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Review

Quality indicators in laboratory medicine: A fundamental tool for quality and patient safety

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ABSTRACT

Objectives: 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 with the body of evidence pointing to the multitude of errors that continue to occur in the pre- and post-analytical phases.

Design and methods: Different QIs and terminologies are currently used and, therefore, there is the need to harmonize proposed QIs.

Results: A model of quality indicators (MQI) has been consensually developed by a group of clinical laboratories according to a project launched by a working group of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC). The model includes 57 QIs related to key processes (35 pre-, 7 intra- and 15 post-analytical phases) and 3 to support processes.

Conclusions: The developed MQI and the data collected provide evidence of the feasibility of the project to harmonize currently available QIs, but further efforts should be done to involve more clinical laboratories and to collect a more consistent amount of data.

Contents

Introduction

"You cannot manage what you cannot measure" is a well known and perhaps tired management mantra, but it certainly applies to improve quality and safety in laboratory medicine.

It has been documented that performance and outcome measures can improve the quality of patient care. Such measures support accountability and enable the comparison over time between providers, evaluating the effectiveness of delivered services and the improvement in patient safety through the development and monitoring of specific indicators [1]. Laboratory-associated error has a completely different meaning today than a century ago, as pre- and post-analytical processes are more vulnerable to errors than the analytical phase [2,3]. This is due, at least in part, to the evidence that in the last decades reliable quality indicators and quality specifications have been developed and introduced for an effective management of analytical procedures [4]. The internal quality control rules, as well as the 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 analytical performances over time. In addition, these programs

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allow a valuable benchmark among clinical laboratories based on objective data. Unfortunately, while some interesting programs on indicators of the extra-analytical phases have been developed in some countries, no consensus exists for producing joint recommendations focused on the adoption of universal quality indicators and common terminology in the total testing process [5].

Quality indicators in laboratory medicine

Quality indicators (QIs) are fundamental tools for enabling users to quantify the quality of a selected aspect of care by comparing it against a defined criterion. A quality indicator is thus "an objective measure that potentially evaluates all critical care domains as defined by the Institute of Medicine (patient safety, effectiveness, equity, patient-centeredness, timeliness and efficiency), that is based on evidence associated with those domains, and can be implemented in a consistent and comparable manner across settings and over time" [6].

QI data should be collected over time to identify, correct, and continuously monitor defects and improve performance and patient safety by identifying and implementing effective interventions. In addition, they comply with the purpose of increased consistency and standardization of key processes in patient care. According to the approach of the Institute of Medicine (IOM) on the quality in healthcare, the identification of reliable QIs represents a crucial step in programs aiming to evaluate and improve the quality of care [7]. On assessing the quality of laboratory services using QIs, it is important to ensure systematic and consistent data collection and analysis using a comprehensive set of indicators that address all stages of the total testing process (TTP), with a focus on the areas with an important impact on patient care and health outcomes. In addition, 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: 2007) [8]. It should be remembered that this International Standard, in addition to requirements for personnel, environmental and laboratory equipment conditions, recognizes the evidence of 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 clauses and sub-clauses, but it does not, and cannot, specify quality indicators and quality specifications [9].

Yet, as pointed out by Shahangian and Snyder, there is a "considerable challenge in identifying, defining, and ultimately implementing indicators that cover the various stages of the total testing process" The same authors identified, through an internet searching of peer-reviewed publications from January 1990 through July 2008, 14 QIs that met two inclusion criteria: 1) the use of a quantitative measure associated with laboratory testing; and 2) the potential to be related to at least one IOM health care domain. All QIs identified except one are process measures, while the unique QI related to an outcome measure is "patient satisfaction with phlebotomy" [10]. This strongly underlines that the efforts to reduce laboratory errors and improve quality and safety in laboratory medicine have been based on process measures, thus reaffirming difficulties in linking laboratory testing to ultimate patient outcomes.

Quality indicators in laboratory medicine: currently available experiences

Different experiences have been described in the recent literature concerning the use of QIs in laboratory medicine. A working group of the Catalonian Health Institute (ICS) identified 32 indicators, including 12 indicators for key processes (3 for pre-analytical, 4 for analytical and 5 for post-analytical steps), as well as 8 indicators for strategic and 12 for support processes [11]. A further study from the same working group described the results on the identified indicators and quality specifications for the non-analytical processes. The median values recorded over 1 year were considered to be state-of-the-art and proposed as a quality specification for the indicators stated [12]. Subsequently, the same working group described its experience of monitoring quality indicators over 5 years (2004–2008). Of particular interest is the evidence that the authors divided the pre-analytical indicators into two categories: a) pre-analytical processes outside the laboratory (e.g.: samples not received and incorrect or missing patient data), and b) pre-analytical processes within the laboratory (e.g.: errors in sample management) [13].

In Brazil, a national program has been promoted and developed by the Brazilian Society of Clinical Pathology/Laboratory Medicine (SBPC/ML). The Brazilian Laboratory Program provided 61 QIs classified into three groups: demographic indicators (n = 16) used to evaluate the market position of laboratory and direct strategic decision-making; process performance indicators (n = 18) to monitor the effectiveness of the operational processes comprising the pre-, intra- and post-analytical phases; and resource management indicators (n = 27) to verify data as to costs, productivity and training [14]. The Program did not define quality specifications to evaluate the laboratory results; but provided a graphic representation of laboratory results in box plot form helping each laboratory to evaluate its performance in comparison with the others. Sigma metric is also used for indicators related to the failure of processes: a performance around 4 is acceptable, and level 6 is equivalent to the desired performance.

The authors underlined that the success of the Program has been affected by poor participation of laboratories in Brazil, due probably to an incomplete learning about topics of quality and improvement and by difficulties to standardize the data collection and obtain comparable data. Table 1 summarizes the information available in the literature on quality indicators in laboratory medicine.

Another interesting experience has been lately developed and it is in progress in Australia and New Zealand. The Quality Assurance Scientific and Education Committee (QASEC) of the Royal College of Pathologists of Australasia (RCPA), supported by the Australian Government Department of Health and Ageing, has launched the project "Key Incident Monitoring & Management Systems (KIMMS)". This project has been designed to provide pathology practices with the tools for continuous measurement and monitoring of key incident indicators. The KIMMS QA Program provides a system for laboratories to record a defined set of key incidents and errors that occur within the test–request–report cycle (including those in the pre- and post-analytical phases) and provides a framework for laboratories to benchmark their error rates against their peers [15]. The aims of the project are the following: a) to establish a national data set for pathology incidents; b) to develop the data set to enable participants to measure and monitor pathology incidents; c) to utilize the data to set achievable national benchmarks for good pathology practice in the pre- and post-analytical phases of testing; d) to exchange information with participants to educate laboratories on methods to reduce errors; e) to raise awareness of safe work practices which will in turn reduce errors and increase patient safety; and f) to set standards for best practice in the pre- and post-analytical areas of laboratory work.

In particular, the focus on identification problems and related clinical outcomes, as well as the mechanisms and indicators to detect "wrong

Table 1
Currently available experiences on quality indicators.

Study (reference)	Shahangian and Snyder [10]	Kirchner et al. [11]	Shcolnik et al. [14]
Processes			
Pre-analytical	6	3	8
Intra-analytical	2	4	1
Post-analytical	6	5	8
Strategic		8	
Support		12	
Demographic			16
Resource management			27