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Performance criteria and quality indicators for the post-analytical phase

Abstract

Background: Quality indicators (QIs) used as performance measurements are an effective tool in accurately estimating quality, identifying problems that may need to be addressed, and monitoring the processes over time. In Laboratory Medicine, QIs should cover all steps of the testing process, as error studies have confirmed that most errors occur in the pre- and post-analytical phase of testing. Aim of the present study is to provide preliminary results on QIs and related performance criteria in the post-analytical phase.
Methods: This work was conducted according to a previously described study design based on the voluntary participation of clinical laboratories in the project on QIs of the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC).
Results: Overall, data collected highlighted an improvement or stability in performances over time for all reported indicators thus demonstrating that the use of QIs is effective in the quality improvement strategy. Moreover, QIs data are an important source for defining the state-of-the-art concerning the error rate in the total testing process. The definition of performance specifications based on the state-of-the-art, as suggested by consensus documents, is a valuable benchmark point in evaluating the performance of each laboratory.
Conclusions: Laboratory tests play a relevant role in the monitoring and evaluation of the efficacy of patient outcome thus assisting clinicians in decision-making. Laboratory performance evaluation is therefore crucial to providing patients with safe, effective and efficient care.

Keywords: performance criteria; post-analytical phase; quality indicators.

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Introduction

Efforts to reduce errors and enhance patient safety in medicine must focus on risk procedures and processes with a high potential for error generation. Achieving consistently high levels of quality in laboratory medicine calls for moving beyond analytic activities. In the last few decades, performance measurements have focused mostly on the analytical processes with a view to meeting the quality specifications of precision and trueness [1, 2]. Internal Quality Control (IQC) procedures and External Quality Assessment Programs (EQA) have significantly improved the intra-analytical quality of laboratory testing; however, medical error studies confirm that most errors occur in the pre- and post-analytical phases of testing [3–6]. The implementation of performance measurements to evaluate the pre- and post-analytical stages of the total testing process (TTP) is therefore needed in order to maximize the overall testing cycle and the quality of patient care. In addition, recent regulation and accreditation guidelines now require laboratories to focus their improvement efforts on, not only on the analytical step, but also the other steps of the TTP [7]. Performance measurement, an important component of the quality management system, has been a core feature of quality improvement programs across many health organizations. In laboratory medicine this valuable tool can improve and standardize performance and, by reducing inefficiency, can lead to a better health outcome.

The use of quality indicators (QIs), as performance measurements, is an effective tool for achieving an accurate estimate of the degree of quality, identifying problems that may need to be addressed, and monitoring processes over time [8]. A project of the Working Group "Laboratory

Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has provided a list of QIs (MQI) for monitoring all TTP activities. This project has been designed to define appropriate QIs for use in all laboratories worldwide, collect data from them, identify the current state-of-the-art and define performance criteria to better address improvement actions, decrease the error rate and suggest steps to take in order to further improve performance [9–11].

Aim of the present study was to present the state-of-the-art concerning QIs for the post-analytical phase on the basis of the consensually defined MQI, and submit a proposal for identification of related performance specifications. The list of consensually defined QIs, and the rationale and aims of the Project, described elsewhere [11], are available on a specifically developed website (www.ifcc-mqi.com). The rationale of the selected QIs in the post-analytical phase is briefly summarized below.

Errors and quality indicators in the post-analytical phase

Poor communication between laboratory professionals and clinicians is generally cited as a chief issue affecting quality during the pre- and post-analytical phases. In particular, post-analytic communication entails laboratory professionals' communications with the clinician about timeliness of reporting, notification of significant abnormal test results, and presentation of relevant information through reports and interpretative comments. Breakdowns in communication lead to errors, events affecting patient safety, and inefficient and ineffective use of resources.

QIs, an effective tool for monitoring all activities in TTP, have been well described in several studies [8, 12], but laboratories have highlighted the difficulties involved in using them, particularly in the post-analytical phase, when for data collection calls for the clinicians' collaboration.

Turnaround time (TAT)

Clinicians are interested in service quality, which encompasses total testing error (imprecision and trueness), availability, cost, relevance and timeliness. However, since they often judge the quality of a laboratory on the basis of timeliness, many laboratories may be ready to sacrifice analytical quality for a faster TAT.

The timeliness with which test results are delivered is one of the most prominent parameters of laboratory medicine and a common indicator of performance, which is measured by monitoring the TAT of some specific tests, and the time 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 of 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 [13].

