



Promoting value-based laboratory medicine: Moving towards an innovative model of clinical laboratory

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ARTICLE INFO

Keywords:

Value-based laboratory medicine
Clinical laboratory
Post-analytical phase
Laboratory report
Longitudinal data
Personalized reference intervals

ABSTRACT

The shift to value-based healthcare, emphasizing quality and clinical outcomes rather than volumes and volume-based payment models presents challenges and opportunities for clinical laboratories. In order to promote value-based laboratory medicine (VBLM), it is imperative to transition from a subjective interpretation of laboratory information by clinicians and/or users to an objective interpretation based on sound and measurable variables. This transition is of the utmost importance to provide evidence of the role of laboratory information and of the fundamental role of laboratory professionals. Therefore, laboratory professionals must promote the adoption of personalized reference intervals (pRIs), personalized decision limits (pDLs) and personalized reference change values (pRCVs), and the remodeling of laboratory information into valuable clinical insights should be achieved through the utilization of longitudinal data. Another essential issue is the role of laboratory medicine in promoting the shift from the prevailing emphasis on “sick care” to that of “well care”, as laboratory data play a crucial role in monitoring the health status of both healthy individuals and patients. Finally, clinical laboratories need to move out of the silo and implement integrated practice units rather than focused factories focused on efficiency metrics such as volume, economies of scale and cost per test.

1. Introduction

There is growing evidence of the paradox between the value of laboratory medicine in modern medicine and its visibility and perception by both clinicians and patients. Laboratory medicine, in fact, touches virtually all aspects of the human condition in a highly effective “patient-centered” way. Until a few decades ago, the role of laboratory tests was simply to confirm the clinical diagnosis and to monitor the progress of the disease and/or treatment response. Now, however, thanks to formidable technological developments, to the identification of innovative biomarkers and the omics revolution, laboratory medicine plays an increasingly dominant role in modern medicine, strongly influencing clinical decision-making. It enables early and timely diagnosis, effective counselling and targeted therapy [1]. As a fundamental component of wellness, preventive care, and treatment for disease, clinical laboratories are involved in the lives of nearly all individuals as they have access to not only individual patient data but that of communities. Consequently, laboratory diagnostics represent a wide-ranging opportunity to facilitate the realization of healthcare innovations for both individuals and populations. In the context of the

current shift in the way medical services are delivered by promoting the change from volume-based to value-based models, clinical laboratories are ideally placed to serve as catalysts for change. This transition is compelling clinical laboratories to re-evaluate their business strategies, as shown in Fig. 1. Under evolving value-based care models, the laboratory will increasingly have to influence the numerator and the denominator of the value equation as defined by Porter and Tiesberg—health outcomes achieved per dollar spent [2]. However, in the last two decades clinical laboratories have focused their efforts on reducing the cost per test and other efficiency indicators to achieve economies of scale by increasing volumes and reducing turnaround time. By focusing on these efforts within the laboratory walls and missing the link to the clinical context, they are currently viewed as a commodity with exclusive regard to internal efficiency indicators, to the exclusion of measuring and improving clinical outcomes [3]. In fact, the perception of the value of laboratory medicine is still limited to the extent that it has been defined a “faceless profession”, often lacking visibility to patients and the public.

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<https://doi.org/10.1016/j.cca.2025.120269>

Received 24 March 2025; Received in revised form 25 March 2025; Accepted 25 March 2025

Available online 27 March 2025

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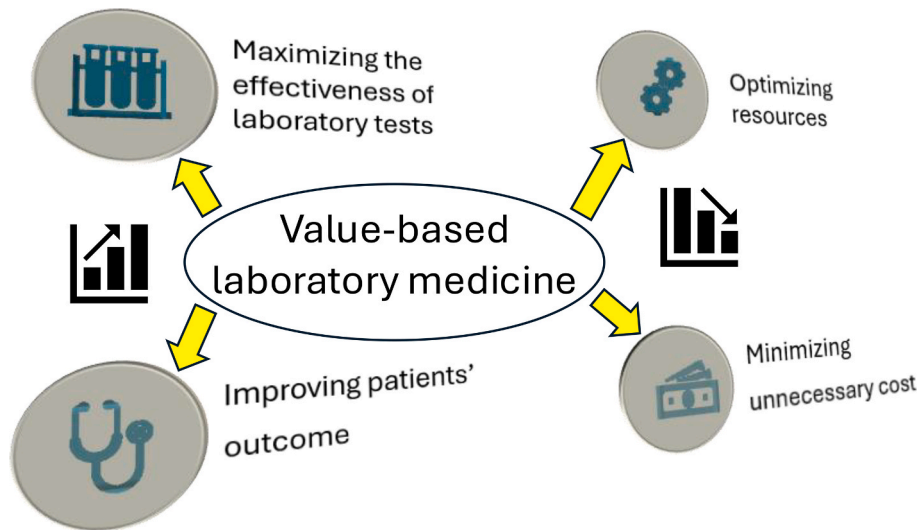


