Opinion Paper

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A value-based score for clinical laboratories: promoting the work of the new EFLM committee

https://doi.org/10.1515/cclm-2025-0490
Received April 23, 2025; accepted April 26, 2025;
published online May 5, 2025

Abstract: After the dissemination of a manifesto for the implementation of value-based laboratory medicine (VBLM) and a Strategic Conference dedicated to this issue, a novel initiative of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) is to be initiated with the objective of developing a "value-score for clinical laboratories". The initial proposition of this value score should be based on the following features: (1) traceability throughout the total testing process (TTP); (2) level of automation (number of manual procedures); (3) laboratory performance on quality indicators; (4) data management and quality of laboratory information; and (5) interaction with clinicians and multidisciplinary initiatives. This paper represents a first conceptualization of the value-based score, which should facilitate a more effective work of the new EFLM Committee (C-VS) to better define the characteristics that can add value to clinical laboratories and allow a benchmark based on effective indicators.

Keywords: value-based laboratory medicine; value-score; clinical laboratory; traceability; automation; quality indicators

Introduction

In the context of the contemporary transition in medical service delivery, characterized by the promotion of a shift from volume-based to value-based models, clinical laboratories are in an optimal position to function as catalysts for change [1]. Clinical laboratories, in fact, contribute to improving clinical outcomes and healthcare sustainability by reducing time to diagnosis, enhancing diagnostic accuracy, providing effective guidance for tailored therapies and monitoring, as well as for supporting screening and wellness care [2]. The concept of Value-Based Laboratory Medicine (VBLM) is therefore attracting increasing interest as a means of ensuring greater visibility and effectiveness of laboratory services [3, 4]. Translating the principles of VBLM into clinical practice, however, will require major efforts, including new and improved skills, and practical tools to promote interlaboratory comparisons based on effective indicators. After the dissemination of a 10-point manifesto for the implementation of VBLM [2], a novel initiative of the European Federation of Clinical Chemistry and Laboratory Medicine (EFLM) is to be initiated with the objective of developing a value-based score for clinical laboratories [3]. Therefore, a new EFLM "Value-Score for clinical laboratories" Committee (C-VS) has been established with the following aims: a) to identify some fundamental requirements which allow to understand the true quality of clinical laboratory services; b) to accomplish an objective evaluation of quality in the TTP; c) to develop a value-based score based on the previously cited requirements – with information that should be easily collected (avoiding manual collection as automation is the goal); and finally, d) to accomplish an effective program of benchmark between clinical laboratories. The initial proposition of this value score should be based on the following features (1): traceability throughout the total testing process (2); level of automation (number of manual procedures) (3); laboratory performance on quality indicators (4); data management and quality of laboratory information; and (5) interaction with clinicians and multidisciplinary initiatives (Figure 1). The aim of this paper is to stimulate the work of the new EFLM Committee through the initial proposal of the rationale and definition of the elements of the value-based score.

Traceability

In laboratory medicine, the term "traceability" is generally used to define a crucial element in ensuring analytical accuracy and comparability of results, namely "metrological

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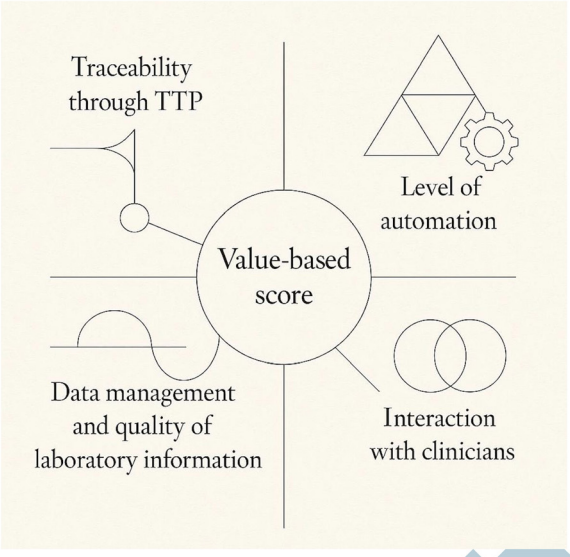

Figure 1: Value-based score.

