Quality Indicators for the Total Testing Process

Mario Plebani, MD*, Laura Sciacovelli, Biol Sci, Ada Aita, Biol Sci

KEYWORDS

• Errors in laboratory medicine • Quality indicators • Extra-analytical phases
• Quality specifications • External quality assurance program

KEY POINTS

- In laboratory medicine the extra-analytical phases have the highest error rates.
- ISO 15189:2012 requires the establishment of quality indicators to monitor and evaluate laboratory performance throughout critical aspects of pre-examination, examination, and postexamination processes.
- The use of quality indicators that meet requirements for effectiveness and harmonization is an important quality improvement tool.
- The participation in External Quality Assurance Program managed by the working group Laboratory Errors and Patient Safety of IFCC (www.ifcc-mqi.com) allows a laboratory to compare its performance with that of other participants.

INTRODUCTION

The increasingly dominant role of laboratory medicine in clinical decision making and the pressure on cost containment have led to a more careful evaluation of the effectiveness of, and improvement in, clinical outcomes. Because laboratory tests play an extremely important role in diagnosing, monitoring, and evaluating patient outcomes, evidence-based evaluation of laboratory performances is crucial to ensuring that patients receive safe, efficient, and effective care.

Efforts to reduce errors and enhance patient safety in medicine must focus on risk procedures and processes with a high likelihood of error generation. Analytical activities must be improved in the effort to achieve consistently higher levels of quality in laboratory medicine. Yet, in the last few decades, performance measurements have focused mainly on analytical processes with a view to meeting the quality specifications of precision and trueness.[1,2] Clinical laboratories can measure, monitor, and improve their analytical performances over time thanks to internal quality control

The authors have nothing to disclose.
Department of Laboratory Medicine, University Hospital of Padova, via Giustiniani, 2, 35128 Padova, Italy
* Corresponding author.
E-mail address: mario.plebani@unipd.it

Clin Lab Med 37 (2017) 187–205
http://dx.doi.org/10.1016/j.cll.2016.09.015 **labmed.theclinics.com**

(IQC) rules, objective analytical quality specifications, and proficiency testing/external quality assessment (EQA) programs, which have provided clinical laboratories with a valuable benchmark based on objective data. IQC procedures and EQA programs have significantly improved the intra-analytical quality of laboratory testing. However, studies on errors in laboratory medicine confirm that most errors occur in the preanalytical and postanalytical phases of testing.[3–6] The implementation of performance measurements to evaluate the preanalytical and postanalytical stages of the total testing process (TTP) is therefore needed to maximize the overall testing cycle and the quality of patient care. In addition, recent regulation and accreditation guidelines require laboratories to focus improvement efforts not only on the intra-analytical phase, but also on all steps of the TTP.[7]

ERRORS IN THE EXTRA-ANALYTICAL PHASES

Although the frequency of laboratory errors varies greatly depending on the study design and steps of the TTP investigated, a series of papers have drawn the attention of laboratory professionals to the preanalytical and postanalytical phases, which have been demonstrated to be more vulnerable to errors than the analytical phase; the preanalytical phase has the highest error rates, accounting for up to 70% of all mistakes in laboratory diagnostics.[3–6,8–10] Several technological, informatics, and computer science advances introduced in the preanalytical phase have the potential to decrease the risk of errors. The complexity of the process, and the variety of owners and mutual responsibilities at the interfaces of several steps calls for adequate governance based on reliable measures. Indeed, the development of preanalytical robotic workstations and their employment in clinical practice have significantly reduced errors in the conventional preanalytical steps involved in making a sample suitable for analysis (centrifugation, aliquoting, diluting, and sorting specimens into batches for their introduction into automated analyzers).[11–13] The preanalytical phase consists of a pre-preanalytical phase and "true" preanalytical phase. The pre-preanalytical phase involves selecting and ordering appropriate tests, and collecting, identifying, labeling, handling, and transporting biologic samples. These processes are neither performed by, nor usually under the control of, laboratory staff. Evidence collected demonstrates that the staff in clinical wards is at a significantly higher risk of error than those in the laboratory.[14–16] In the preanalytical phase, the laboratory accepts samples, centrifuging, aliquoting, diluting, and sorting the biologic samples. This categorization is not only of "taxonomic" value, but also underpins the responsibilities and duties of nonlaboratory personnel, most of the processes being performed by other health care operators (eg, nurses and physicians).[9]

An important factor affecting quality in the postanalytical phase is poor communication between laboratory professionals and clinicians, in particular in relation to timeliness of reporting, notification of significantly abnormal test results, and presentation of relevant information through reports and interpretative comments. Breakdowns in communication lead to errors that compromise patient safety, and lead to the inefficient and ineffective use of resources.

Clinicians are interested in service quality, which encompasses total testing error (imprecision and trueness), availability, cost, relevance, and timeliness. However, because the quality of a laboratory is often judged on timeliness, many laboratories may be ready to sacrifice analytical quality for a faster turnaround time (TAT). Timeliness is measured by monitoring the TAT of some specific tests, and the time required for notification of critical results. The automation of various steps in the analytical phase, the increased use of electronic results reporting, and the development of

automatic electronic alerting systems for critical values have contributed to reducing the time required for results reporting. Prompt reporting of test results can improve efficiency in patient care and enhance clinician and patient satisfaction, even when it does not affect health outcomes.[8,17]

