

Editorial

Mario Plebani*

Quality indicators: an evolving target for laboratory medicine

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Quality in clinical laboratories is the main subject in laboratory medicine and can be precisely defined. As previously reported, quality in laboratory medicine has two interdependent dimensions. The ‘internal dimension’, performed and assured within the laboratory environment to ensure efficiency, is based on the accuracy and reliability of analytical results, the timeliness of their production and communication, and finally, cost containment activities. The ‘external dimension’ is assured by diagnostic accuracy, value in test-treatment pathways, effect on clinical and economic outcomes, and finally, patient safety [1]. As quality is an ongoing process, it should be assessed and monitored over time. This assessment can be made using quality indicators (QI), which provide information on the quality of laboratory services. In medicine, indicators are defined as measurement tools that can be used to monitor and evaluate important governance, management, clinical and support functions [2]. They provide a quantitative basis for clinicians, organizations and planners who are aiming to improve care and the processes by which patient care is provided. Clinical laboratories have pioneered the development and adoption of quality indicators to measure and improve analytical performance through internal quality control (IQC) and external quality assurance (EQA). Thereafter, a consensus was reached on the need to ensure quality in laboratory medicine from a patient-centered perspective, covering not only the analytical phase, but the entire testing process [3]. This process encompasses all stages, from selecting the test during the patient evaluation, through to interpreting the results, until a clinical conclusion is reached. In 2008, the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) established the Working Group on Laboratory Errors and Patient Safety (WG-LEPS). The

IFCC Working Group made significant efforts in harmonizing and standardizing QI to monitor and improve the total testing process (TTP) [4–7] and developed a model of quality indicators (MQI) aligned with ISO 15189:2012 and later ISO 15189:2022 [8]. This issue of the *Journal* includes two papers that offer new insights about QIs, which are a moving target. The first is a recommendation for adopting quality indicators for glucose point-of-care testing (POCT) [9]. There is increasing interest in the integration of centralized and decentralized laboratory testing, particularly in the context of the post-pandemic era [10]. This integration is crucial for enabling easy access to diagnostic testing and rapid results, and point-of-care testing (POCT) is a valuable tool for achieving these goals [11]. In their paper, the authors provide recommendations to adopt five QIs, including positive patient identification, operator training, internal quality control monitoring, external quality assessment and critical results follow-up. This panel of five QIs which allows the regular monitoring of glucose POCT is applicable to other POCT programs, particularly for quantitative measures covering all phases of the TTP. In fact, despite its advantages in terms of user-friendly devices and rapid results, a growing body of evidence highlights the vulnerability of POCT to errors, particularly because POCT is performed by non-laboratory professionals. Therefore, a list of QI measures is essential for identifying areas for process improvement that will impact the quality of testing and patient safety [11]. The second paper by Zubanov and Coll. provides a proposal for a list of indicators for medical laboratories, grouped into four categories: a) velocity of testing; b) quality and accuracy; c) number of tests performed and productivity; and finally, d) economic efficiency [12]. Based on these four groups, the Authors describe a new “four-dimensional model” for assessing the performance of medical laboratories, which is based on different combinations of indicator groups for different types of laboratories. In fact, the authors highlight that different types of medical laboratories require a different focus on QIs. For example, the evaluation of a STAT laboratory in an intensive care unit which “requires a focus on fast and accurate testing, which is of vital importance, should be based on quality and performance indicators”. Economic and productivity indicators are less important in

*Corresponding author: Mario Plebani, MD, University of Padova, Padova, Italy, E-mail: mario.plebani@unipd.it. <https://orcid.org/0000-0002-0270-1711>

this type of laboratory. Conversely, “in a centralized medical laboratory where large volumes of routine tests are performed, economic efficiency and productivity become more important, albeit while maintaining high-quality standards. Additionally, specialized types of laboratory testing, such as routine mass screening programs or patient self-testing, require a different set of priorities” [12]. In their conclusions, the authors emphasize that “our comprehensive model assists the management of a medical organization or healthcare system leaders in selecting target indicator groups correctly for assessing the effectiveness of laboratories based on their priority goals and profiles of the medical institution”. Further discussion and debate of the paper and the authors’ proposal is warranted, particularly because a recent proposal for a value-based score for clinical laboratories highlights the need to adopt valuable indicators that demonstrate the vital role of laboratories in modern healthcare, including measures of clinical outcomes [13]. Ideally, QIs should be based on evidence, automatically collected and cover all the steps of the TTP, including clinical outcomes. They should also be useful for promoting corrective and preventive actions. Therefore, clinical laboratories should easily collect evidence-based indicators to avoid wasting time and ensure a valuable evaluation of the quality of services delivered to users (patients and physicians), which should be acknowledged by other stakeholders (e.g. administrators). They should be used for internal improvement projects and to benchmark individual laboratory performance against that of other medical laboratories: the ultimate goal is continuous quality improvement.

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