Opinion Paper

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Harmonization of quality indicators in laboratory medicine. A preliminary consensus

Abstract: Quality indicators (QIs) are fundamental tools for enabling users to quantify the quality of all operational processes by comparing it against a defined criterion. QIs data should be collected over time to identify, correct, and continuously monitor defects and improve performance and patient safety by identifying and implementing effective interventions. According to the international standard for medical laboratories accreditation, the laboratory shall establish and periodically review QIs to monitor and evaluate performance throughout critical aspects of pre-, intra-, and post-analytical processes. However, while some interesting programs on indicators in the total testing process have been developed in some countries, there is no consensus for the production of joint recommendations focusing on the adoption of universal QIs and common terminology in the total testing process. A preliminary agreement has been achieved in a Consensus Conference organized in Padua in 2013, after revising the model of quality indicators (MQI) developed by the Working Group on "Laboratory Errors and Patient Safety" of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The consensually accepted list of QIs, which takes into consideration both their importance and applicability, should be tested by all potentially interested clinical laboratories to identify further steps in the harmonization project.

Keywords: harmonization; patient safety; post-analytical phase; pre-analytical phase; quality indicators; total testing process.

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Introduction

Laboratory testing is an integral part of modern medicine as it impacts patient management regarding both screening, early diagnosis, prognosis, appropriate treatment and monitoring [1]. Assessing the quality of medical laboratories has become increasingly important not only for pressures to reduce costs, but also for the evidence of testing-related diagnostic errors [2]. It has been demonstrated that performance and outcome measures improve the quality of patient care [3]. In particular, quality indicators (QIs) represent valuable tools for quantifying the quality of selected aspects of care by comparing it against a defined criterion. QIs therefore may support accountability, help to make judgements and set priorities, enabling comparison over time between providers and the effectiveness of interventions [4]. Laboratory medicine is one of the most dynamic discipline of the health care system and the dramatic decrease in the analytical error rates achieved in the last decades is due, at least in part,

to the development and implementation of valuable QIs and quality specifications for the effective management of analytical procedures [5]. Current evidence, however, emphasizes the vulnerability of pre- and post-analytical phases of the total testing process (TTP) which, in turn, translates into risk for patient safety [6].

According to the last version of the international standard for clinical laboratory accreditation (ISO 15189: 2012) "quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes" [7]. In addition, the document specifies that "the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes". Clinical laboratories can now measure, monitor and improve their analytic performances over time thanks to internal quality control rules, objective analytical quality specifications, and proficiency testing (PT)/external quality assessment (EQA) programs, which have provided clinical laboratories with a valuable benchmark based on objective data. The identification of reliable QIs in the TTP is therefore a key step in enabling users to quantify the quality of laboratory services, but the current lack of attention to extra-laboratory factors is in stark contrast with the numerous studies on the multitude of errors that continue to occur in the pre- and post-analytical phase. In the last decade, interesting programs on indicators of the extra-analytical phases have been developed in some countries, such as Australia and New Zealand [8], Brazil [9], and Catalonia [10], and other surveys and programs have been promoted in the UK [11, 12], in China and Croatia [13].

However, there is no consensus for the production of joint recommendations focusing on the adoption of universal QIs and common terminology in the TTP [14].

In 2008 the IFCC launched a working group named "Laboratory Errors and Patient Safety" (WG LEPS), its primary goal being to identify a list of valuable QIs and related quality specifications to be used as a benchmark between different laboratories around the world and to promote the reduction or errors in the TTP as well as an improvement in quality and patient safety. The preliminary model of quality indicators (MQI) has been developed, evaluated by some voluntary laboratories at an international level and preliminary results reported [15]. As a further step of this initiative, the WG LEPS has organized a Consensus Conference to design a road map for the harmonization of QIs. The conference, held in Padua on 24 October, 2013 and titled "Harmonization of quality indicators: why, how and when?" aimed to bring together all experts and interested parties and to find a preliminary consensus on the steps towards harmonization of QIs.

Here we report the main results of the conference in order to spread the information to all possible interested individuals and organizations, and to promote further efforts to harmonizing QIs in laboratory medicine.

The conference organization: background and preliminary work

Although the invited experts have been aware of the state-of-the-art of QIs in laboratory medicine, a series of preliminary documents and questions have been circulated among all invited delegates to achieve a preliminary consensus on terminology, rationale, purpose of each and all QIs. It should be highlighted that the different steps required to develop and test QIs previously described [16–18] have been carefully followed.