The correct monitoring of TAT calls for knowledge of the different measurement approaches used by laboratories, such as test typology, need for priority reporting (eg, urgent or routine), patient typology (eg, inpatients, outpatients, urgent cases), and the activities incurred (eg, interval of measurement). Another important aspect is the procedure used for notifying critical values; this plays a key role in safe and effective patient care. Yet there is still a lack of consensus on the choice of analytes and critical ranges, and notification times vary depending on patient typology (inpatients or outpatients). Likewise, mistakes in the content and completeness of laboratory reports and misunderstanding by the treating physician as to the significance of the information in the report, among other factors, can delay the treatment of a serious disease and alter outcomes. Specific report content issues can include any of the following: noninterpretable information, incorrect reference interval data, inaccurate personal patient details, and/or incorrect reporting of measurements. Moreover, different types of error can occur during report formatting. Reports lacking units of measurement or using inappropriate units of measurement can lead to harmful misinterpretation of results and/or underestimation of vital information. The correct interpretation of results is crucial to patient outcome yet, wishing to avoid giving inappropriate advice, many laboratories fail to provide interpretative comments in the absence of complete clinical information. Studies conducted have revealed that although most comments provided in laboratory reports are acceptable, some are inappropriate or misleading and, in a few cases, dangerous, leading to inaccurate assumptions by staff, particularly if the available clinical information is insufficient or the expertise in a clinical chemistry subspecialty area (eg, toxicology, endocrinology, and tumor markers) is inadequate.[18] The aim of interpretative comments on laboratory reports is to help clinicians interpret complex data provided, particularly when dynamic or rare test results are reported, when significant abnormalities are present, and/or when analytical or preanalytical factors might compromise the interpretation. Although several authors have described this process and indicated its value, there is little evidence that it has improved patient outcomes, mainly because of difficulties involved in collecting data.[19–22]

IMPROVEMENT PROCESS

Quality improvement initiatives, in compliance with systematic criteria and organization, are key elements in ensuring an effective quality management system and favorable outcomes by reducing errors. That which is not measured cannot be improved on. Improvement actions in laboratory activities are as many and varied as the relationships and interactions between multiple processes and activities are complex. Success depends on leadership committed to improving quality as its modus operandi, organizational culture that calls for efforts from all employees involved in improvement activities, integrated and well-defined processes and procedures that define how the improvement can be implemented and how shared responsibility is to be achieved, and application by management and staff of knowledge and skills for continuous improvement and tools.[23]

The identification of improvement opportunities in clinical laboratories must include all TTP activities, especially those in the extra-analytical phases; this calls for proactive and reactive methods, not only concerning the processes but also, and above all, regarding the risks related to patient safety.[4,5,24,25] Improvement opportunities are

based on information arising from a robust and integrated quality management system that provides a wide variety of information sources, generated from symptomatic (eg, incident reporting) or asymptomatic (eg, analysis of the strengths, weaknesses, opportunities) events, and managed within processes pertaining to evaluation, monitoring, and improvement.[23] In particular, results of quality indicators (QIs), performances obtained in EQA programs, reports of external audits for accreditation and/or certification, and management of undesirable events (errors, complaints, adverse events, nonconformities).

Other important sources of information are activities focusing on users outside (eg, citizens, patients, clinicians) and within (laboratory staff) the organization. Surveys on user satisfaction and the analysis of users' needs provide data for the definition of organizational and quality goals, and values and intervention priorities. The reliability of information on opportunities for improvement reflects the criteria to be used, and the way the information itself is to be collected and handled.

QUALITY INDICATORS

The need to reduce the error rate has highlighted, especially in preanalytical and postanalytical phases, the difficulty involved in identifying adverse events and complying with the International Standard for Accreditation of Clinical Laboratories, ISO 15189:2012, thus prompting laboratory professionals to develop and implement QIs.[26–30] As stated by the ISO 15189:2012, "The laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post examination processes"; and "The process of monitoring QIs shall be planned, which includes establishing the objectives, methodology, interpretation, limits, action plan and duration of measurement."[7]

In recent years, different QIs have been developed to monitor critical processes and identify errors and mistakes in laboratories based on their particular characteristics and organization. This monitoring is based on the laboratories' different health care contexts, purposes and goals, patient number and typology, activity typology, and sensitivity and training of staff.

Many laboratories have introduced QIs based on different criteria and methods and, in the last decade, interesting programs for indicators of the extra-analytical phases have been developed in some countries and regions, such as Australia and New Zealand, Brazil, and Catalonia, and other surveys and programs have been promoted in the UK, China, and Croatia.[31–36]

The different experiences worldwide in the use of QIs have made it difficult to establish a reliable state-of-the art because data reported are not comparable.[37–40] Because of differences in methods used for data collection processing and analysis of results this incomparability underlines the need for international consensus on the adoption of universal QIs and common terminology. Because laboratory results have such an important impact on patient safety, activities related to evaluation, monitoring, and quality improvement within the TTP, it is clearly of crucial importance for laboratory professionals to focus their attention on harmonization of the management of QIs. The harmonization process must hinge on the recognition, understanding, and explanation of the differences between criteria used and procedures used to overcome the differences and achieve uniformity in compliance with organizational and management peculiarities. The first step must therefore be designed with an awareness of the differences, and the recognition that a common model must be used to assess appropriateness, identify strengths and weaknesses, and define uniform criteria and procedures.[41]

Because various QIs and terminologies are currently used in laboratory medicine, the path toward harmonization should be based on sound criteria. Consensus has been achieved regarding the main characteristics of QIs, which should be (1) patient-centered to promote total quality and patient safety; (2) consistent with the definition of "laboratory error " specified in the ISO/TS 22367: 2008[42] and conducive to addressing all TTP stages, from initial pre-preanalytical (test request and patient/sample identification) to post-postanalytical (acknowledgment of data communication, appropriate result interpretation, and use) steps; and (3) consistent with ISO 15189: 2012[7] requirements. In addition, essential prerequisites of QIs, as measurable and objective tools, are (1) importance and applicability to a wide range of clinical laboratories worldwide, (2) scientific robustness 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 use as a measure of laboratory improvement.

The revision issued in 2012 of ISO 15189 focuses on the definition of QIs and the rationale for their use, and calls for establishment of QIs concerning the preanalytical, intra-analytical, and postanalytical phase; definition of goals, method, interpretation, limits, action plans, and measurement times to ensure a monitoring process; and appropriateness continued through periodic reviews enabling the systematic monitoring and evaluation of the laboratory's contribution to patient care.

