcome measures	3	5	Priority 1 = 5

1. Statistical data:

- a. laboratory result related to the specific period during which data has been collected and the relative value calculated using Six-Sigma Metric (sigma value=short-term sigma, which allows drift of 1.5);
- b. mean of sigma values for participants of the same country:
- c. mean of sigma values for all participants.
- 2. Time trends of both results and sigma values.
- 3. Frequency distribution of both results and sigma values.
- 4. Laboratory performance categorization according to the performance specifications.

Future achievements

Despite the large number of papers published and the many presentations during international scientific meetings, a large and steady participation of clinical laboratories to the MQI project has been difficult to achieve. At the 2016 Conference, the need of using QIs has been emphasized once again, and proposals on applicable strategies were discussed among participants. An agreement on the following activities was finally reached:

- involvement of national scientific societies, accreditation bodies and EQA/PT providers of different countries, as a means for disseminating the MQI project and promoting the participation of laboratories;
- selection and appointment of a National Leader, who should coordinate and manage the MQI project in each country. It is expected that the National Leader should (i) encourage the use of MQI; (ii) "personalize" the use of QIs in daily practice according to national practices, requirements and regulations; (iii) co-operate with members of the WG-LEPS and TFG-PEPS providing valuable suggestions or improving the project;
- definition of guidelines supporting the use of QIs along with implementation of improvement actions in clinical laboratories.
- update of the website www.ifcc-mqi.com (i.e. entering QIs data).
- identification of automated and computerized systems for a easy and systematic data collection and recording [18].

Table 5: Example of performances specifications for some QIs of the key processes.

Quality indicator	Code		Performance	specifications
		High	Medium	Low
Pre-anaytical phase				
Misidentification errors	Pre-MisR	< 0.002	0.002-0.13	>0.13
	Pre-MisS	0	0-0.056	>0.056
	Pre-Iden	0	0-0.23	>0.23
Incorrect sample type	Pre-WroTy	0	0-0.03	>0.03
	Pre-WroCo	< 0.003	0.003-0.03	>0.03
Incorrect fill level	Pre-InsV	< 0.014	0.014-0.092	>0.092
	Pre-SaAnt	< 0.07	0.07-0.57	>0.57
Unsuitable samples for transportation and	Pre-NotSt	0	0-0.01	>0.01
storage problems	Pre-ExcTim	0	0-0.13	>0.13
Clotted samples	Pre-Clot	< 0.11	0.11-0.43	>0.43
Intra-anaytical phase				
Unacceptable performances in EQA-PT schemes	Intra-Unac	<2.4	2.4-3.8	>3.8
Post-anaytical phase				
Inappropriate turnaround times	Post-PotTAT	<55	55-70	>70
Incorrect laboratory reports	Post-IncRep	0	0-0.03	>0.03

Conclusions

The valuable experts' contribution and the consensus statements described in this article should hopefully pave the way to better understand the need of a harmonized MQI. On the other hand, the definition of performance specifications for each of the identified QI is as an essential prerequisite for improving the quality and safety in Laboratory Medicine. Although the conclusions of the Consensus Conference should be disseminated to the laboratory community to allow for further advancements in this area, supplementary changes and improvements should probably be introduced in the future according to experience and information from collected data.

The projects aimed to lower the risk of errors in the TEP, and in particular in extra-analytical phases of the TEP, require continuous monitoring of laboratory performances by measuring QIs combined with reliable corrective/preventive actions driven by the evidence collected. Therefore, the MQI developed and managed by the WG-LEPS shall be seen as an external quality assurance project which may allow clinical laboratories to receive a report of their performances over time and a trustworthy benchmark with other laboratories participating in the project and, most importantly, with objectively established performance specifications. This may also provide evidence-based information for worldwide benchmarking and definition of efficient improvement policies.

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