The correct monitoring of times calls for the knowledge of the different measurement approaches used by laboratories. For example, test typology, need for priority reporting, (e.g. urgent or routine), patient typology (e.g. inpatients, outpatients, urgent cases) and the included activities (interval of measurement). The different factors characterizing TAT measurement compromise comparability of data among laboratories. Typically, TAT is assessed by determining the difference between recorded starting times (test ordering or specimen collection time or laboratory sample receipt time) and end points (test reporting time). Some laboratories are also expanding the scope of measurement by evaluating "therapeutic TAT", the time from test order initiation to clinical decision implementation (e.g. change in treatment) [14].

The choice of timing points (start and end) is relevant to identifying the state-of-the-art and defining related quality specifications. The most widely used TAT measurement includes the activities under laboratory control, from sample receipt to the result sending. The choice of statistical approach for data analysis must also be defined to allow reliable evaluation of data over time. For example, the mean and standard deviation are not an appropriate bases for defining TAT distribution, the most commonly used measurement being the time interval during which 90% of results are completed (corresponding to 90th percentile) [15].

The use of QIs, which have well defined measurement characteristics, is therefore important in monitoring the TAT, knowing the state-of-the-art and identifying the improvement possibilities. Because TAT monitoring for all tests provided by the laboratory would require a lot of work, only some test have been chosen in the MQI as representative of laboratory performance in relation to timing. Moreover, to enhance comparability between participants' data, TAT was measured only on urgent samples (shortest turnaround time priority, STAT) in which it is probably affected less by differences in the inherent features of laboratories (e.g. different size and workload).

Notification of critical values

Critical values notification procedures play a key role in safe and effective patient care. To assure effective procedures, every clinical laboratory must periodically review its list of critical values, both for internal policy and for clinical purpose, and review their procedures [16]. The continuous monitoring of successfully communicated critical values within a defined time and relative time measurement helps laboratories to focus with renewed vigor on critical value management. Yet there is still a lack of consensus and benchmark data. Nor has harmonization been achieved for procedures, choice of analytes and critical ranges and moreover, notification times vary depending on patient typology (inpatients or outpatients). Systematic monitoring using consensually approved QIs helps laboratories to evaluate their performances, and to compare them with that of other laboratories.

Laboratory reports

Errors leading to incorrect or delayed patient results can affect medical decisions and compromise the efficacy of patient treatment. The content, format and physical presentation of information provided can significantly affect the interpretation and use of laboratory data by clinicians. Mistakes in the content and completeness of laboratory reports as well as 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: uninterpretable information, incorrect data of reference intervals, inaccurate personal details of patient or incorrect reporting of measurand. Moreover, different types of error can occur during report formatting. Reports that lack units of measurement or use inappropriate units of measurement can lead to harmful misinterpretation of results and/or undervaluation of important information. The definition of QIs that includes the measurement of these aspects aims to obviate any misinterpretation and to promote accuracy and completeness.

Interpretative comments with a positive impact on the patient outcome

The aim of interpretative comments on laboratory reports is to help clinicians to interpret complex data provided, particularly when dynamic or uncommon test results are reported, when significant abnormalities are present, and/or when analytical or pre-analytical factors may compromise the interpretation of results. Although several authors have described this process and indicated its value, there is little evidence that it has improved patient outcomes, mainly due to difficulties involved in collecting data [17–20]. The interpretation of results is crucial to patient outcome yet, hoping to avoid giving inappropriate advice, many laboratories fail to provide interpretative comments in the absence of complete clinical information. According to studies available in the literature, the majority of comments provided in laboratory reports are acceptable, but some are inappropriate or misleading and, in a few cases, dangerous, leading to inaccurate assumptions by staff, especially if the available clinical information is insufficient or expertise in a clinical chemistry subspecialty area (e.g. toxicology, endocrinology, and tumor markers) is inadequate [21].

Interpretative comments in line with current guidelines are generally welcomed by physicians because they prevent an inordinate focus on certain values from leading to a disregard of other potentially important values [22, 23]. The use of QIs to monitor the effectiveness of interpretative comments provided should therefore be encouraged and developed because a laboratory result is not complete until it has been interpreted and incorporated into patient care, as appropriate.

Materials and methods

The present work was conducted according to a previously study design described elsewhere [12] and relied on the voluntary participation of clinical laboratories worldwide enrolled in the IFCC WG-LEPS project on QIs [11]. Two hundred and eighty-one laboratories are enrolled in the project from different countries (Table 1) but the number of participating laboratories changed over time. In addition, the number may differ from a indicator to another one as any clinical laboratory may select some QIs and is not obliged to collect data for the entire list. Thirty-nine clinical laboratories (2 Argentina, 1 Brazil, 2 China, 1 Croatia, 1 Estonia, 1 Great Britain, 1 Ireland, 12 Italy, 16 Serbia, 1 Spain, 1 Uruguay) continuously and systematically collected data for QIs of the post-analytical phase in the timeframe considered in the present study (from 2012 to 2014). Public laboratories account for 82% of participants while 18% are private Institutions.