In the harmonization process, a model QI (MQI) is defined as an indicator where identification of indicator and reporting system is well designed; is of strategic importance in comparing the results of different laboratories, identifying the true state-of-the-art, and defining quality specifications for each indicator; and contributes to reducing errors and maximizing patient safety. An accurate definition of each indicator helps staff to understand the following:

- What they must measure
- The performance standard expected of them
- The TTP phase involved
- The reason for the importance of the previous points
- The way in which events under control have to be measured and what the measurement problems are
- The information to be transmitted

Likewise, it is of great importance to implement a reporting system that specifies the

- Individual who is to collect or analyze data and identify the corrective actions
- Frequency of data collection
- Way in which data are to be analyzed
- Approach required for evaluating quality improvement

Moreover, to be effective, the management of QIs must be designed as part of a coherent and integrated system in quality improvement strategies,[43] and based on an internal assessment evaluation system and participation in an interlaboratory program.

The internal assessment system includes the definition of a list of QIs to be used in different laboratory areas, both technical and managerial; a form for each indicator that defines the specifications (what has to be measured, how to collect data, acceptability limits for results, laboratory areas where they are to be carried out, responsibilities); and instructions describing operational arrangement for managing the QIs system.

The effectiveness of QIs is closely related to the complete understanding of all staff involved as to the importance of using the specific indicator, the method for data collection and processing, and result evaluation. The definition of a form for each indicator that describes the rationale, the activities/processes involved, and any necessary information regarding the collection and analysis of data is conducive to achieving full staff awareness (Table 1). The form not only formalizes statements, but also obliges staff to assume full responsibility by signing it.

Likewise, it is important to issue an operating instruction to describe the operational procedures to be followed and to ensure uniform behavior so that goals can be achieved. The operating instructions must describe all activities involved in the QIs management system and, in particular, the criteria and procedures for the following:

- Identification and definition of indicator
- Design of QIs system
- Method for data collection and analysis of results and related frequency
- Method for reviewing the system
- Responsibilities for each step, including system testing, putting into practice, implementing improvement actions

Employment of QIs calls for a data collection system that guarantees:

- Accuracy, so that all events to be measured are effectively collected
- Traceability, which raises staff awareness of their responsibilities in recording information to provide evidence of procedures used and to simplify investigation into causes of error

Table 1
Quality indicator form

Identification code		
Purpose/rationale		
Process/activity involved		
Method of data collection		
Times for data collection		
Method for data processing		
Results presentation		
Goal for corrective action		
Goal for improvement action		
Person appointed for data collection		
Person in charge of data collection		
Person in charge of periodic data analysis		
Problems of the measurement		
Classification		
☐ Efficiency	☐ Structure	☐ Preanalytical phase
☐ Effectiveness	☐ Activity/process	☐ Intra-analytical phase
☐ Timeliness	☐ Results	☐ Postanalytical phase
☐ Safety of the staff	☐ Outcome	☐ Support processes
☐ Competence		
Laboratory area where the indicator has to be used		
Note		

- Standardization, so that data collected in different periods of time are comparable
- Efficiency, making data analysis easier and timelier for the implementation of improvement actions

It is therefore advisable to use software to guarantee standardized data collection independently of operator, the measure of all events that must be recorded, reduced recording and processing times, ease of procedures, and improved staff satisfaction.

A well-designed and managed internal assessment system enables the laboratory to assess QIs results over time but does not provide information on its performance with respect to other laboratories, at either a national or international level. The participation in an interlaboratory program, proposed and approved by the scientific community, is therefore indispensable in improving on process and reducing error, and in monitoring the appropriateness of the internal assessment system used.

To promote the harmonized use of QIs, since 2008 the Working Group on Laboratory Errors and Patient Safety (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has implemented a project aiming to develop an MQI for use in clinical laboratories throughout the world.[44,45] It is designed, above all, to identify a list of QIs that can be applied in all laboratories worldwide, define the procedures for data collection, and provide quality specifications for evaluating laboratory results.

Three different MQIs have followed in succession because during the project's experimental phase it emerged that there was a need to improve aspects, such as wording, the number of indicators, and the information included in the periodic and confidential report.

The MQI, discussed and approved in the Consensus Conference held in Padova (Italy) in 2013, has been tested since 2014 through an external quality assurance program (EQAP). A dedicated Web site (www.ifcc-mqi.com) has been implemented to manage uniform data collection and centralized data processing, and to provide a report for each participant. Participation is free and confidentiality is ensured. A criterion to define the performance specifications for each indicator has been proposed. MQI includes 53 QIs of which, concerning the key processes, 28 indicators were defined for the preanalytical phase, six for the intra-analytical phase, and 11 for the postanalytical phase. Moreover, five indicators were defined to monitor the support processes (two for staff competence, two users' satisfaction, one efficiency of laboratory information system) and three the outcome measures (**Tables 2–4**).

To facilitate the introduction into practice for each indicator, an order of priority has been assigned based on the importance of the specific indicator and the difficulty of data collection (one the highest priority, four the lowest). The QIs with priority one, which are mandatory, are to be put into practice first.

In many cases in the MQI, different measures have been defined to keep a single event under control to make data from laboratories comparable. In fact, in cases of different laboratories (ie, for context or user typology) it is important to split the collected data to guarantee that, for the same QI, the data collected have the same origin.

