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Quality indicators to detect pre-analytical errors in laboratory testing

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ABSTRACT

The identification of reliable quality indicators (QIs) is a crucial step in enabling users to quantify the quality of laboratory services. The current lack of attention to extra-laboratory factors is in stark contrast to the body of evidence pointing to the multitude of errors that continue to occur, particularly in the pre-analytical phase. The ISO 15189: 2012 standard for laboratory accreditation defines the pre-analytical phase, and recognizes the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the testing cycle, including those performed in the phase of requesting tests and collecting samples, the so-called "pre-pre-analytical phase". Therefore, QIs should allow the identification of errors and non-conformities that can occur in all steps of the pre-analytical phase. Traditionally, pre-analytical errors are grouped into identification and sample problems. However, appropriate test requesting and complete request forms are now recognized as fundamental components in providing valuable laboratory services.
The model of QIs developed by the Working Group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) includes indicators related to both identification and sample problems as well as all other pre-analytical defects, including those in test requesting and request forms. It, moreover, provides the framework (with objective criteria) necessary for promoting the harmonization of available QIs in the pre-analytical phase.

1. Introduction

The journey towards quality and patient safety in laboratory medicine is complicated by myths, imperfect knowledge and human fallibility. One myth is that a "zero error rate" can be achieved, while "imperfect knowledge" reflects the poor understanding of the total testing process (TTP) and its complexity. In addition, human frailty makes processes incapable of high reliability. Further barriers to a safer system are the changing face of the discipline accompanied by the need for interventions that are multifactorial, complex and involve numerous individuals, including laboratory professionals, those in care teams and patients. The approach to errors in laboratory medicine has varied greatly in the last two decades, shifting from a "laboratory-centered" scenario that might recognize only analytical errors, to a "patient-centered" scenario that focuses on errors in the total testing process. In fact, the new millennium has hailed a formidable improvement in the analytical phase with a ten-fold reduction in error rates, thanks to an improved standardization of analytic techniques and reagents, advances in instrumentation and information technologies, as well as to the availability of more qualified and better trained staff [1]. In addition, this achievement is due, at least in part, to the evidence that in the last few years, reliable quality indicators and quality specifications have been developed and introduced for the effective management of analytical procedures [2]. Internal quality control rules, as well as objective analytical quality specifications, and the availability of Proficiency Testing (PT)/External Quality Assessment (EQA) programs have allowed clinical laboratories to measure, monitor and improve their analytic performance over time. According to recent evidence, most errors fall outside the analytical phase, while pre- and post-analytical steps have been found to be more vulnerable to the risk of error [3,4]. Achieving consensus on a comprehensive definition of errors in laboratory testing [5] was a milestone in reducing errors and improving upon patient safety since this definition emphasizes the need to evaluate all the steps in the TTP whether or not they fall under the direct control of laboratory personnel, the ultimate goal being to improve, first and foremost, quality and safety for patients. However, the current lack of attention to extra-laboratory factors and related quality indicators is in stark contrast to the body of evidence pointing to the multitude of errors that continue to occur, particularly in the pre-analytical phase. The present paper therefore aims to suggest a possible road map for the harmonization of quality indicators in the pre-analytical phase.

2. Quality indicators

Quality indicators (QIs) are fundamental tools enabling users to quantify the quality of laboratory services: they are objective measures

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that can evaluate all critical domains of the testing cycle, including pre-analytical procedures and processes [6]. Data should be collected continuously over time to identify, correct defects improving on performance and patient safety by identifying and implementing effective interventions.

As previously underlined [6], QIs should be part of a coherent and integrated quality improvement strategy implemented according to the specifically-developed International Standard for Medical Laboratories Accreditation (ISO 15189: 2012) [7] which, in addition to requirements for personnel, environmental and laboratory equipment conditions, recognizes the need to subdivide the TTP into pre-examination, examination and post-examination procedures, commonly defined as pre-, intra-, and post-analytical phases. For each phase, the International Standard identifies several components in clauses and sub-clauses without specifying quality indicators and quality specifications [8]. However, QIs and related quality specifications are essential both for the institution (the laboratory in this case) and the inspectors as objective criteria of documentation and translation in practice of the standards; they are the most valuable available evidence of compliance with all, but particularly the most relevant, requirements for the accreditation of a clinical laboratory. Although there is a "considerable challenge in identifying, defining, and ultimately implementing indicators that cover the various stages of the total testing process" [9], we propose QIs that meet three inclusion criteria: 1) the use of a quantitative measure associated with laboratory testing; 2) the coverage of all stages of the TTP, as required by the current definition of "laboratory error" (ISO/TS 22367: 2008); and 3) the potential to be related to at least one IOM (Institute of Medicine) health care domain [9,10].