traceability" [5, 6]. In the last decade, however, a growing body of evidence has been accumulated to highlight the vulnerability of the extra-analytical phases of the total testing process (TTP) and the interrelationship and interdependence between these different phases [7, 8]. Indeed, it is well known that only "good samples make good analytical results", thus emphasizing the importance of quality assurance in the pre-analytical steps. Similarly, only "good post-analytical phase makes good laboratory information" which is the essential prerequisite for achieving valuable clinical outcomes. This means that individual sample journeys should become fully traceable throughout the TTP, from blood draw to the notification of laboratory information, its timely acknowledgment, interpretation and utilization [9]. According to the International Standardization Organization (ISO), traceability is defined as "*the ability to trace the history, application or location of your product*" and it can relate to a number of things such as the *origin* of the materials (e.g. biological samples from an individual subject), the *processing history (e.g. the steps of the TTP)*, and the distribution and *location of the product* or service after delivery (e.g. laboratory data and their communication to the right users) [10]. Innovative technologies have been developed through the implementation of an effective traceability system based on electronic patient and specimen identification using barcode scanning technology and a user interface to guide, track and digitize the specimen collection process to reduce errors and improve patient safety [11]. When combined with clinical laboratory automation solutions, these pre-analytical advances can ensure traceability in the TTP, which is a prerequisite for accurate, timely and reliable laboratory data. The lack of traceability in laboratory medicine and pathology was ironically commented on by Soufiane Z. Azdad after using a food delivery app: "we appear to have better traceability for fast food than for biosamples that can determine a patient's diagnosis and treatment" [12]. Therefore, the necessity to ensure the ability to trace the process at each stage of the laboratory testing process must be given due consideration.

Level of automation

The development of laboratory automation systems has been driven by the need to enhance laboratory performance. These systems have been designed to minimize repetitive tasks, which have the potential to result in human errors, thereby ensuring optimal operational efficiency. Additionally, these systems facilitate the standardization of procedures within the TTP, contributing to the consistency and reliability of laboratory information. Following laboratory automation, a study performed in two academic centers reported more than 90 % reduction in specimen processing errors, including errors in sorting, routing, labelling and biohazard exposure events [13]. The opportunity to automate most of the manual tasks characterizing routine clinical laboratory activities, such as manual pipetting of samples, manual measurement, and reagent preparations enables the laboratory professional to produce analytically more accurate results and focus on procedures of higher

value, such as validation of results, interpretation, test development and translation of innovative tests into clinical practice [14]. A plethora of laboratory automation systems are currently available, encompassing pre-analytical modules, task-targeted automation (TTA), and total laboratory automation (TLA) systems [15]. Regardless of the size of the clinical laboratory, automation is a fundamental requirement to improve workflow management, timely reporting and quality assurance. The reduction/management of human intervention is, therefore, mandatory to promote value-based laboratory medicine.

Laboratory performance on quality indicators

Quality in laboratory medicine has evolved in concert with the transformation and the changes (technological, scientific and organizational) in this sector, and it has been defined an unfinished journey [16], as "the more essential the laboratory information provided, the more assured its quality will be" [17]. 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" [18]. In laboratory medicine, QIs must be adequately identified in order to control the most critical TTP procedures and activities, and to improve the processes designed to reduce risk of error. QIs should therefore 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) [19]. In 2009, with a view to boosting activities designed to control and to measure the quality of laboratory performance, the Working Group "Laboratory Errors and Patient Safety" (WG-LEPS) of the International Federation of Clinical Chemistry and Laboratory Medicine (IFCC) implemented a Model of Quality indicators (MQI) for use in medical laboratories worldwide [20, 21]. Since 2008, three different MQI, proposed by IFCC WG-LEPS, have been followed in turn: their use in several laboratories throughout the world has highlighted the need for improvement in aspects such as wording, number of indicators and information included in periodical and confidential reports. In 2016, the Consensus Conference held in Padova (Italy) MQI was discussed and approved and is now in use. Thanks to a dedicated website (www.ifcc-mqi.com), uniform data collection is managed, and data processing centralized, and a report for each participant provided. Last year, a new Consensus Conference has been organized to discuss the state-of-the-art of the IFCC MQI model and to provide new input to the development of the project through the identification of a reduced number of 'essential QIs' and the devolution of data collection to regional level [21, 22]. In the context of VBLM the quality indicator assessing the contribution of the clinical laboratory to the measurement and improvement of clinical outcomes is of central value. Therefore, the quality indicator on patient-oriented and outcome-oriented activity takes on fundamental value. The use of QIs, specifically designed for laboratory medicine is effective in assessing and monitoring all critical events occurring in the different phases of TTP, in particular, in the extra-analytical phases. The availability of MQI as proposed by the WG-LEPS, and validated by experts in consensus conferences, offers an important window of opportunity for the medical laboratory to demonstrate the use of an effective quality assurance tool fit for this purpose. Currently, innovative software and middleware solutions are available to avoid the manual collection of data, which represented a major bottleneck for the adoption of the MQI in clinical practice. Therefore, QIs are tool of crucial importance in improving the total quality of laboratory services and patient safety as they provide an objective benchmark between different laboratories, thus allowing the comparison of performances in the TTP and are a pre-requisite for being accredited according to the specific International Standard (ISO 15189).