In particular, as concerns laboratory medicine, since a variety of QIs and terminology are currently used. Therefore, the path towards harmonization should be based on sound criteria, and in particular, a consensus has been achieved regarding the main characteristics of QIs. In particular, they should be: 1) patient-centered to promote total quality and patient safety; 2) consistent with the definition of "laboratory error" which has been specified in the ISO/TS 22367: 2008 [19] and conducive to addressing all stages of the TTP, from initial pre-pre-analytical steps (test request and patient/sample identification) to post-post-analytical steps (acknowledgment of data communication, appropriate result interpretation and utilization); 3) consistent with the requirements of the ISO 15189: 2012 [7].

In addition, essential pre-requisites of QIs, as measurable and objective tools, appear to be: 1) importance and applicability to a wide range of clinical laboratories at an international level; 2) scientific soundness with a focus on areas of great importance for quality in laboratory medicine; 3) the definition of evidence-based thresholds for acceptable performance; and 4) timeliness and possible utilization as a measure of laboratory improvement.

Another fundamental issue is the awareness that the process of harmonization of QIs consists of two compulsory steps: the identification of common QIs and a standardized reporting system. While the identification of harmonized and universal QIs seems to be the "core" issue, standardization of systems for data collection and reporting represent critical steps towards effective harmonization initiatives [17]. After discussing a preliminary document, and answering to a series of related questions, all experts did agree to work on the revision of currently available QIs, starting

from the already described IFCC MQI [15], taking into consideration the relevance of each QI, its generalizability and applicability by clinical laboratories from different countries. All speakers accepted to present their experience on QIs focusing on the main advantages and limitations of their experiences, as well as on eventual agreement and disagreement with the IFCC WG LEPS program.

Results

Revised list of QIs

The QI chart (Table 1) developed by IFCC LEPS was presented as a means of harmonizing measurement of TTP. This list contains a comprehensive series of QIs, covering all steps of the TTP, that have been considered to be applicable to all laboratories despite their complexity, technological level, and need of close interaction with clinicians and other healthcare staff. This was considered to be too ambitious as a first step and a priority score (1 is the highest priority) was performed to determine the critical QI that could be used as an initial international survey. For each QI, the reporting system has been simplified to allow homogeneous data collection and reporting. Each attendee agreed to pilot this error analysis in a number of laboratories in their country.

Definitions

Table 2 reports the proposed definitions of all QIs and some examples to allow a better comprehension of the meaning of each indicator to interested laboratory professionals.

Documents

In the IFCC WG LEPS website (www.ifcc-mqi.com) interested professionals may find the program of the Consensus Conference, the list of QIs, and questionnaire on the feasibility of data collection for the selected QIs.

Further steps

Further steps of the harmonization project are: 1) testing of the revised list of QIs by clinical laboratories that are already involved in existing programs to collect data during a 6-month period, and establishing preliminary quality specifications of the individual QI; 2) collect data on the proposed questionnaire by potentially interested clinical laboratories that up to now have no experience in the management of QIs; 3) organize a further Consensus Conference for discussing the results (steps 1 and 2) in order to better understand the feasibility of data collection for all QIs by clinical laboratories operating at an international level and in different countries.

Conclusions

Indicators for performance and outcome measurement allow the quality of care and services to be measured and provide a quantitative basis for interested parties aiming to achieve improvement in care and processes by which patient care and services are provided. The measurement and monitoring of QIs in laboratory medicine serve many purposes: 1) document the quality of the service provided; 2) improve performance and patient safety; 3) make comparison (benchmarking) over time between laboratories; 4) make judgments and set priorities (corrective actions to be performed); and 5) support accountability, quality improvement and accreditation.

In particular, the implementation and revision of QIs represent fundamental requirements of the ISO 15189: 2012 [7]. This document recognizes the need to assure quality in all aspects of the TTP, 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 form") to the post-post-analytical" phase ("Right interpretation with the Right advice as to what to do next with the result") [20]. QIs, therefore, should cover all aspects of the TTP, including the evaluation of the appropriateness of test request and result interpretation [21]. However, the harmonization of currently available QIs should take into consideration also the feasibility by all potentially interested clinical laboratories around the world of data collection and reporting. Therefore, the experts participating at the Consensus Conference did agree to revise existing QIs at the light of both their importance and applicability.

As quality is a never-ending journey, the implementation and adoption of QIs should be viewed as dynamic process, starting from a high priority QIs and moving toward a more sophisticated level which necessitates of a close interaction between laboratory professionals and other healthcare operators.