Fig. 1. Value-based laboratory medicine. The primary goal of value-based laboratory medicine is to maximize the effectiveness of laboratory testing by leveraging disruptive technologies and patient-based algorithms to improve patient outcomes, optimize resource utilization, and minimize unnecessary costs.

2. Practicing value-based laboratory medicine

Emerging from a commodity mindset requires the creation of a formidable evidence-base that demonstrates the value impact of laboratory expertise to patient journey and outcomes. In the traditional paradigm of medicine, laboratory services have been defined “a *transactional event*”: a provider orders a test based on her/his clinical impression of a patient’s ailment at a given point in time and interprets the individual test results at the time of receiving the test results” [4]. The value of this activity is thus finite and may be defined only as reducing the cost of services while maintaining similar quality. This is even more evident if one considers the lack of ability of users (both clinicians and patients) to understand differences in the analytical quality of laboratory results, also because data on measurement uncertainty are not communicated in the laboratory reports to users. This is also the reason for the success of point-of-care testing (POCT) because

the simplicity and speed of response are appreciated by users in spite of the lower analytical quality [5]. Therefore, a fundamental step in promoting value-based laboratory medicine (VBLM) is to improve the provision and interpretation of laboratory data in a timely and strait forward manner, which is critical to reducing medical errors and improving patient safety [6]. In fact, current evidence shows that misinterpretation of laboratory information is the second most common cause of medical errors arising for diagnostic tests [7–9]. 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. These parameters, usually defined as “comparators”, aim to make the data “actionable” [10]. In addition to the lack of harmonization in the adoption of the recommended measurement units [11], current references costs.

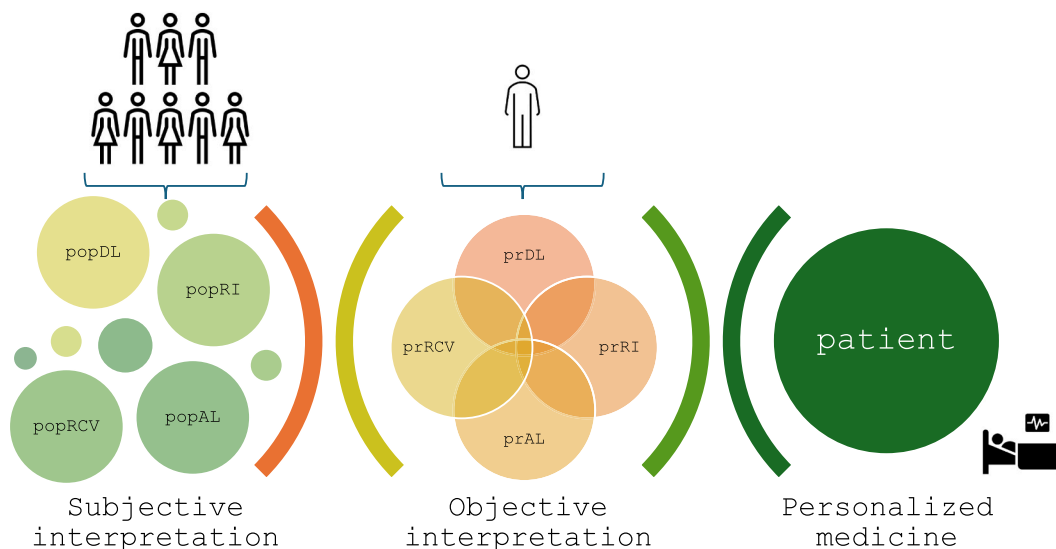


Fig. 2. Transitioning from subjective to objective interpretation of laboratory data is a key step toward personalized laboratory medicine. While patient-based references derived from population data remain inherently subjective due to population heterogeneity, personalized reference values are grounded in an individual’s own data and therefore offer a more objective approach. popRI: population-based reference interval; popDL: Population-based decision limit; popRCV: population-based reference change value, popAL: population-based action limit; prRI: personalized reference interval; prDL: personalized decision limit; prRCV: personalized reference change value, prLA: personalized action limit.