Data management and quality of laboratory information

A fundamental step in promoting value-based laboratory medicine (VBLM) is to improve the provision and interpretation of laboratory data, transforming analytical results in actionable information [2]. Indeed, current evidence demonstrates that the erroneous interpretation of laboratory information constitutes the second most prevalent cause of medical errors arising from diagnostic tests [23]. The interpretation of laboratory results is a comparative process that necessitates the availability of reliable additional information beyond the numerical data itself, including accurate terminology, harmonized measurement units, reference values such as reference intervals (RI) and decision limits (DL), and interpretative comments. The aforementioned

parameters, which are typically designated as "comparators", are intended to transform data into "actionable" information. Nevertheless, extant evidence underscores two salient issues. Firstly, there is a conspicuous paucity of harmonization among these comparators. Secondly, and more concerning, current references utilized for decision-making purposes are contingent on data derived from population studies. Coskun and Coll. have emphasized the evidence that due to the heterogeneous nature of the population, laboratory data of individuals can be misinterpreted and promoted the adoption of pRIs, personalized decision limits (pDLs) and personalized reference change values (pRCVs) [24, 25]. Therefore, the effective utilization of laboratory results should be based on the longitudinal data analysis considering both analytical and biological variations. Moving from a subjective interpretation of laboratory information by clinicians or users to an objective interpretation based on sound and measurable variables is of paramount importance to provide evidence of the role of laboratory information and of the fundamental role of laboratory professionals in promoting personalized medicine [4]. The adoption of objective, evidence-based interpretation criteria based on analytical uncertainty, personalized reference intervals, personalized decision limits (diagnosis) and individual reference change values (monitoring) should be linked to the implementation of innovative Information Technology (IT) solutions [26]. Improvement and harmonization in the post-analytical phase and laboratory report are therefore needed to promote VBLM [27].

Interaction with clinicians and multidisciplinary initiatives

It has been asserted that the business model underpinning the delivery of laboratory medicine is predominantly characterized by a siloed approach, wherein its design, management and execution are compartmentalized within individual units. All processes and procedures within the silos are managed in accordance with performance metrics that correspond to the discipline, as opposed to the product of the clinical pathway and the contribution of all stakeholders [2, 28]. Breaking down organizational silos and facilitating closer interaction with all stakeholders in the field of modern medicine represent a fundamental step in the implementation of VBLM. Fragmentation in diagnostics, in particular, includes sub-specialties of laboratory medicine, anatomic pathology, radiology and the interaction with physicians. The integration of the data from different subdisciplines of laboratory medicine (e.g., clinical biochemistry, hematology, hemostasis, molecular diagnostics) is an essential step to improve the quality of laboratory information and to provide a unique, coordinate and clear laboratory report that is better suited to improve clinical decision making and patient management [29]. Other important projects to improve the interaction with clinicians to promote patient-centered and personalized medicine are: a) the implementation and revision of clinical diagnostic-therapeutic pathways; b) consensually achieved introduction of innovative tests and deletion of obsolete examinations; and c) multidisciplinary team initiatives. Indeed, the degree of interaction with clinicians is the unique means of measuring and improving clinical outcomes in the complex cycle of patient diagnosis and treatment.

Conclusions

The proposal of a 'value-score for clinical laboratories' constitutes a tentative move towards the practical implementation of VBLM. This paper should be considered as a first conceptualization of the score, which should facilitate a more effective work of the new EFLM Committee to better define the characteristics that can add value to clinical laboratories and allow a benchmark based on effective indicators. The ultimate goal of the value-based score is to enable clinical laboratories to benchmark their performance by measuring and improving clinical outcomes, adding outcome measurement to traditional process measures, including internal quality control and external quality assurance. Clinical laboratories have been at the forefront of introducing process measures (internal quality control, external quality assurance and the model of quality indicators) with a view to enhancing the accuracy and reliability of laboratory results. It is therefore incumbent upon them to now play a key role in promoting value-based laboratory medicine, with a view to ensuring more effective, safe and patient-centered clinical diagnostic and therapeutic pathways.

Research ethics: Not applicable.
Informed consent: Not applicable.
Author contributions: The author has accepted responsibility for the entire content of this manuscript and approved its submission.
Use of Large Language Models, AI and Machine Learning Tools: None declared.
Conflict of interest: The author states no conflict of interest.
Research funding: None declared.
Data availability: Not applicable.

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