Data collection was undertaken quarterly for all QIs evaluated except for TAT, for which it was performed monthly.

The results have been reported in a percentage (%) and, in addition where appropriate, the short term sigma has been calculated for each result as the Six Sigma metric is widely recognized as "a metric for measuring defects and improving quality" [24, 25].

Table 1: Laboratories involved in the project on MQI of the IFCC WG-LEPS.

Countries	Labs, n	Countries	Labs, n
Algeria	1	Italy	74
Argentina	13	Libya	1
Australia	4	Netherlands	2
Austria	2	New Zealand	1
Belgium	5	Palestine	1
Brazil	12	Poland	1
Canada	8	Portugal	3
China	45	Saudi Arabia	2
Croatia	6	Serbia	25
Egypt	1	Singapore	2
Estonia	3	Slovenia	4
France	1	Spain	11
Germany	7	Sweden	3
Great Britain	13	Switzerland	2
Greece	2	Turkey	5
Hungary	2	United Arab Emirates	2
India	4	United States	7
Ireland	3	Uruguay	2
Israel	1		

Results

Table 2 shows participants' results for the post-analytical phase, collected in the years 2012, 2013 and 2014, and expressed as a 50th percentile/median. Overall, performance for all indicators was stable or had improved. The data collected in the different years (2012, 2013, 2014) are surely affected by different typologies and number of laboratories; however this should be not considered a limitation when evaluating the changes over time (improvement or worsening).

TAT

QIs data for TAT concerning the most urgent priority samples (STAT) are reported in Table 2: Potassium, from 2012 to 2014; International Normalized Ratio (INR), white blood cell count (WBC) and troponin only for 2014 because these values were added during the Consensus Conference on QIs held in 2013 [10]. Potassium TAT highlights a variable trend from 2012 to 2014 and a wide range

Table 2: Median value calculated on all results provided by laboratories participating in the IFCC "Laboratory Errors and Patient Safety" project on quality indicators, from 2012 to 2014.

| Quality indicators for the post-analytical phase	Unit	Year	Median
Turnaround times			
Number of reports delivered outside the specified time/total number of reports	Percentage	2012	0.66
		2013	0.67
		2014	0.060
Turnaround time (min) of potassium (K) at 90th percentile (STAT)	Time	2012	59.0
		2013	48.0
		2014	53.2
Turnaround time (min) of International normalized ratio (INR) value at 90th percentile (STAT)	Time	2014	54
Turnaround time (min) of white blood cell count (WBC) at 90th percentile (STAT)	Time	2014	28
Turnaround time (min) of troponin I (TnI) or troponin T (TnT) at 90th percentile (STAT)	Time	2014	68.82
Laboratory reports			
Number of incorrect reports issued by the laboratory/total number of reports issued by the laboratory	Percentage	2012	0.009
		2013	0.009
		2014	0.008
Notification of critical values			
Number of critical values notified after a consensually agreed time (from result validation to result communication to the clinician)/total number of critical values to communicate	Percentage	2012	67.2
		2013	17.8
		2014	0
Time taken (from result validation to result communication to clinician) to communicate critical values of inpatients (min)	Time	2014	4.66
Time taken (from result validation to result communication to clinician) to communicate critical values of outpatient (min)	Time	2014	11.03

TAT of potassium at 90th percentile (STAT)
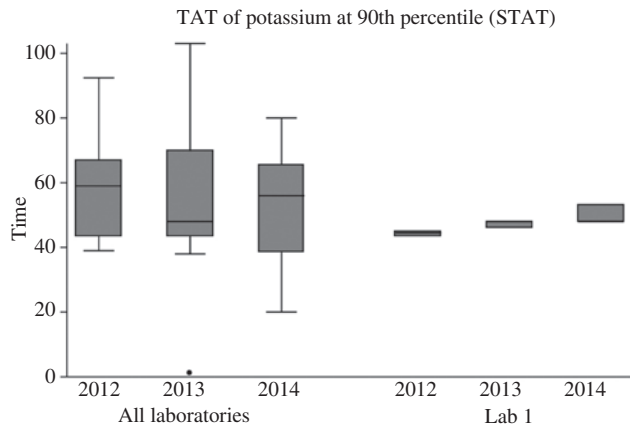
Figure 1: Turnaround time (TAT) of potassium in emergency: graph showing statistical measures (median, upper and lower quartiles, the minimum and maximum of all data and outliers).