3. The pre-analytical phase

The ISO 15189:2012 standard for laboratory accreditation defines the pre-analytical phase as "steps starting in chronological order, from the clinician's request and including the examination requisition, preparation of the patient, collection of the primary sample, and transportation to and within the laboratory, and ending when the analytical examination procedure begins" [7]. This definition clearly recognizes the need to evaluate, monitor and improve all the procedures and processes in the initial phase of the TTP, including the procedures performed in the so-called "pre-pre-analytical phase". According to a previously proposed definition, the pre-pre-analytical phase includes all initial procedures of the testing process including test request, patient identification, sample collection, handling and transportation. These procedures – usually performed neither in the clinical laboratory nor, at least in part, under the control of laboratory personnel – are evaluated and monitored unsatisfactorily, often because the process owner is unidentified and the responsibility falls in the boundaries between laboratory and clinical departments. As evidence, currently recommended quality indicators in the pre-analytical phases should be grouped into two categories. The first should focus on pre-analytical error related to identification problems, while the second should deal with sample problems. Both error types are taken into consideration in several proposals and projects on quality indicators. However, some further issues affect quality and safety in the pre-analytical steps. In particular, the appropriateness of the test request and the completeness of the request forms are now recognized as fundamental components in providing valuable laboratory services. Moreover, in recent decades, due to increasing pressure to cut costs in healthcare organizations, we have experienced the increasing consolidation and centralization of laboratory diagnostics within large facilities, with a consequent need to transport a large number of specimens from peripheral collection sites to the core laboratories; this has led to a dramatic increase in the risk of errors in this step, and the urgent need for appropriate sample transportation conditions and adequate quality indicators.

4. "Traditional" quality indicators for the pre-analytical phase

As previously mentioned, there are two main categories of pre-analytical errors that are related to identification and sample problems, respectively. Table 1 summarizes the main identification problems.

Although the correct identification of patient samples should be easily perceived by all care operators as an essential issue for safety in laboratory testing, a large body of evidence demonstrates that the level of quality in this fundamental step is unsatisfactory. In some longitudinal studies on laboratory specimen misidentification, a rate of 1 in 1000 opportunities was found, the most common categories of misidentification events being mislabeled (1%), mismatched (6.3%), and unlabeled specimens (4.6%), respectively [11]. In another study, the misidentification rate in transfusion medicine was found to occur in 1 in 2000 of specimens, while it occurred at a much higher rate (approximately 1 in 100) in clinical laboratory specimens. Sample misidentification can have significant consequences for patients as it may result in unnecessary diagnostic procedures, delays in diagnosis or treatment, and physical harm [12]. This is why the Joint Commission and the WHO Alliance for patient safety have established that the first goal for clinical laboratories should be to "improve patient and sample identification" [13]. In transfusion medicine, technological improvements, better education and training, and changes in policy and procedures have led to a significant reduction in, but not the elimination of, misidentification errors [14]. In clinical laboratories, problems persist, and the current misidentification rates will be reduced only if a cultural change takes place: technological tools can play a major role but this is not enough.

The second category of pre-analytical errors includes sample problems, as shown in Table 2 which reports findings made using data collected in our department from 2009 to 2011.

Hemolysis and samples in inadequate quantity are the primary cause of errors, while the error rates for inpatients are significantly higher than that for out-patients These observations are confirmed in a study reporting an error rate of 74.6% for inpatients and 25.4% for outpatients [15]. Although this difference may be related to the clinical complexity of blood drawing procedures in patients admitted to hospitals, a body of evidence demonstrates that the compliance with standard operating procedures and guidelines in the wards is unsatisfactory, as underlined elsewhere [16,17].