Regarding the identification of common QIs, mounting evidence underscores the importance of a standardized reporting system as an essential step toward harmonization. First and foremost, the standardization of the system for data collection and reporting plays a key role in ensuring the comparability of data collected by different

Table 2
Quality indicators of key processes

Code	Quality Indicator	Priority Order
Preanalytical Phase		
Misidentification errors		
Pre-MisR	Percentage of number of misidentified requests/ total number of requests	1
Pre-MisS	Percentage of number of misidentified samples/ total number of samples	1
Pre-Iden	Percentage of number of samples with fewer than two identifiers initially supplied/total number of samples	1
Pre-UnlS	Percentage of number of unlabeled samples/ total number of samples	1
Inappropriate test requests		
Pre-Quest	Percentage of number of requests without clinical question (outpatients)/total number of requests (outpatients)	2
Pre-OutReq	Percentage of number of inappropriate requests, with respect to clinical question (outpatients)/number of requests reporting clinical question (outpatients)	4
Pre-InReq	Percentage of number of inappropriate requests, with respect to clinical question (inpatients)/number of requests reporting clinical question (inpatients)	4
Test transcription errors		
Pre-OutpTN	Percentage of number of outpatients requests with erroneous data entry (test name)/total number of outpatients requests	1
Pre-OutpMT	Percentage of number of outpatients requests with erroneous data entry (missed test)/total number of outpatients requests	1
Pre-OutpAT	Percentage of number of outpatients requests with erroneous data entry (added test)/total number of outpatients requests	1
Pre-InpTN	Percentage of number of inpatients requests with erroneous data entry (test name)/total number of inpatients requests	1
Pre-InpMT	Percentage of number of inpatients requests with erroneous data entry (missed test)/total number of inpatients requests	1
Pre-InpAT	Percentage of number of inpatients requests with erroneous data entry (added test)/total number of inpatients requests	1
Unintelligible requests		
Pre-OutUn	Percentage of number of unintelligible outpatients requests/total number of outpatients requests	3

(*continued on next page*)

Table 2
(*continued*)

Code	Quality Indicator	Priority Order
Pre-InpUn	Percentage of number of unintelligible inpatients requests/total number of inpatients requests	3
Incorrect sample type		
Pre-WroTy	Percentage of number of samples of wrong or inappropriate type (ie, whole blood instead of plasma)/total number of samples	1
Pre-WroCo	Percentage of number of samples collected in wrong container/total number of samples	1
Incorrect fill level		
Pre-InsV	Percentage of number of samples with insufficient sample volume/total number of samples	1
Pre-SaAnt	Percentage of number of samples with inappropriate sample-anticoagulant volume ratio/total number of samples with anticoagulant	1
Unsuitable samples for transportation and storage problems		
Pre-NotRec	Percentage of number of samples not received/ total number of samples	1
Pre-NotSt	Percentage of number of samples not properly stored before analysis/total number of samples	1
Pre-DamS	Percentage of number of samples damaged during transportation/total number of samples	1
Pre-InTem	Percentage of number of samples transported at inappropriate temperature/total number of samples	1
Pre-ExcTim	Percentage of number of samples with excessive transportation time/total number of samples	1
Contaminated samples		
Pre-MicCon	Percentage of number of contaminated samples rejected/total number of microbiologic samples	1
Sample hemolysed		
Pre-Hem	Percentage of number of samples with free Hb >0.5 g/L (clinical chemistry)/total number of samples (clinical chemistry)[a]	1
Samples clotted		
Pre-Clot	Percentage of number of samples clotted/total number of samples with an anticoagulant	1
Inappropriate time in sample collection		
Pre-InTime	Percentage of number of samples collected at inappropriate time of sample collection/total number of samples	2

(*continued on next page*)

Table 2
(*continued*)

Code	Quality Indicator	Priority Order
Intra-analytical Phase		
Test with inappropriate ICQ performances		
Intra-Var	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 • Potassium • C-reactive protein • Troponin I or troponin T • TSH • CEA • PT (INR) • Hb	1
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
Unacceptable performances in EQA-PT schemes		
Intra-Unac	Percentage of number of unacceptable performances in EQAS-PT schemes, per year/ total number of performances in EQA schemes, per year	1
Intra-PPP	Percentage of number of unacceptable performances in EQAS-PT schemes per year occurring to previously treated cause/total number of unacceptable performances	3
Data transcription errors		
Intra-ErrTran	Percentage of number of incorrect results for erroneous manual transcription/total number of results that need manual transcription	1
Intra-FailLIS	Percentage of number of incorrect results for information system problems-failures/total number of results	1
Postanalytical Phase		
Inappropriate turnaround times		
Post-OutTime	Percentage of number of reports delivered outside the specified time/total number of reports	1
Post-PotTAT	Turnaround time (minutes) of potassium (K) at 90th percentile (STAT)	1
Post-INRTAT	Turnaround time (minutes) of INR value at 90th percentile (STAT)	1
Post-WBCTAT	Turnaround time (minutes) of WBC at 90th percentile (STAT)	1
Post-TnTAT	Turnaround time (minutes) of troponin I or troponin T at 90th percentile (STAT)	1

(*continued on next page*)

Table 2
(*continued*)

Code	Quality Indicator	Priority Order
Incorrect laboratory reports		
Post-IncRep	Percentage of number of incorrect reports issued by the laboratory/total number of reports issued by the laboratory	1
Notification of critical values		
Post-InpCV	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	1
Post-OutCV	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	1
Results notification (TAT)		
Post-InCVT	Time (from result validation to result communication to the clinician) to communicate critical values of inpatients (minutes)	4
Post-OutCVT	Time (from result validation to result communication to the clinician) to communicate critical values of outpatient (minutes)	4
Interpretative comments		
Post-Comm	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	4

Abbreviations: CEA, arcinoembryonic antigen; CV, coefficient of variation; Hb, hemoglobin; INR, international normalized ratio; IQC, Internal Quality Control; PT, prothrombin time; TSH, thyroid-stimulating hormone; WBC, white blood cell count.