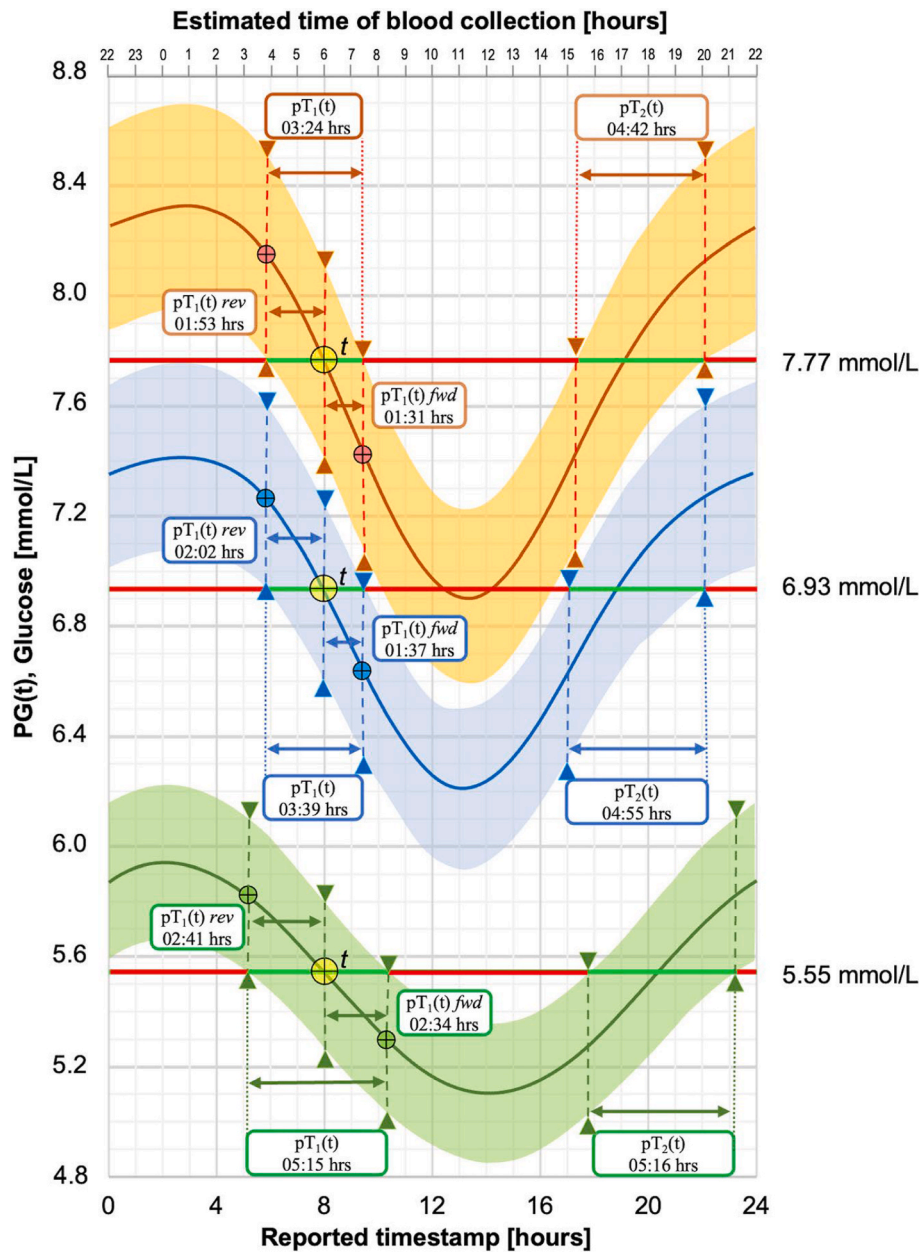


Fig. 3. Diurnal variation in glucose levels observed in patient data. This figure was reprinted with permission from reference 27.