In the last few decades, data have been accumulated to identify the rates of sample errors [18–20], to document the different rates between inpatients and outpatients and to establish whether error rates are related to inadequate collection techniques and non-compliance with existing operational procedure guidelines [21]. Differences in complying with operational procedures may explain why the sample error rate is lower for outpatients with care operators in this situation being under the direct control of the laboratory Director. The introduction of pre-analytical workstations and tools such as serum indices has been proven effective in decreasing most errors due to specimen preparation, centrifugation, aliquoting, pipetting and sorting [20,22], while no significant decrease in pre-pre-analytical mistakes (e.g. patient/sample identification, unsuitable samples due to wrong collection procedures) has been achieved. With intra-laboratory procedures deemed safer, greater attention should be paid to extra-laboratory procedures, guidelines for blood collection, the training and education of health care operators,

Table 1
Main identification problems.

a) Unlabeled samples
b) Mislabeled samples
c) Insufficiently labeled samples
d) Samples suspected of being from the wrong patient, sometimes referred to as "wrong blood in tube"
e) Irregularities in transfusion labeling requirements (e.g. signature of phlebotomist)

Table 2
Sample problems.

Type of sample error	Total (%)	Outpatients (%)	Inpatients (%)	
			Routine	Emergency
Hemolyzed	49.72	4.69	43.69	51.62
Clotted	9.09	1.77	53.10	43.13
Icteric/lipemic	2.01	4.00	96.00	0
Incorrect filling level	7.32	0	42.86	57.14
Incorrect	3.78	8.51	78.72	12.77
Inadequate quantity	24.25	14.75	84.26	0.98
Lost/not received	3.54	9.09	90.91	0

and the use of serum indices to reduce this type of pre-analytical error. Quality indicators for the two main categories of pre-analytical errors have been developed and used in several national and international programs, and the data collected are available [23–26]. However, in addition to the identification of common QIs, mounting evidence underlines the importance of a standardized reporting system as an essential step toward harmonization. This major lesson was imparted when we discussed and revised the Model of Quality Indicators (MQI) developed by the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) working group on "Laboratory errors and Patient Safety" (WG-LEPS). The criteria used for splitting the same indicators into subgroups in order to facilitate data collection and the set of pre-analytical quality indicators proposed have been described elsewhere [10,27]. In particular, in addition to "traditional" pre-analytical indicators, mounting evidence underlines the importance of improving upon both the appropriateness of test requesting and the compilation of request forms. These issues must be evaluated and monitored by means of specific QIs.

5. "Innovative" quality indicators for the pre-analytical phase

The paradigm shift in the delivery of laboratory medicine to a clinical service measured by outcomes [28] calls for the provision of advice on the right test or test profile and timing for that test/test profile. The consensus achieved on the importance of test advice for maximizing the appropriateness of test requesting led to the inclusion of a specific requirement (clause 5.4.2) in the ISO 15189 International Standard for laboratory accreditation [7]. The emerging need to manage test demand to avoid unnecessary expenditure, reduce undue risk for patients and improve the use of laboratory services is now expressed in the mantra "the right test in the right patient at the right time" [29]. The success of the various methods used in the effort to manage demand depends on the medical context, and the different settings in which these approaches are employed. While there is as yet no magic bullet, the steps taken to improve appropriateness in test requesting must always be evaluated using indicators and long-term monitoring.

Another key issue related to the test request, is the completeness of the request forms, indispensable for the ultimate quality of laboratory results, as requested by the ISO 15189 International Standard (clause 5.4.3) [7]. Therefore, even if national, regional and local requirements should issue a better definition of the specific information required, QIs should be used to identify, document and monitor the quality of request forms, whatever their format (e.g. electronic or paper) and the manner in which requests are communicated to the laboratory.

Finally, the increasing trend towards the consolidation of laboratory services with the consequent need to transport numerous specimens from peripheral collection sites to core laboratories has led to a dramatic increase in the risk of errors in this step, and the urgent need for appropriate sample transportation conditions [30,31]. Valuable QIs are therefore required in order to identify, record and monitor the quality of

Table 3
Indicators for pre-analytical phase (percentages).