[a] Clinical chemistry: all samples that 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. We suggest that a color chart is provided for this purpose.

laboratories worldwide. This aspect prompted us to split some QIs into different groups to facilitate the understanding and collection of data:

a. Four measures are included in MQI for misidentification errors: misidentified requests, misidentified samples, samples with fewer than two identifiers initially supplied, and unlabeled samples
b. Six measures for the test transcription errors: the errors concerning the missed test, the added test, the misnamed test, split into outpatients and inpatients
c. Seven measures for unsuitable samples: samples of wrong or inappropriate type; samples collected in wrong container; samples with insufficient sample volume; samples with inappropriate sample-anticoagulant volume ratio; and hemolyzed, clotted, and/or contaminated samples

Table 3
Quality indicators of support processes

Code	Quality Indicator	Priority Order
Employee competence		
Supp-Train	Number of training events organized for all staff, per year	2
Supp-Cred	Percentage of number of credits obtained by employee, per year/total number of credits to be obtained, per year	2
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 downtime episodes, per year	3

d. Five measures for unsuitable samples caused by transportation and storage problems: samples not received, not properly stored before analysis, excessive transportation time, transported at inappropriate temperature, and/or damaged during transport
e. Seven measures to evaluate the appropriateness of time to release results: number of reports delivered outside the specified time, TAT (minutes) at 90th percentile (STAT) (potassium, international normalized ratio, white blood cell count, troponin I or troponin T), number of critical values notified after a mutually agreed time (from result validation to result communication to the clinician for inpatients and outpatients)
f. One measure for incorrect laboratory report

Data from participating laboratories are collected and processed, and a report issued by the WG-LEPS contact person. In the report the laboratory results are described in relation to a specific period of time and the corresponding Sigma value

Table 4
Quality indicators of outcome measures

Code	Quality Indicator	Priority Order
Sample recollection		
Out-RecOutp	Percentage of number of outpatients with recollected samples for laboratory errors/total number of outpatients	1
Out-RecInp	Percentage of number of inpatients with recollected samples for laboratory errors/total number of inpatients	1
Inaccurate results		
Out-InacR	Percentage of number of inaccurate results released/total number of results released	1

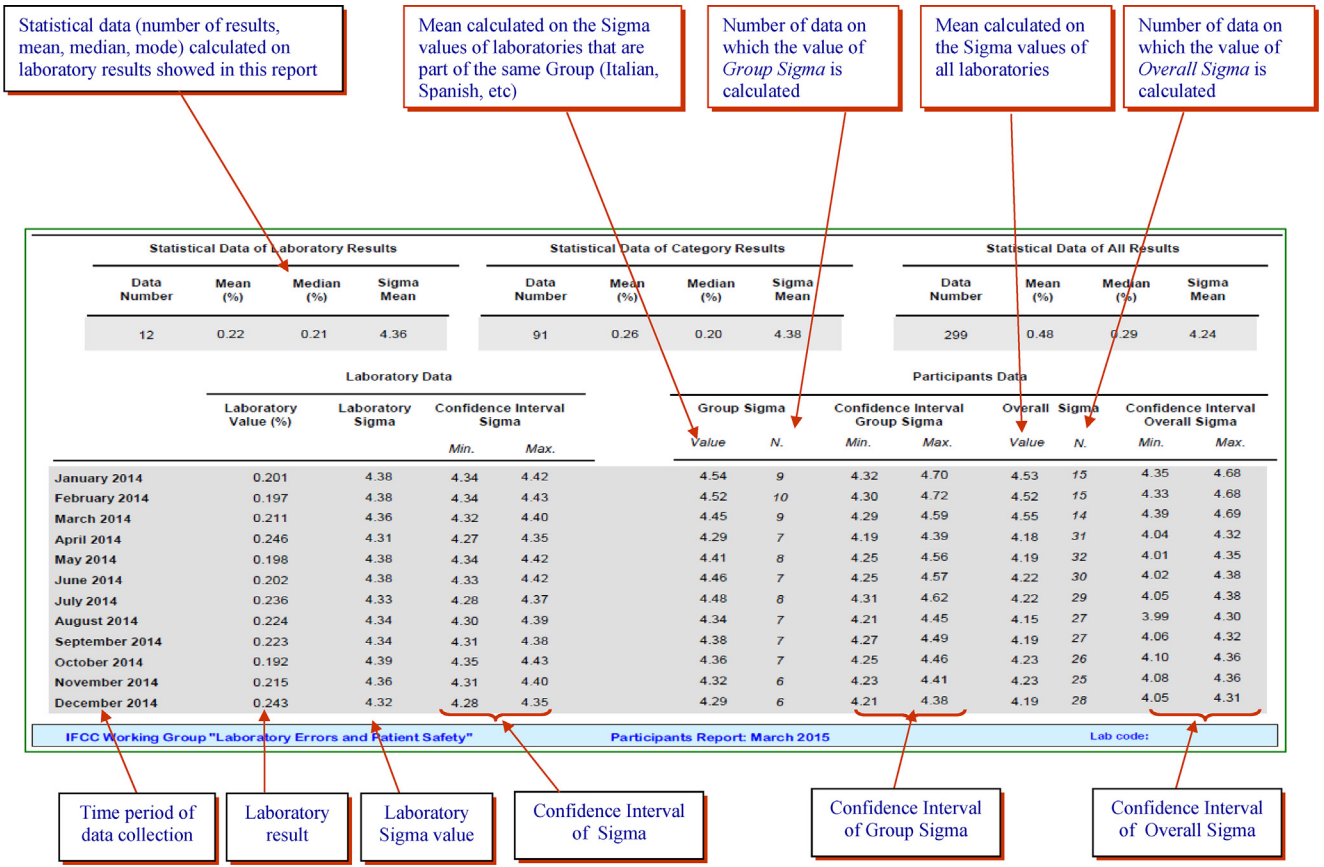

Fig. 1. Report concerning quality indicator results and Sigma values of participating laboratory.