Critical values communicated after a consensually agreed time

Figure 2: Critical values notification: graph showing statistical measures (median, upper and lower quartiles, the minimum and maximum of all data and outliers).

of results within 1 year (Figure 1), underlining the different results from participating laboratories. As expected, the variability of results from a single laboratory (Lab. 1) is narrower.

Notification of critical values

The QIs proposed by IFCC WG-LEPS for critical values aim to determine the level of successful reporting of critical values in the laboratory, for inpatients and outpatients, and to ensure that participant results are comparable across institutions by providing a clear definition of time measurement (start and end points). When there was evidence that the critical value was communicated according to a given laboratory's policy and procedure, the notification was considered successful. The data collected highlight that the percentage of critical values notified after the defined time significantly decreased over time for all laboratories (Kruskal-Wallis rank test: $X^2=16.9$, p<0.001) and Lab. 1 (Kruskal-Wallis rank test: $X^2=5.33$, p=0.021) demonstrating that Laboratories have developed practices ensuring that each critical result is promptly transmitted to caregivers, and that staff awareness of this issue has been raised. The monitoring of notification time highlights the fact that procedures are carried out rapidly and effectively (Table 2 and Figure 2).

The time needed to communicate outpatients' results was found to be longer than that required for communicating inpatients' results (median time, 11.03 min and 4.66 min, respectively).
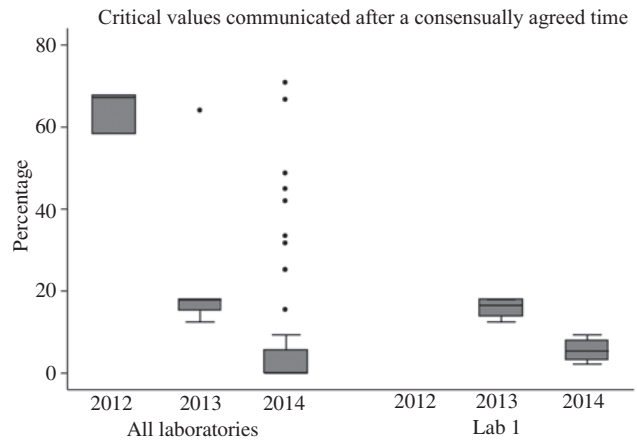
Laboratory reports

Data demonstrated a decrease in the number of reports delivered outside the specified time during the year (Table 2), and an improvement in quality level (short term sigma, from 3.9 to 4.5). Whereas a stable pattern for incorrect laboratory reports is highlighted (Table 2) with a high quality level for process (short-term sigma, from 5.1 to 5.2).

Interpretative comments with a positive impact on the patient outcome

The laboratories did not collect data on QIs for interpretative comments; the explanation for this is given in the discussion section.

Performance specifications

Table 3 reports on the proposal for performance specifications drawn up on the basis of data collected in 2014 in order to provide a reliable picture of the current state-of-the-art, and in according with the proposal by Fraser et al. [26] that classified the performances into: optimum, desirable, and minimum [12]. However, as the ideal performance criteria should be "zero defect", we made a preliminary definition of the following three levels: high, medium and low. In fact, while for analytical performance criteria the levels are defined with respect to biological variation, for pre- and post-analytical issues, errors and defects are linked specifically to the quality of the

Table 3: Proposal for quality specifications based on percentile values calculated on the basis of laboratories' results (expressed as percentages and, where appropriate, short term sigma) collected in 2014.

Quality indicators	Unit	Performance specifications based on 75th – 50th – 25th percentile		
		Low	Medium	High
Number of reports delivered outside the specified time/total number of reports	Percentage	0.22	0.060	0.006
	Sigma	3.904	4.5	4.795
Turnaround time (min) of potassium (K) at 90th percentile (STAT)	Time	66	53.2	39
Number of incorrect reports issued by the laboratory/total number of reports issued by the laboratory	Percentage	0.035	0.008	0.0002
	Sigma	4.7	5.1	5.4
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	Percentage	6.62	2.43[a]	0
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	Percentage	7.14	5.00[a]	0

[a]These values are different from those reported in Table 2 because, the median value is now calculated on data grouped by patient typology (inpatient and outpatient) on the basis of the improved formulation of the indicator introduced in 2014.

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 recognize a possible negative trend when their performance shifts from a high, to a medium or low level (e.g. Figure 1, Lab. 1).