making practice rely on data derived from population studies. We have known for many years that many measurands (biomarkers) are highly individualized and regulated around unique stable values, called homeostatic setpoints (HSP), that vary from person to person. For many people, their 'normal' blood values fall within a narrow range—a range that is much smaller than the population-based reference range [12]. However, this evidence has not translated into information for users capable of improving laboratory reporting and interpretation of results. Recently, Coskun and Coll. developed an algorithm to estimate personalized reference intervals (pRI) based on analytes' HSPs and within-subject biological variations (CV_I) [13,14]. Additionally, Foy and Coll. suggested that integrating pRIs into clinical diagnostics could enhance precision medicine to a new and better level [15]. As underlined by Foy and Coll. "results are usually interpreted relative to one-size-fits-all reference intervals undermining the precision medicine goal to tailor care for patients on the basis of their unique characteristics", while "intra-patient variation in laboratory biomarkers over weeks or months is significantly narrower than standard reference intervals. As

a result, when assessing the deviation between two consecutive test results, diagnostic sensitivity can often be improved by adjusting the threshold deviation that defines a change". 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). [16–18]. In particular, the remodeling of laboratory information into valuable clinical insights should be achieved through the utilization of longitudinal data [19]. For personalized reference data, individual specific information is needed, and this can be obtained using the repeated measurements of the single individuals. For every analyte, each individual exhibits unique fluctuations, known as within-person variation (CV_P), which highlight the inherent biological diversity among individuals. 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, as shown in Fig. 2.

3. From “sick” to “well” care

Another essential issue is the role of laboratory medicine in promoting the shift from the prevailing emphasis on “sick care” to that of “well care”. Laboratory data plays a crucial role in monitoring the health status of both healthy individuals and patients. To effectively utilize laboratory data for this purpose, it is necessary to employ statistical algorithms designed for small sample sizes using individual’s own data should be employed to analyze their longitudinal. These algorithms must account for all types of physiological variations associated with the analyte, as well as variations stemming from the measurement procedure [17,20]. Whereas pathologists’ and radiologists’ data take an accurate picture of the anatomical situation of the organ or organism in the state of disease, clinical laboratory data should be used as a film that follows the dynamics of the development of the clinical situation. It is imperative to transition from a one-dimensional interpretation of a solitary laboratory result to a more comprehensive evaluation of the trend in both wellness maintenance and early disease diagnosis, in order to enhance the value of clinical laboratories. A body of evidence highlights the paramount importance to reduce the increasing total costs in health care and assuring future sustainability of all health care systems. Swanson and Coll. underlined the laboratory role in interventions that would prevent future disease burden and healthcare costs with some examples [17]. The first one is the example of diabetes as the laboratory intervention to proactively identify and track patients with prediabetes to avoid disease progression offers high clinical utility at low costs compared with reactive efforts identifying cases of uncontrolled diabetes with related diabetes-associated complications and comorbidities. A second example is the role of clinical laboratory in identifying acute conditions such as acute kidney injury that, if not appropriately managed and treated, could lead to chronic kidney disease, hemodialysis and renal transplant. In the last few years many biomarkers have been developed and evaluated to assure not only an accurate and early diagnoses, but also valuable prognostication information and guide for tailored therapies. In addition, some of these biomarkers are increasingly used as additional diagnostic tools for screening and preventive interventions. For example, the role of cardiac-specific biomarkers in assessing cardiovascular risk has garnered significant attention in recent years, not only among patients with cardiovascular diseases but also in the general population. The suggestion to measure cardiac natriuretic peptides –NPs- (atrial and B-type NPs and related cardiac NPs) along with high-sensitivity cardiac troponin I/T (hs-cTnI and hs-cTnT) reflects a shift toward a more nuanced understanding of cardiovascular risk assessment [21–23]. Recent advances in modelling and analytic techniques, including omics, have expanded our toolbox to explore various aspects of early cancer with ever-increasing spatiotemporal resolution, now enabling clinical laboratories to map the milestone biological events and molecular interactions guiding the journey from a single mutated cell to a precancerous state and ultimately to malignant tumors. [24]. As highlighted by Crawford and Coll., the implementation of a new paradigm that moves beyond the provision of transactional test results to promote population care and “well care” by implementing biomarkers that identify risk factors and may allow preventive strategies plays a key role in achieving value-based laboratory medicine [25].