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Table 1 List of QIs (order of priority: 1, mandatory; 2, important; 3, suggested; 4, valuable).

	Priority	Quality indicator	Reporting systems
Process indicators – Priority 1			
Pre-analytical	1	Misidentification errors	Samples suspected to be from wrong patients a) Percentage of "Number of misidentified requests/Total number of requests" b) Percentage of "Number of misidentified samples/Total number of samples" c) Percentage of "Number of samples with fewer than 2 identifiers initially supplies/Total number of samples" d) Percentage of "Number of unlabeled samples/Total number of samples"
Pre-analytical	1	Test transcription errors	a) Percentage of "Number of outpatients requests with erroneous data entry (test name)/Total number of outpatients requests" b) Percentage of "Number of outpatients requests with erroneous data entry (missed test)/Total number of outpatients requests" c) Percentage of "Number of outpatients requests with erroneous data entry (added test)/Total number of outpatients requests" d) Percentage of "Number of inpatients requests with erroneous data entry (test name)/Total number of inpatients requests" e) Percentage of "Number of inpatients requests with erroneous data entry (missed test)/Total number of inpatients requests" f) Percentage of "Number of inpatients requests with erroneous data entry (added test)/Total number of inpatients requests"
Pre-analytical	1	Incorrect sample type	a) Percentage of "Number of samples of wrong or inappropriate type (i.e., whole blood instead of plasma)/Total number of samples" b) Percentage of "Number of samples collected in wrong containers/Total number of samples"
Pre-analytical	1	Incorrect fill level	a) Percentage of "Number of samples with insufficient sample volume/Total number of samples" b) Percentage of "Number of samples with inappropriate sample-anticoagulant volume ratio/Total number of samples with anticoagulant"
Pre-analytical	1	Unsuitable samples for transportation and storage problems	a) Percentage of "Number of samples not received/Total number of samples" b) Percentage of "Number of samples not properly stored before analysis/Total number of samples" c) Percentage of "Number of samples damaged during transportation/Total number of samples" d) Percentage of "Number of samples transported at inappropriate temperature/Total number of samples" e) Percentage of "Number of samples with excessive transportation time/Total number of samples"
Pre-analytical	1	Contaminated samples	Percentage of "Number of contaminated samples rejected /Total number of samples"
Pre-analytical	1	Samples hemolyzed	Percentage of "Number of samples with free Hb>0.5 g/L/Total number of samples (clinical chemistry)*" *Clinical chemistry: i.e., all samples which are analyzed on the chemistry analyzer which is used for detection of HIL indices. If laboratories are detecting hemolysis visually, they count all samples with visible hemolysis (clinical chemistry). We suggest that a color chart is provided for this purpose.
Pre-analytical	1	Samples clotted	Percentage of "Number of samples clotted/Total number of samples with an anticoagulant"
Intra-analytical	1	Test with inappropriate ICQ performances	Percentage of "Number of tests with CV% higher than selected target, per year/Total number of tests with CV% known for at least: – Glucose – Creatinine

(Table 1 Continued)

	Priority	Quality indicator	Reporting systems
			– Potassium
			– C-Reactive Protein (CRP)
			– Troponin
			– TSH
			– CEA
			– PT (INR)
			– Hemoglobin (Hb)"
Intra-analytical	1	Test uncovered by an EQA-PT control	Percentage of "Number of tests without EQA-PT control/Total number of tests in the menu"
Intra-analytical	1	Unacceptable performances in EQA-PT schemes	Percentage of "Number of unacceptable performances in EQAS-PT Schemes, per year/Total number of performances in EQA Schemes, per year"
Post-analytical	1	Data transcription errors	a) Percentage of "Number of incorrect results for erroneous manual transcription/Total number of results that need manual transcription"
			b) Percentage of "Number of incorrect results for information system problems-failures/Total number of results"
Post-analytical	1	Inappropriate turnaround times	a) Percentage of "Number of reports delivered outside the specified time/Total number of reports"
			b) Turn Around Time (minutes) of Potassium at 90th percentile (STAT)"
			c) Turn Around Time (minutes) of International Normalized Ratio value at 90th percentile (STAT)"
			d) Turn Around Time (minutes) of White Blood Cell count at 90th percentile (STAT)"
			e) Turn Around Time (minutes) of Troponin I or Troponin T at 90th percentile (STAT)"
Post-analytical	1	Incorrect laboratory reports	Percentage of "Number of incorrect reports issued by the laboratory/Total number of reports issued by the laboratory"
Post-analytical	1	Notification of critical values	a) 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"
			b) 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"
Process indicators – Priority 2			
Pre-analytical	2	Inappropriate test requests	a) Percentage of "Number of requests without clinical question (outpatients)/Total number of requests (outpatients)"
			b) Percentage of "Number of requests without clinical question (inpatients)/Total number of requests (inpatients)"
Pre-analytical	2	Inappropriate time in sample collection	Percentage of "Number of samples collected at inappropriate time of sample collection/Total number of samples"
Process indicators – Priority 3			
Pre-analytical	3	Intelligible request	a) Percentage of "Number of unintelligible outpatients requests/Total number of outpatients requests"
			b) Percentage of "Number of unintelligible inpatients requests/Total number of inpatients requests"
Intra-analytical	3	Unacceptable performances in EQA-PT	Percentage of "Number of unacceptable performances in EQAS-PT Schemes per year occurring to previously treated cause/Total number of unacceptable performances"