Discussion

The activities in the post-analytical phase call for a sound understanding of the analytical processes involved in generating results, the awareness of potential pre-analytical and intra-analytical errors, and the correlation of results with the patient's clinical status. The collaboration between pathologist and clinician is of fundamental importance in ensuring that this process is effective.

The knowledge of state-of-the-art is the simplest possible means for enabling laboratories to reliably compare their performances. It has been accepted as a basis for defining specifications for analytical quality in the hierarchical model described in the Stockholm Consensus Conference [1], reviewed in the Milan 1st EFLM Strategic Conference [2], and used in the present study to define specifications for post-analytical quality.

The use of QIs for post-analytical phases, although still not widely adopted [27], is important for assessing the error rate and determining the level of risk acceptable for prioritizing interventions, and is required by the

International Standard for laboratory accreditation (ISO 15189:2012) [7]. The performance specifications define the extent of change in performance to be allowed before the specific activity under control can be considered out-of-control.

Participation in inter-laboratory comparison on QIs, such as that proposed by IFCC WG-LEPS, raises awareness of the significance of both quality-enhancing practice and the current level of performance. Moreover, continuous QIs monitoring is helpful in the provision of education and continuing professional development, and contributes to the improvement of patient care and minimization of medical errors.

The data collected show that the variability observed in the TAT results of all laboratories can depend on the different policies and procedures used by the individual laboratories. Shorter TAT measurements do not necessarily indicate a superior performance, as they do not reflect whether the laboratory concerned meets the expectations of clinicians using its services. It is known, however, that the majority of identified problems directly affecting TAT (e.g. for selected chemistry tests) are associated with pre-analytical steps (e.g. test ordering and sample collection) and analytical-related personnel and technical issues. The use of QIs allows the identification of appropriate improving actions taken as a result of regular monitoring, and may therefore improve laboratory performance [28, 29]. Regarding laboratory reports, the feed-back from participating laboratories in the MQI project of the IFCC WG-LEPS highlighted that the collection of these data

is straightforward and, although there may be room for improvement, the process is under control.

The time taken to communicate critical values to outpatients is longer than that for inpatients because the notification procedure is often difficult in the former case, as laboratory professionals may make repeated attempts to contact the appropriate outpatient's physician, sometimes unsuccessfully. The communication process for inpatients is easier due to the constant presence of physicians in clinical wards. Moreover, the communication method can affect the notification time: most institutions rely on the telephone, while others use electronic devices that automatically dial a beeper or send a short message service (SMS), thus reducing the time spent in critical value notification – and increasing the likelihood that the physician, or another person in charge of the patient's care, will receive the result [30, 31]. Further QIs could be established for monitoring critical values procedures and promoting harmonization. For example, close attention must be paid to the following: staff receiving critical values notification (the person receiving the information must be authorized and capable of interpreting and using the results appropriately); the procedure used when critical values from the same patients are observed over the following days; the procedure used during the notification; the clinical wards to exclude from receiving the notification because all patients are critical; the list of analytes; the lower and higher limit values. The evidence of many outliers, particularly in 2014 (see Figure 2), that led to unsatisfactory performances highlights, once again, the need for a careful revision of internal policies and procedures to achieve better performances. This, in turn, reinforces the use of the data for a valuable benchmark and harmonization between different clinical laboratories.

Findings in an investigation into the reasons for not having measured the effectiveness of interpretative comments highlight that it is both difficult and time-consuming to collaborate with the clinician in order to evaluate an outcome following the introduction of a specific interpretative comment in the patient's report. Moreover, physicians often fail to record the actions undertaken in response to laboratory reports. The need to evaluate and monitor outcome measures in order to assure the effectiveness of laboratory processes calls for an improvement in the communication between clinicians and laboratory professionals in the ordering of tests and the interpretation of results [32]. The paper presents some limitations and, in particular, the number of data collected by a limited number of clinical laboratories requires further confirmation in future surveys.

Conclusions

In Laboratory Medicine, the time is now ripe to focus attention on the assessment and monitoring procedures for the extra-analytical quality. Professionals are responsible for facilitating the assimilation and comprehension of laboratory information by clinicians, and efforts should be made to identify the areas in which the harmonized use of consensually defined QIs is needed, in all laboratories worldwide, in order to strive for improvement in intra-analytical activities by means of the continuous use of IQC and EQA, also in the extra-analytical phases. Further efforts must be made to encourage laboratories to collect QIs data and undertake the actions for improvement when results go beyond the defined quality specifications.

Since laboratory tests play an extremely important role in monitoring and evaluating patient outcomes and assisting clinicians in their decision making, the rigorous evaluation of laboratory performance is crucial to providing patients with safe, effective and efficient care.

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