4. Integrating Chronobiology into laboratory medicine

Patient samples can be collected at any time of the day, and medical laboratories continuously analyze these samples and generate data. However, the reference values used to interpret laboratory results, particularly RIs, are traditionally derived from samples collected from reference individuals in the morning. It is well established that nearly all

biomolecules exhibit at least one type of chronobiological variation, including rhythmic variations such as ultradian (within-day), circadian (daily), infradian (monthly or seasonal), and non-rhythmic lifelong variations [17,20]. Despite this, RIs suitable for time periods other than the morning—such as the afternoon, evening, and night—are not available for all biomolecules used in clinical practice. Chronobiological variations, whether rhythmic or non-rhythmic, represent systematic physiological fluctuations that can be predicted in healthy individuals, as shown in Fig. 3 [26]. Implementing continuous population-based or personalized RIs adjusted for chronobiological variation has the potential to improve the accuracy of laboratory data interpretation and reduce medical errors associated with laboratory testing.

5. Clinical pathways and multidisciplinary teams

It was already highlighted that integration of laboratory tests to care pathways is still a major challenge in laboratory testing as inappropriate requests, incorrect interpretation of results and the vision of tests as commodities are compromising the efficacy of the discipline in improving the patient’s journey and clinical outcome [27]. However, given its impact on multiple phases of the care pathway and its potential as a quality measure for the services offered, laboratory medicine can be a strategic lever when designing value-based care pathways. Recently published studies emphasized that it is possible to redesign care pathways in a way that maximizes value for the patient while generating positive spillovers for the entire healthcare ecosystem. For example, the appropriate measurement of natriuretic peptides has been found to allow for timely interventions that lower the risk of acute episodes, the prevention of acute heart failure and, consequently, the lower number of hospitalizations benefit healthcare organizations in terms of lighter workload and economic burden. Simultaneously, the designed pathway would facilitate healthcare professionals in navigating the system and make them feel more confident in making decisions to ultimately improve clinical outcomes and patient satisfaction [28]. Similar improvements have been reported through the appropriate adoption of laboratory biomarkers and diagnostic tests for the diagnosis and management of dilated cardiomyopathy, emphasizing the need for the implementation of multidisciplinary teams and coordinated efforts between different diagnostic specialties [29]. In oncology, disruptive imaging and innovative laboratory technologies can improve clinical decision processes and outcomes, but an integrative diagnostic approach represents a unique opportunity to unleash the full diagnostic potential and paves the way towards personalized cancer diagnostics [30].

6. Integrated diagnostics

It was highlighted that health care currently is fragmented and siloed, often involving multiple providers at multiple facilities who may even be in different networks and often do not share information with one another [31]. Fragmentation in diagnostics involves subspecialties of laboratory medicine, anatomic pathology, radiology and interaction with physicians, so we need to move out of the silo to implement integrated practice units rather than focused factories concentrating on narrow groups of interventions. Therefore, integrated diagnostics can be considered one of the greatest opportunities for future healthcare, since it would permit to deliver more patient-centric care, obtain better outcomes and ultimately decrease cost over time. The chance to merge different diagnostic modalities within a single medical record will also boost the development of population-level databases, containing aggregated information on million of patients, and thus enabling to achieve a more holistic picture of many human diseases and developing more effective treatment. As highlighted by Beuchamp and Coll “because diagnostic test data are gathered and processed within the “silo” of each diagnostic discipline, they are fragmented, and the electronic health record does little to synthesize new and existing data into usable information. Therefore, despite great promise, diagnoses may