Appropriateness of test request	Number of requests with clinical question (outpatients)/total number of requests (outpatients)
	Number of appropriate requests with respect to clinical question (outpatients)/total number/number of requests reporting clinical question (outpatients)
Patient identification	Number of requests with errors concerning patient identification/total number of requests
	Number of requests with errors concerning patient identification, detected before release of results/total number of requests
	Number of requests with errors concerning patient identification, detected after release of results/total number of requests
	Number of misidentified patients/total number of patients
Request form	Number of unintelligible outpatient requests/total number of outpatient requests
Order entry	Number of outpatient requests with erroneous identification of physician in physician's identification/total number of outpatients requests
	Number of outpatient requests with errors concerning test input (missing)/total number of outpatient requests
	Number of outpatient requests with errors concerning input of tests (added)/total number of outpatient requests
	Number of outpatient requests with errors concerning test input (misinterpreted)/total number of outpatient requests
	Number of inpatient requests with errors concerning test input (missing)/total number of inpatient requests
	Number of inpatient requests with errors concerning input of tests (added)/total number of inpatient requests
	Number of inpatient requests with errors concerning test input (misinterpreted)/total number of inpatient requests
Sample identification	Number of samples improperly labeled/total number of samples
Sample collection	Number of samples collected at inappropriate time/total number of samples
	Number of samples collected with inappropriate sample type/total number of samples
	Number of samples collected in inappropriate container/total number of samples
	Number of samples in insufficient volumes/total number of samples
Sample transportation	Number of samples damaged/total number of samples
	Number of samples transported at inappropriate time/total number of samples for which transport time is checked
	Number of samples transported under inappropriate temperature conditions/total number of samples for which the transport temperature is checked
	Number of samples improperly stored/total number of samples
	Number of samples lost or not received/total number of samples
Sample acceptance/rejection	Number of contaminated blood cultures/total number of blood cultures
	Number of samples with inadequate sample-anticoagulant volume ratio/total number of samples with anticoagulant
	Number of samples hemolyzed (hematology)/total number of samples (hematology)
	Number of samples hemolyzed (chemistry)/total number of samples (chemistry)
	Number of samples clotted (hematology)/total number of samples with anticoagulant (hematology)
	Number of samples clotted (chemistry)/total number of samples with anticoagulant (chemistry)
	Number of samples clotted (immunology)/total number of samples with anticoagulant (immunology)
	Number of samples hemolyzed (immunology)/total number of samples (immunology)
	Number of lipemic samples/total number of samples
	Number of samples unacceptable (microbiology)/total number of samples (microbiology)

biological specimens. Table 3 lists the QIs proposed for the pre-analytical phase.

6. From quality indicators to error detection

As stated elsewhere [32,33], the appropriate utilization of QIs for identifying and reducing the error rates in the TTP can be achieved through a sound awareness of each QI aim, the effective involvement of care operators (both within and outside the laboratory), and standardized systems for data collection and reporting.

Staff made aware of the reasons for which the individual QI has been selected can make a critical analysis of the process under review, understand the different aspects of problems and justify any need for additional time and resources. The description of the QI rationale clarifies the meaning of data collected and the actions to be taken to avoid future errors and nonconformities. The entire staff must be involved in this activity because the individual who operates in a specific process can better identify its critical activities, identify and record all errors, decide upon any adequate corrective actions required, and implement the "barriers" to obviate any recurrence of the error identified. Collection of data by a single operator for all laboratory activities incurs the risk of underestimating the true error rates. As the focus should be on the entire system, a designated professional verifies the congruity of data from different operative sections, validates the preventive and corrective actions, defines the intervention priorities, proposes times for data collection, and, on the basis of the results obtained, specifies both new QIs that are required and outmoded QIs that should be scrapped. These aspects are particularly important when the workflow involves facilities and staff outside the laboratory. Although the detection of sample problems usually occurs inside the laboratory, this process can also pinpoint incorrect procedures performed outside the laboratory; the operators working outside the laboratory must be aware of the procedures carried out in the laboratory if this type of error is to be detected. If the staff understand and manage QIs effectively, the efficacy of these tools will be enhanced and the staff will be aware of the importance of undertaking corrective and preventive actions. The error rate will be reduced if the staff inside and outside the laboratory share the same goals and communicate with each other. Future efforts must focus on promoting the quality culture that has grown inside the laboratory and on involving all staff members in the management of QIs that themselves are efficient tools in promoting the very same process. Although these criteria are valid for all QIs, their application is particularly important for QIs concerning the pre-pre-analytical phase [34].