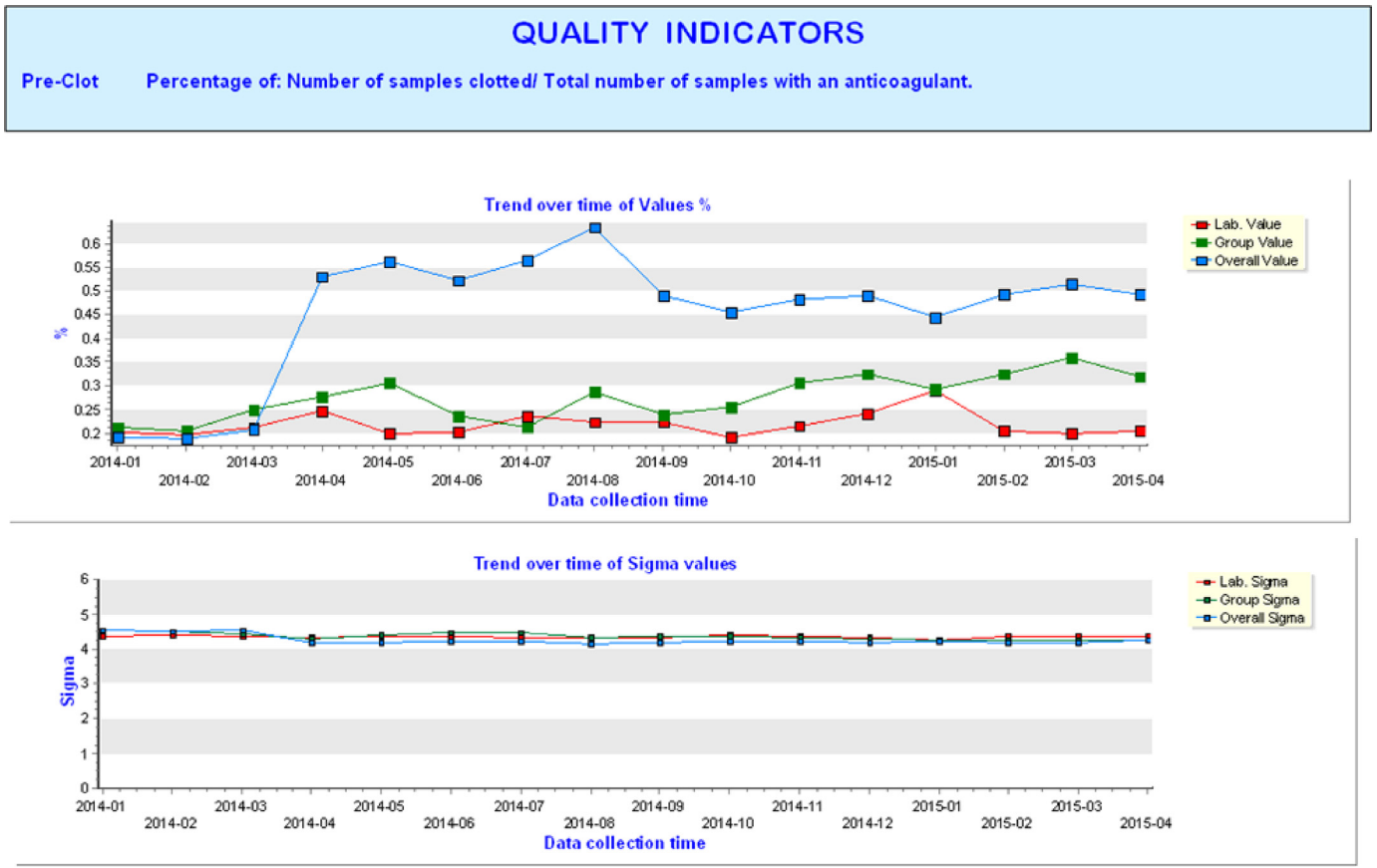

Fig. 2. Trend concerning quality indicator results and Sigma values of participating laboratory.