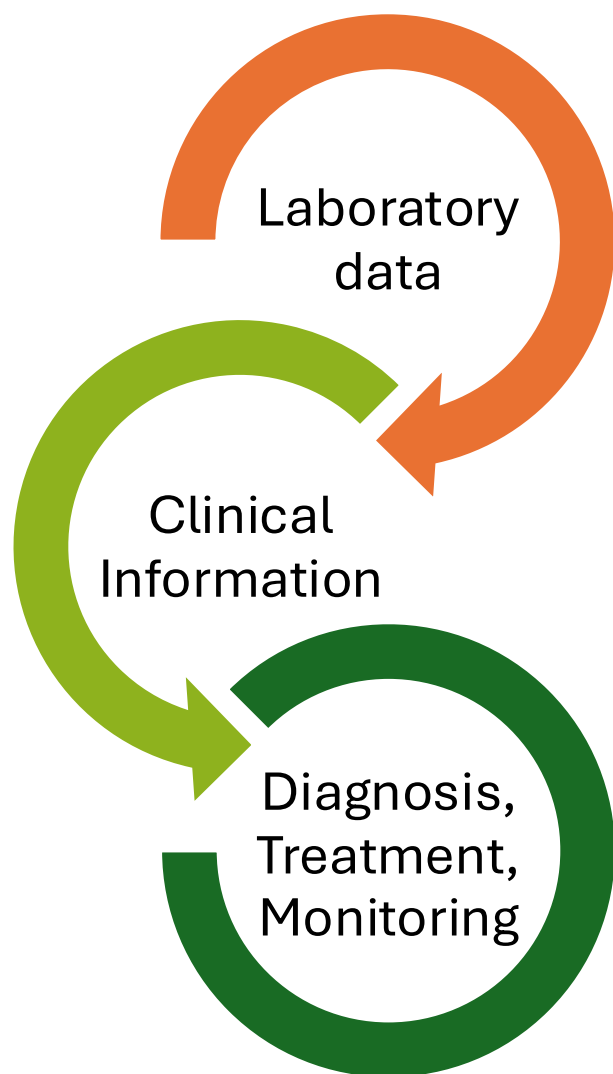


Fig. 4. The transformation of laboratory data into clinical information is essential for accurate diagnosis, monitoring, and treatment decisions.

still be incorrect, delayed, or never made” [31]. In the same paper, the authors provided examples of organizations in which radiologists, pathologists, and other diagnosticians work as teams with shared access to continuously updated patient data, from which experts and clinical decision support (CDS) tools extract relevant clinical information and formulate dynamic differential diagnosis and management pathways. Changes require time and leadership but the process has already started and must be sustained. Additional efforts shall hence be made to foster the collaboration among different diagnostic disciplines, overcoming cultural, political and technical boundaries, for developing the diagnostic discipline of the future [32]. Although it seems unavoidable that this process shall be further catalyzed and supported, there are some important obstacles that should be overcome, but there are also some possible solutions that can be identified. The information technology (IT) infrastructure can perhaps be seen as one of the biggest drawbacks in integrated diagnostics. The current laboratory, radiology, pathology and even hospital information systems have been constructed and developed independently, so that their connectivity is poor and functional integration is challenging, time-consuming and expensive. Therefore, a fundamental step to promote integrated diagnostics is to develop new integrated information systems. Recently reported examples, particularly in some regional settings, well document that the integration is feasible and should allow not only the “traditional”

integrated diagnostics but also integration of information by decentralized testing settings [33].

7. Conclusions

As healthcare systems are redesigning service delivery systems in medicine and promoting a shift from value-based to volume-based payment models, clinical laboratories are ideally placed to serve as catalysts for these changes [25]. A 10-point manifesto was recently proposed to promote the transition to value-based laboratory medicine (VBLM) [6] and other articles have been published to support efforts to apply the principles of VBLM in practice [34–36]. In this paper, further important considerations are reported to change the current model of delivery laboratory services and in particular to promote a better interpretation of laboratory data based, particularly for longitudinal data, on objective criteria. This should change the interactions between laboratory professionals and clinicians/users to allow the provision of a more actionable information [37], as shown in Fig. 4. This in turn should ultimately assure better clinical outcomes, a more efficient use of economic resources and the transition from “sick care” to “well care”. As a matter of fact, the promotion of “well care” and personalized medicine has to be based not on clinical symptoms and signs but to laboratory data which may identify risk factors and pre-clinical conditions. Therefore, the take home message is “Value-based laboratory medicine: the time is now” [38].

CRediT authorship contribution statement

Mario Plebani: Writing – review & editing, Writing – original draft, Validation, Methodology, Investigation, Data curation, Conceptualization. **Abdurrahman Coskun:** Validation, Data curation, Conceptualization.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

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