

## Editorial

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# Value-based laboratory medicine: the time is now

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In the last few decades, laboratory medicine has undergone monumental changes and the landscape of clinical laboratories is still evolving over time. In particular, data on laboratory errors and associated diagnostic errors and risk for patient safety emphasize the need for a paradigmatic shift [1, 2]: from a focus on volumes and efficiency to a patient-centered vision restoring the nature of laboratory services as an integral part of diagnostic and therapeutic pathways [3]. After focusing on internal indicators of analytical quality and efficiency, efforts are shifting toward indicators of total quality, clinical effectiveness and patient outcomes with an emphasis on the benefit created for patients by “value”, defined as the “outcomes achieved relative to costs” [4]. While this proposal is widely accepted as it is based on the seminal vision by Michael Porter that “health care is shifting focus from the volume of services delivered to the value created for patients, with ‘value’ defined as the outcomes achieved relative to the costs” [5], it is still poorly translated in practice. Progress is slow and halting, partly because outcomes measurements remain limited, not standardized and in laboratory medicine a well-defined link between laboratory quality and patient outcomes has proven to be elusive [6]: in fact, the “ultimate” measures of patient welfare, such as health status achieved or retained, as well as measures related to the process of recovery, and hospital discharge and readmission reflect the combined activities of clinicians, nurses, laboratory and radiology professionals, various other healthcare professionals as well as the patient. However, moving from volumes to value measured with reliable sets of outcomes represents a decisive step in accelerating value improvement in health care. Therefore, the paper by Tomaiuolo and Banfi published in this issue of the *Journal* should be welcome as it provides new and interesting data to support efforts to promote “value-based laboratory medicine” [7]. In their article, the authors underline that “the clinical laboratory could accelerate the

transition from volume (output, understood as the mere numerical value obtained from the laboratory analysis) to value (outcome, understood as the laboratory data contextualized to the patient)..... aiming to produce the best outcomes possible in a real-life context (as opposed to clinical research settings),..... the laboratory specialists being part of a team responsible for clinical and operational decision-making” [7]. In the context of value-based laboratory medicine, a fundamental goal is to achieve not only efficiency but effectiveness, as the authors underline that “the effectiveness of clinical laboratory is achieved through understanding of the medical needs and delivering timely and high-quality tests. The role of clinical laboratories is closely linked to the increase in value; therefore, the main objective of the clinical laboratory professionals is to enhance the value of laboratory testing, optimizing their correct use both in the test selection request phase and in the reporting phase” [7]. Another fundamental step in promoting value-based laboratory medicine is to assure comparability of test results as the authors highlight that “the accountability and credibility of the clinical laboratory in low-volume vs. high-value settings are linked to total testing process harmonization”. First and foremost, there is the need to stimulate cooperation with *in vitro* diagnostic companies to achieve better analytical standardization for an increasing number of measurands. However, as mentioned by the authors, these efforts should not be limited to increase the comparability of analytical results, but to provide harmonization in all steps of the testing process, including “homogenization of reference values” and the evaluation of cost-effectiveness in this challenging regulatory framework. In a challenging scenario for all healthcare systems, the promotion of value-based laboratory medicine is a contribution not only to the sustainability but to the increasing need for measuring clinical and economical outcomes. If value is defined by the ratio between the outcomes and related costs, clinical laboratories have to promote improved outcomes (clinical effectiveness) while decreasing costs (efficiency). In other words, efforts based only on increasing volumes and economy of scales are totally inappropriate if the ultimate goal is to achieve better and higher quality of care. Combined efforts are needed to improve clinical outcomes while reducing costs, taking into consideration that the laboratory information is increasingly important but only in the right clinical context. Clinical

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laboratories have been pioneers in introducing process measures (internal quality control, external quality assurance and the model of quality indicators) to improve accuracy and reliability of laboratory results [8], and now they should play a key role in promoting value-based laboratory medicine to assure more effective, safe and patient-centered clinical diagnostic and therapeutic pathways.

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