Editors

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The quality indicator paradox

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The old management adage “You can’t manage what you don’t measure” is applicable to the field of clinical laboratories. Quality in laboratory medicine can be improved upon without being measured, for example, by introducing new technologies or more effective tests. Yet measurement itself is of fundamental importance in achieving improvement [1]. In laboratory medicine, the measurement of analytical quality through internal quality control and external quality assessment programmes has led to a significant improvement in accuracy in terms of both precision and trueness [2]. However, in the last few decades, a large body of evidence has demonstrated the high vulnerability of the pre- and post-analytical phases [3]. This finding depends on numerous factors, including the complexity of the processes entailed, limited automation and standardization, and the involvement of different health care operators at the interface between laboratories and clinical practices [4]. In this context, a pressing issue is the lack of valuable quality indicators for evaluating, monitoring and improving the extra-analytical phases [5].

Quality indicators (QIs) have been explicitly defined as measurable items pertaining to processes and/or outcomes allowing the measurement of quality of care and services [6]. According to the definition of quality of care made by the Institute of Medicine, a QI is a tool enabling the user to quantify the quality of a selected aspect of care by comparing it with an appropriate criterion [7]. In order to promote measurement and improvement programmes, quality indicator data should be collected over time to identify, correct, and continuously monitor performance and patient safety by identifying and implementing effective corrective and preventive interventions in the total testing process (TTP). According to the latest version of the International Standard for clinical laboratory accreditation (ISO 15189:2012), “quality indicators can measure how well an organization meets the needs and requirements of users and the quality of all operational processes”. In addition, the document specifies that: “the laboratory shall establish QIs to monitor and evaluate performance throughout critical aspects of pre-examination, examination and post-examination processes” [8]. Implementing QIs is therefore a pre-requisite for being accredited, as the reported requirements highlight the importance of these tools for measuring and improving not only analytical but also extra-analytical processes. The question, indeed, is not whether QIs should be implemented, but which QIs should be used, and how they should be measured. Any clinical laboratory should select and use its own list of QIs for “in-house quality improvement programs”, but by doing so they miss the opportunity to use QIs for two other main goals. The first, most interesting goal is to provide an objective benchmark between different laboratories, thus allowing the comparison of performances in the extra-analytical phase. The data thus obtained should be part of effective external quality assessment (EQA/PT) programmes that aim to evaluate all steps of the TTP. The second goal is to provide interested stakeholders, including physicians, patients and administrators, with a source of objective information on the total quality of laboratory services.

The harmonization of QIs represents a fundamental step in achieving these goals, as only a list of harmonized QIs and a standardized reporting system will allow the inter-laboratory comparison of data and performances [9, 10]. Based on these premises, the Working Group “Laboratory Errors and Patient Safety” (WG LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) has developed a preliminary model of QIs (MQI) and a specific website (www.ifcc-mqi.com) in order to enable interested laboratories to undertake data collection [11, 12]. As a further step in this initiative, a Consensus Conference bringing together all experts and interested parties was organized in order to design a road map for the harmonization of QIs. An account of the consensus achieved in the Conference on the characteristics of harmonized QIs, and on the standardized system of data collection and reporting has been given [13]. The list of harmonized QIs and information on a dedicated website designed to explain the rationale of the MQI project and enable clinical laboratories to collect data and to compare individual performances with all participating laboratories (benchmark) have been made available thanks to participation in national and international scientific meetings, issuing of documents through the International
Federations and national societies, and publications in scientific journals [14–20]. The collection of data received by clinical laboratories participating in the MQI programme on the list of harmonized QIs has recently led to the definition of preliminary performance specifications in the pre-analytical phases [21].