Standardized data collection is also crucial to enhancing the effectiveness of QIs. A well-structured system for data collection assures the "repeatability" of the results reporting, the comparability of data over time and a standard evaluation of any preventive and/or corrective actions implemented. In huge departments that include different and, often, distant locations in which the TTP is carried out, all operators must follow the same criteria and procedures for data collection and pursue the quality objectives pursuing the same goals. The laboratory information system can, in a standardized way, aid data collection by using different operators that employ the same procedure at different times. The system implemented to manage the QIs can be validated through the participation in an external comparison program, such as the "Model of Quality Indicators" project proposed by the WG-LEPS, which allows operators to evaluate the efficacy of an internal system and evidence possible areas in which improvement is needed [32,33].

7. A road map for harmonization

QIs, in particular those for the pre-analytical phase, can be considered a fundamental step in the journey toward quality and patient safety. Currently, the road is riddled with bumps and bends that can only be straightened out through awareness that QIs are an effective improvement tool. However, although the identification of valuable QIs is an essential step, other issues should be taken into consideration to assure a harmonized approach to the appropriate utilization of QIs.

First and foremost, the standardization of the system for data collection and reporting plays a key role in assuring the comparability of data collected by different laboratories in all countries. This aspect prompted us to split some QIs into different groups in order to facilitate the understanding and collection of data [10].

Secondly, most QIs cannot be managed without the collaboration and active cooperation of different care operators both within and outside the laboratory. For example, the appropriateness of test requesting as well as the quality of collected samples can be improved only through the active involvement of requesting physicians, phlebotomists and nurses. Laboratory professionals and other stakeholders should never lose sight of the meaning and value to patients of QIs developed for identifying and reducing errors for procedures and processes at the interface between the clinic and the laboratory. Only by sharing awareness of the value of QIs to patients will laboratory professionals manage to secure the active involvement of other care operators in programs aiming to collect and monitor data on the QIs themselves. The development and release of practice guidelines for appropriate test requesting and blood collection at an international and national level should facilitate compliance and quality improvement.

Thirdly, another fundamental issue is the automated collection of data on QIs, a current project of the IFCC WG-LEPS. The three pillars for harmonizing QIs in laboratory medicine are therefore: 1) identification of valuable QIs covering all steps of the TTP, 2) standardization of the system for data collection and reporting, and 3) active involvement of all stakeholders and care operators both within and outside the laboratory in the rational use of QIs to reduce error and the risk of error.

8. Conclusions

Several lines of evidence attest to the fact that the more frequent errors and non-conformities encountered in the TTP occur in the pre-analytical phase. Developments in automation and information technologies have played a major role in decreasing some pre-analytical errors. In particular, the automation of repetitive, error-prone and biohazardous pre-analytical processes performed within the laboratory has effectively decreased errors in specimen preparation, centrifugation, aliquot preparation, pipetting and sorting. However, greater efforts should be made to improve upon the appropriateness of test requesting, patient and sample identification procedures and other pre-analytical steps performed outside the laboratory. The development of QIs in laboratory medicine is a fundamental step in providing sound evidence of quality in all procedures and processes of the TTP in pursuing accreditation programs, and in ensuring that continuous improvement activities are undertaken to reduce the risk of errors in clinical practice [35]. Valid QIs are therefore crucial in identifying, monitoring and decreasing errors and non-conformities in the pre-analytical phase and guaranteeing the ultimate quality and safety of laboratory information.

References

[1] Plebani M. The detection and prevention of errors in laboratory medicine. Ann Clin Biochem 2010;47:101–10.
[2] Plebani M. Review: the CCLM contribution to improvements in quality and patient safety. Clin Chem Lab Med 2013;51:39–46.
[3] Plebani M, Carraro P. Mistakes in a stat laboratory: types and frequency. Clin Chem 1997;43:1348–51.
[4] Carraro P, Plebani M. Mistakes in a stat laboratory: types and frequency 10 years later. Clin Chem 2007;53:1338–42.
[5] International Organization for Standardization ISO/PDTS 22367:2008. Medical laboratories — reducing error through risk management and continual improvement. Geneva, Switzerland: International Organization for Standardization; 2008.
[6] Plebani M. Quality indicators to detect pre-analytical errors in laboratory testing. Clin Biochem Rev 2012;33:85–8.