(Table 1 Continued)

	Priority	Quality indicator	Reporting systems
Process indicators – Priority 4			
Pre-analytical	4	Inappropriate requests	a) Percentage of "Number of inappropriate requests, with respect to clinical question (outpatients)/Number of requests reporting clinical question (outpatients)"
			b) Percentage of "Number of inappropriate requests, with respect to clinical question (inpatients)/Number of requests reporting clinical question (inpatients)"
Post-analytical	4	Interpretative comments	Percentage of "Number of reports with interpretative comments, provided in medical report, impacting positively on patient's outcome/Total number of reports with interpretative comments"
Post-analytical	4	Results notification (TAT)	a) Time (from result validation to result communication to the clinician) to communicate critical values of inpatients (minutes)
			b) Time (from result validation to result communication to the clinician) to communicate critical values of outpatient (minutes)
Outcome measure			
Outcome measure	1	Sample recollection	a) Percentage of "Number of outpatients with recollected samples for laboratory errors/Total number of outpatients"
			b) Percentage of "Number of inpatients with recollected samples for laboratory errors/Total number of inpatients"
Outcome measure	1	Inaccurate results	Percentage of "Number of inaccurate results released/Total number of results released"
Support processes indicators			
Support process	3	Efficiency of laboratory information system	Number of laboratory information system downtime episodes, per year
Support process	2	Employee competence	a) Number of training events organized for all staff per year
			b) Percentage "Number of credits obtained by employee, per year/Total number of credits to be obtained, per year"
Support process	2	Client relationships	a) Client satisfaction: physician
			Percentage of "Sum of point given in the enquiry to the question of global satisfaction/Total number of enquiries answered"
			b) Client satisfaction: patient
			Percentage of "Sum of point given in the enquiry to the question of global satisfaction/Total number of enquiries answered"

CV, coefficient of variation; EQA, external quality assessment; IQC, internal quality control; PT, proficiency testing.

Table 2 Some definitions about QIs with priority 1.

Type of error	Quality indicator	What definitions do you use?	How do you currently measure?
Process indicators – Priority 1			
Pre-analytical	Misidentification errors		
Pre-analytical	Test transcription errors	Any sample registration error, e.g., missed test or wrong test entered at registration but sample was not able to be tested; wrong sample collection time entered into LIS; sample too old/unsuitable for add on	Please note, only those samples rejected are counted in these categories
Pre-analytical	Incorrect sample type	The specimen has been collected in the wrong tube type or the wrong type of specimen has been collected, e.g., PT test collected in an EDTA tube (wrong preservative used), or a first stream urine was collected instead of a mid-stream urine or a plasma sample instead of a serum sample for Vit B12, spot sample instead of time sample	
Pre-analytical	Incorrect fill level	ESR (PT, INR, PTT) or other whole blood/plasma tubes or syringes not filled to correct level	
Pre-analytical	Unsuitable samples for transportation and storage problems	The sample has not been stored or transported correctly, e.g., biochemistry or fresh cytology sample stored overnight at room temp before analysis; sample left and not centrifuged on time; incorrect transport temperature; pneumatic tube; sample not frozen in prescribed time; delayed transportation resulting in the sample too old to process requested tests	
Pre-analytical	Contaminated samples	Any sample rejected due to contamination, e.g., drip arm collection; sample cross contaminated; the wrong preservative; tipping blood from EDTA tube to sodium citrate tube; drug screening; deliberate or accidental contamination; diluted samples and include contaminated blood cultures	
Pre-analytical	Samples hemolyzed	Any samples where one or more tests were not performed or one or more results were rejected or not reported due to hemolysis	
Pre-analytical	Samples clotted	e.g., clotted FBC tubes	
Intra-analytical	Test with inappropriate ICQ performances		
Intra-analytical	Test performance error uncovered by an EQA-PT control		
Intra-analytical	Unacceptable performances in EQA-PT schemes		
Post-analytical	Data transcription errors	Errors in manual transcription data	
Post-analytical	Inappropriate turnaround times	Excessive TATs for STAT assay of "target" tests (troponin, K, INR, WBC)	
Post-analytical	Incorrect laboratory reports	Number of incorrect reports/results issued by the laboratory	
Post-analytical	Notification of critical values	Failure to notify critical results	