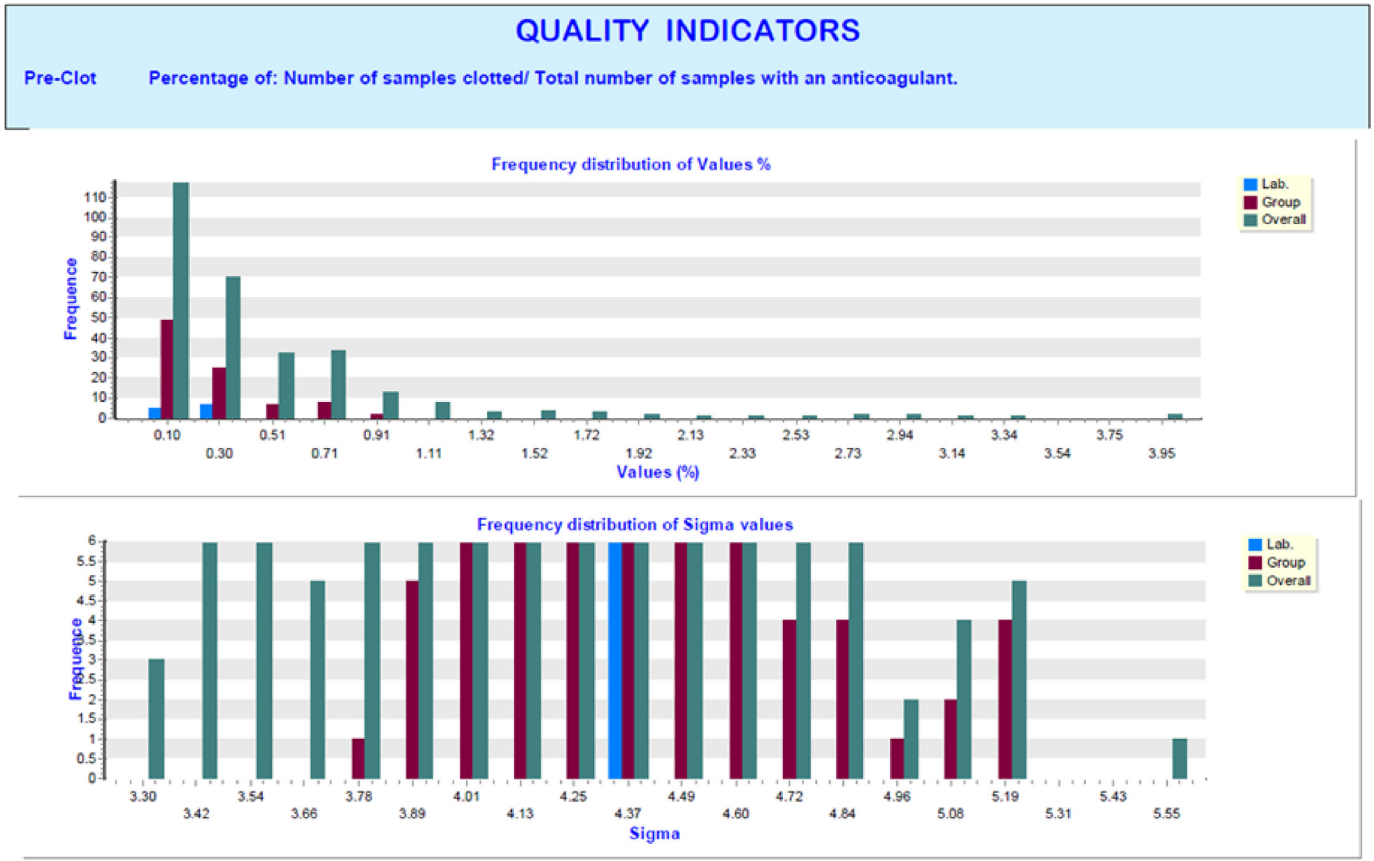

Fig. 3. Frequency distribution of quality indicator results and Sigma values of participating laboratory.

with confidence range is specified. The laboratory can compare its performance with that of other participants on the basis of the mean calculated on the Sigma values of laboratories from the same country and all participating laboratories. Laboratories are provided with the results and Sigma value trends in a graph, and the frequency distribution (**Figs. 1–3**).

QUALITY SPECIFICATIONS IN THE EXTRA-ANALYTICAL PHASES

A significant decrease in error rates in the analytical phase has been achieved in the last three decades thanks to automation; standardization and optimization of reagents; improved training of the laboratory staff; and above all to the development and implementation of valuable analytical quality specifications and their use in setting objective goals in routine practice, and in measuring, recording, and improving laboratory performances in IQC and EQAPs.[4] The hierarchy of models to establish analytical quality specifications defined in the Stockholm Conference was the fruit of years of work, publications, and scientific debate, whereas only a few preliminary proposals are available for the extra-analytical phases.

The definition of performance specifications for each indicator facilitates the interpretation of QIs results and the identification of action priorities. This criterion is based on the results of participating laboratories. The definition of three different performance goals allows laboratories to compare their performance with that of other laboratories, and to ascertain whether improvement actions are possible and feasible: the lower percentiles represent the better, and the higher percentiles, the worse performance. The use of the 75th percentile as a lower limit seems to be the most practical possible approach, because no more than 25% of laboratories are considered to have a poor performance.

The proposal for performance specifications is based on data collected in the last year by IFCC WG-LEPS to provide a reliable picture of the current state-of-the-art. However, because the ideal performance criteria should be “zero defects,” we made a preliminary definition of the following three levels: high, medium, and low. Although for analytical performance criteria the levels are defined with respect to biologic variation, for preanalytical and postanalytical issues, errors and defects are linked specifically to the quality of the procedures and, at least in theory, the final goal is zero tolerance. This approach allows laboratories not only to ascertain whether their performance lies within an acceptable range, but also to identify any negative trend when their performance shifts from a high, to a medium or low level.

The quality specifications defined represent a starting point for activating the improvement process. In fact, the system cannot be effective without the proper analysis and identification of error sources and the implementation of appropriate corrective actions. Also, the continuous exchange of experience between laboratory professionals is a further key element conferring added value to the system.

SUMMARY

The identification of a management system of QIs that meets requirements for effectiveness and harmonization may have important implications in many aspects of the laboratory. The implementation and management of a QI system that includes internal assessment and participation in interlaboratory comparison, a suitable tool for supporting the management decisions for quality, should be considered one of the fundamental components of a continuous quality improvement system.

Because different QIs and terminologies are currently used, there is the need to pursue a harmonization process involving the identification of common QIs and a

standardized reporting system. Although the identification of harmonized, universal QIs seems to be the mainstay, the standardization of data collection and reporting systems are critical steps in effective harmonization initiatives. The IFCC project WG-LEPS applies to all laboratories nationally and worldwide, thus effectively coordinating opinions and contributions, and promoting quality improvement in laboratory medicine.[45,46]