[7] International Organization for Standardization. ISO 15189:2012: medical laboratories: particular requirements for quality and competence. Geneva, Switzerland: International Organization for Standardization; 2012.
[8] Plebani M. Towards quality specifications in extra-analytical phases of laboratory activity. Clin Chem Lab Med 2004;42:576–7.
[9] Shahangian S, Snyder SR. Laboratory medicine quality indicators: a review of the literature. Am J Clin Pathol 2009;131:418–31.
[10] Plebani M, Chiozza ML, Sciacovelli L. Towards harmonization of quality indicators in laboratory medicine. Clin Chem Lab Med 2013;51:187–95.
[11] Wagar EA, Tamashiro L, Yasin B, Hilborne L, Bruckner D. Patient safety in the clinical laboratory: a longitudinal analysis of specimen identification errors. Arch Pathol Lab Med 2006;130:1662–8.
[12] Dunn EJ, Moga PJ. Patient misidentification in laboratory medicine: a qualitative analysis of 227 root cause analysis reports in the Veterans' Health Administration. Arch Pathol Lab Med 2010;134:244–55.
[13] 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.
[14] Ansari S, Szallasi A. "Wrong blood in tube": solutions for a persistent problem. Vox Sang 2011;100:298–302.
[15] Stark A, Jones BA, Chapman D, et al. Clinical laboratory specimen rejection — association with the site of patient care and patients' characteristics. Findings from a single health care organization. Arch Pathol Lab Med 2007;131:588–92.
[16] Plebani M, Ceriotti F, Messeri G, Ottomano C, Pansini N, Bonini P. Laboratory network of excellence: enhancing patient safety and service effectiveness. Clin Chem Lab Med 2006;44:150–60.
[17] Gonzalez-Porras JR, Graciani IF, Alvarez M, et al. Tubes for pretransfusion testing should be collected by blood bank staff and hand labelled until the implementation of new technology for improved sample labelling. Results of a prospective study. Vox Sang 2008;95:52–6.
[18] Lippi G, Guidi GC, Mattiuzzi C, Plebani M. Preanalytical variability: the dark side of the moon in laboratory testing. Clin Chem Lab Med 2006;44:358–65.
[19] Lippi G, Blanckaert N, Bonini P, et al. Haemolysis: an overview of the leading cause of unsuitable specimens in clinical laboratories. Clin Chem Lab Med 2008; 46:764–72.
[20] Lippi G, Chance JJ, Church S, et al. Preanalytical quality improvement: from dream to reality. Clin Chem Lab Med 2011;49:1113–26.
[21] 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.
[22] Holman JW, Mifflin TE, Felder RA, Demers LM. Evaluation of an automated preanalytical robotic workstation at two academic health centers. Clin Chem 2002;48:540–8.
[23] 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.
[24] 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.
[25] Shcolnik W, de Oliveira CA, Sá de São José A, de Oliveira Galoro CA, Plebani M, Burnett D. Brazilian laboratory indicators program. Clin Chem Lab Med 2012;50:1923–34.
[26] Key Incident Monitoring & Management Systems (KIMMS) project. http://www.rcpaqap.com.au/kimms/.
[27] 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.
[28] Barth JH. Clinical quality indicators in laboratory medicine: a survey of current practice in the UK. Ann Clin Biochem 2011;48:238–40.
[29] Smellie WSA. Demand management and test request rationalization. Ann Clin Biochem 2012;49:323–36.
[30] Zaninotto M, Tasinato A, Padoan A, et al. An integrated system for monitoring the quality of sample transportation. Clin Biochem 2012;45:688–90.
[31] Zaninotto M, Tasinato A, Padoan A, et al. Effects of sample transportation on commonly requested laboratory tests. Clin Chem Lab Med 2012;50:1755–60.
[32] Sciacovelli L, Plebani M. The IFCC Working Group on laboratory errors and patient safety. Clin Chim Acta 2009;404:79–85.
[33] 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.
[34] Sciacovelli L, Sonntag O, Padoan A, Zambon CF, Carraro P, Plebani M. Monitoring quality indicators in laboratory medicine does not automatically result in quality improvement. Clin Chem Lab Med 2011;50:463–9.
[35] Plebani M. Harmonization in laboratory medicine: the complete picture. Clin Chem Lab Med 2013;51:741–51.