CV, coefficient of variation; EQA, external quality assessment; IQC, internal quality control; PT, proficiency testing.

References

1. Plebani M, Laposata M, Lundberg GD. The brain-to-brain loop concept for laboratory testing 40 years after its introduction. Am J Clin Pathol 2011;136:829–33.
2. Epner PL, Gans JE, Graber ML. When diagnostic testing leads to harm: a new outcomes-based approach for laboratory medicine. BMJ Qual Saf 2013;22(Suppl 2):ii6–10.
3. Mainz J, Krog BR, Bjornshave B. Nationwide continuous quality improvement using quality indicators: the Danish National Indicator Project. Int J Qual Health Care 2004;16(Suppl 1): i45–50.
4. Mainz J. Defining and classifying clinical indicators for quality improvement. Int J Qual Health Care 2003;15:523–30.
5. Plebani M, Sciacovelli L, Marinova M, Marcuccitti J, Chiozza ML. Quality indicators in laboratory medicine: a fundamental tool for quality and patient safety. Clin Biochem 2013;46:1170–4.
6. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101–10.
7. ISO 15189:2012. Medical laboratories – requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization, 2012.
8. Khoury M, Burnett L, Mackay M. Error rate in Australian chemical pathology laboratories. Med J Aust 1996;165:128–30.
9. Shcolnik W, de Oliveira CA, de São José AS, de Oliveira Galoro CA, Plebani M, Burnett D. Brazilian laboratory indicators program. Clin Chem Lab Med 2012;50:1923–34.
10. Kirchner MJ, Funes VA, Adzet CB, Clar MV, Escuer MI, Girona JM, et al. Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience. Clin Chem Lab Med 2007;45:672–7.
11. Barth JH. Selecting clinical quality indicators for laboratory medicine. Ann Clin Biochem 2012;49:257–61.
12. Barth JH. Clinical quality indicators in laboratory medicine. Ann Clin Biochem 2012;49:9–16.
13. Simundic AM, Topic E. Quality indicators. Biochem Med 2008;18:311–9.
14. Plebani M, Sciacovelli L, Lippi G. Quality indicators for laboratory diagnostics: consensus is needed. Ann Clin Biochem 2011;48:479.
15. Sciacovelli L, O'Kane M, Skaik YA, Caciagli P, Pellegrini C, Da Rin G, et al. IFCC WG-LEPS. Quality indicators in laboratory medicine: from theory to practice. Preliminary data from the IFCC Working Group Project "Laboratory errors and patient safety". Clin Chem Lab Med 2011;49:835–44.
16. Mainz J. Developing evidence-based clinical indicators: a state of the art methods primer. Int J Qual Health Care 2003;15 (Suppl 1):i5–11.
17. Plebani M, Chiozza ML, Sciacovelli L. Towards harmonization of quality indicators in laboratory medicine. Clin Chem Lab Med 2013;51:187–95.
18. Plebani M, Sciacovelli L, Aita A, Padoan A, Chiozza ML. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Chim Acta 2013 Sep 5. [Epub ahead of print].
19. ISO/PDTS 22367:2008. Medical laboratories – reducing error through risk management and continual improvement. Geneva, Switzerland: International Organization for Standardization, 2008.
20. Tate JR, Johnson R, Barth J, Panteghini M. Harmonization of laboratory testing – current achievements and future strategies. Clin Chim Acta 2013 Aug 31. [Epub ahead of print].
21. Plebani M, Sciacovelli L, Aita A, Chiozza ML. Harmonization of pre-analytical quality indicators. Biochem Med 2014;24: 105–13.