REFERENCES

1. Kallner A, McQueen M, Heuck C. Foreword. The Stockholm Consensus on quality specifications in laboratory medicine 25-26 April 1999. Scand J Clin Lab Invest 1999;59:475–6.
2. Sandberg S, Fraser CG, Horvath AR, et al. Defining analytical performance specifications: consensus statement from the 1st strategic conference of the European Federation of Clinical Chemistry and Laboratory Medicine. Clin Chem Lab Med 2015;53:833–5.
3. Bonini P, Plebani M, Ceriotti F, et al. Errors in laboratory medicine. Clin Chem 2002;48:691–8.
4. Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101–10.
5. Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem 1997;43:1348–51.
6. Carraro P, Plebani M. Errors in a stat laboratory: types and frequencies 10 years later. Clin Chem 2007;53:1338–42.
7. UNI EN ISO 15189. Medical laboratories: requirements for quality and competence. Geneva (Switzerland): International Organization for Standardization; 2013.
8. Sciacovelli L, Aita A, Padoan A, et al. Performance criteria and quality indicators for the post-analytical phase. Clin Chem Lab Med 2016;54:1169–76.
9. Plebani M, Sciacovelli L, Aita A, et al. Performance criteria and quality indicators for the pre-analytical phase. Clin Chem Lab Med 2015;53:943–8.
10. Plebani M. Errors in clinical laboratories or errors in laboratory medicine? Clin Chem Lab Med 2006;44:750–9.
11. Lippi G, Becan-McBride K, Behúlová D, et al. Preanalytical quality improvement: in quality we trust. Clin Chem Lab Med 2013;51:229–41.
12. Holman JW, Mifflin TE, Felder RA, et al. Evaluation of an automated preanalytical robotic workstation at two academic health centers. Clin Chem 2002;48:540–8.
13. Da Rin G. Pre-analytical workstations: a tool for reducing laboratory errors. Clin Chim Acta 2009;404:68–74.
14. Wallin O, Söderberg J, Van Guelpen B, et al. Preanalytical venous blood sampling practices demand improvement: a survey of test-request management, test-tube labelling and information search procedures. Clin Chim Acta 2008; 391:91–7.
15. Söderberg J, Brulin C, Grankvist K, et al. Preanalytical errors in primary healthcare: a questionnaire study of information search procedures, test request management and test tube labelling. Clin Chem Lab Med 2009;47:195–201.
16. Kemp GM, Bird CE, Barth JH. Short-term interventions on wards fail to reduce preanalytical errors: results of two prospective controlled trials. Ann Clin Biochem 2012;49:166–9.
17. Valestein P. Laboratory turnaround time. Am J Clin Pathol 1996;105:676–88.
18. Lim EM, Sikaris KA, Gill J, et al. Quality assessment of interpretative commenting in clinical chemistry. Clin Chem 2004;50:632–7.

19. Dighe AS, Sodeberg BI, Laposata M. Narrative interpretation for clinical laboratory interpretations. Am J Clin Pathol 2001;116:S123–8.
20. Macmillian DH, Sodeberg BI, Laposata M. Regulations regarding reflexive testing and narrative interpretations in laboratory medicine. Am J Clin Pathol 2001;116: S129–32.
21. Kratz A, Sodeberg BI. The generation of narrative interpretations in laboratory medicine. Am J Clin Pathol 2001;116:S133–40.
22. Plebani M. Interpretative commenting: a tool for improving the laboratory-clinical interface. Clin Chim Acta 2009;404:46–51.
23. Clinical and Laboratory Standards and Institute. Quality management system: continual improved. Approved Guideline – Third Edition. QMS06–A3, 2011.
24. Plebani M. Harmonization in laboratory medicine: requests, samples, measurements and reports. Crit Rev Clin Lab Sci 2016;53(3):184–96.
25. Carraro P, Zago T, Plebani M. Exploring the initial steps of the testing process: frequency and nature of pre-preanalytic errors. Clin Chem 2012;58:638–42.
26. Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Biochem Rev 2012;33:85–8.
27. Wagar EA, Tamashiro L, Yasin B, et al. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. Arch Pathol Lab Med 2006; 130:1662–8.
28. Lippi G, Blanckaert N, Bonini P, et al. Causes, consequences, detection, and prevention of identification errors in laboratory diagnostics. Clin Chem Lab Med 2009;47:143–53.
29. Plebani M, Sciacovelli L, Aita A, et al. Quality Indicators to detect pre-analytical errors in laboratory testing. Clin Chim Acta 2014;432:44–8.
30. Plebani M, Sciacovelli L, Marinova M, et al. Quality indicators in laboratory medicine: a fundamental tool for quality and patient safety. Clin Biochem 2013;46: 1170–4.
31. Khoury M, Burnett L, Mackay M. Error rate in Australian chemical pathology laboratories. Med J Aust 1996;165:128–30.
32. Shcolnik W, de Oliveira CA, de São José AS, et al. Brazilian laboratory indicators program. Clin Chem Lab Med 2012;50:1923–34.
33. Kirchner MJ, Funes VA, Adzet CB, et al. Quality indicators and specifications for key processes in clinical laboratories: a preliminary experience. Clin Chem Lab Med 2007;45:672–7.
34. Barth JH. Selecting clinical quality indicators for laboratory medicine. Ann Clin Biochem 2012;49:257–61.
35. Barth JH. Clinical quality indicators in laboratory medicine. Ann Clin Biochem 2012;49:9–16.
36. Simundic AM, Topic E. Quality indicators. Biochem Med 2008;18:311–9.
37. Llopis MA, Trujillo G, Llovet MI, et al. Quality indicators and specifications for key, analytical–extranalytical processes in the clinical laboratory: five years' experience using the six sigma concept. Clin Chem Lab Med 2011;49:463–70.
38. Barth JH. Clinical quality indicators in laboratory medicine: a survey of current practice in the UK. Ann Clin Biochem 2011;48:238–40.
39. Sciacovelli L, Sonntag O, Padoan A, et al. Monitoring quality indicators in laboratory medicine does not automatically result in quality improvement. Clin Chem Lab Med 2011;50:463–9.
40. Sciacovelli L, O'Kane M, Skaik YA, et al. 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.

41. Plebani M. Harmonization in laboratory medicine: the complete picture. Clin Chem Lab Med 2013;51:741–51.
42. ISO/PDTS 22367. Medical laboratories: reducing error through risk management and continual improvement. Geneva (Switzerland): International Organization for Standardization; 2008.
43. Clinical and Laboratory Standards and Institute (CLSI). Development and use of quality indicators for process improvement and monitoring of laboratory quality. Approved Guideline. QMS12–A3, 2010.
44. Sciacovelli L, Plebani M. The IFCC Working Group on laboratory errors and patient safety. Clin Chim Acta 2009;404(1):79–85.
45. Plebani M, Astion ML, Barth JH, et al. Harmonization of quality indicators in laboratory medicine. A preliminary consensus. Clin Chem Lab Med 2014;52:951–8.
46. Plebani M, Chiozza ML, Sciacovelli L. Towards harmonization of quality indicators in laboratory medicine. Clin Chem Lab Med 2013;51:187–95.