In this issue of the Clinical Chemistry and Laboratory Medicine, Sciacovelli et al. report preliminary performance specifications on key QIs of the post-analytical phase, thus contributing further essential information [22]. However, a major drawback of currently available data on the extra-analytical phases and related performance specifications depends on the limited number of clinical laboratories participating in the MQI project and collecting data. This has led to the so-called “quality indicators paradox” (Figure 1). On the one hand, an increasing interest is being expressed by the International Federations of Laboratory Medicine (both IFCC and EFLM), National Scientific Societies and laboratory professionals, with numerous papers on this issue and a specifically developed website to spread the information and collect data (free of charge and treated confidentially). On the other hand, there is the evidence that only a few clinical laboratories are making a regular collection of comprehensive data on indicators for the extra-analytical phases. A recent paper describing the UK situation has confirmed this evidence [23].

Efforts must therefore be made to improve our understanding of the nature of the paradox and to find a solution. The several elements compounding limited participation and inadequate data are listed in Table 1.

Preliminary experiences of making an inter-laboratory comparison of analytical results were gained several decades ago, yet it is still taking time for clinical laboratories to understand the advantages of participation in these new programmes. This is also due to the fact that the collection of data on extra-analytical QIs is not always undertaken using the laboratory information system (LIS), and is a tedious and time-consuming activity. In addition, many clinical laboratories adopt only a few, conventional QIs, thus failing to cover all the steps and processes in the extra-analytical phase. Finally, the awareness of the importance of harmonized QIs and related performance criteria by some national accreditation bodies is still limited [24, 25].

It may be simple to identify current issues limiting the participation of clinical laboratories in the MQI programme, and thus compromising the provision of data needed for defining reliable performance specifications in the extra-analytical phases, but it is far more difficult to identify corrective measures. Recently, the Task & Finish Group on “Performance specifications for the extra-analytical phases” (TFG-PSEP) of the EFLM provided the Presidents and members of all national scientific societies with questionnaires designed to gain a better understanding of the state-of-the-art and to identify the factors compromising participation. A second “Consensus Conference” on the harmonization of QIs and programmes should be held with a view to collecting data and establishing reliable performance specifications. In addition, it is time for the devolution of the programme. This should be achieved by searching for national representatives who could support the MQI program by inviting clinical laboratories in their geographical area to take part in the programme and to exchange data by using “personalized reports” from data collected by the laboratories of each individual area. Finally, the way in which to use the list of harmonized QIs and standardized reporting systems should be discussed with the providers of EQA/PT programmes, and the right utilization of harmonized QIs in accreditation programmes according to the International Standard (ISO 15189:2012) should also be decided upon with the national accreditation bodies.

**Figure 1:** The quality indicators paradox.

**Table 1:** Main causes of limited participation of clinical laboratories in the MQI programme.

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<td>Difficulties in defining and implementing policies and procedures for identifying and monitoring QIs on a regular basis</td>
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<td>Problems in collecting data (manual versus information management)</td>
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<td>Complexity of monitoring QIs over time</td>
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<td>Exclusive use of “conventional QIs” (e.g. hemolyzed, clotted and insufficient samples)</td>
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<td>Lack of external quality assessment (EQA) schemes for the extra-analytical phases of laboratory testing</td>
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<td>Poor awareness of the need for harmonized QIs as well as related performance criteria from national accreditation bodies</td>
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Current evidence on the link between errors in the TTP, the vulnerability of extra-analytical phases and risks to patient safety cannot be ignored, and clinical laboratories should devote more time and effort to identifying the risk of errors not only in the analytical but also in all extra-analytical phases [26]. This, in turn, calls for improved cooperation and collaboration with other healthcare operators with a view to improving test requesting, sample collection and handling, prompt communication of laboratory reports and the correct interpretation and utilisation of laboratory information.

An important achievement made in recent years is the raised awareness that clinical decision making and patient outcomes are affected not only by analytical results, but also by global laboratory information, which is strongly related to the quality of biological samples and to the requesting physician’s reaction to laboratory reports. QIs are tool of crucial importance in improving the total quality of laboratory services and patient safety. The next steps, therefore, should be to raise awareness in laboratory professionals of the importance of QIs and related performance specifications, which are the key to allowing the identification of priorities in improvement programmes and to developing appropriate guidelines at a national and international level.

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