A vision to the future: value-based laboratory medicine

Plebani, M.; Cadamuro, J.; Vermeersch, P.; Jovicic, S.; Ozben, T.; Trenti, T.; ... ; Lippi, G.

Opinion Paper

Mario Plebani*, Janne Cadamuro, Pieter Vermeersch, Snežana Jovičić, Tomris Ozben, Tommaso Trenti, Brian McMillan, Christopher R. Lowe, Jochen Lennerz, Elizabeth Macintyre, Carlo Gabelli, Sverre Sandberg, Andrea Padoan, Joesph R. Wiencek, Giuseppe Banfi, Ira M. Lubin, Matthias Orth, Anna Carobene, Tomáš Zima, Christa M. Cobbaert, Ron H.N. van Schaik and Giuseppe Lippi

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Abstract: The ultimate goal of value-based laboratory medicine is maximizing the effectiveness of laboratory tests in improving patient outcomes, optimizing resources and minimizing unnecessary costs. This approach abandons the oversimplified notion of test volume and cost, in favor of emphasizing the clinical utility and quality of diagnostic tests in the clinical decision-making. Several key elements characterize value-based laboratory medicine, which can be summarized in some basic concepts, such as organization of *in vitro* diagnostics (including appropriateness, integrated diagnostics, networking, remote patient monitoring, disruptive innovations), translation of laboratory data into clinical information and measurable outcomes, sustainability, reimbursement, ethics (e.g., patient empowerment and safety, data protection, analysis of big data, scientific publishing). Education and training are also crucial, along with considerations for the future of the profession, which will be largely influenced by advances in automation, information technology, artificial intelligence, and regulations concerning *in vitro* diagnostics. This collective opinion paper, composed of summaries from presentations given at the two-day European Federation of Laboratory Medicine (EFLM) Strategic Conference "A vision to the future: value-based laboratory medicine" (Padova, Italy; September 23–24, 2024), aims to

***Corresponding author: Prof. Mario Plebani**, Honorary Professor, Clinical Biochemistry and Clinical Molecular Biology, University of Padova, Padova, Italy; Adjunct Professor, Department of Pathology, University of Texas, Medical Branch, Galveston, TX, USA; and Department of Laboratory Medicine, University of Padova, Padova, Italy,
E-mail: mario.plebani@unipd.it
Janne Cadamuro, Department of Laboratory Medicine, Paracelsus Medical University, Salzburg, Austria
Pieter Vermeersch, Clinical Department of Laboratory Medicine, UZ Leuven, Leuven, Belgium
Snežana Jovičić, Department of Medical Biochemistry, Faculty of Pharmacy, University of Belgrade, Belgrade, Serbia
Tomris Ozben, Medical Faculty, Department of Medical Biochemistry, Akdeniz University, Antalya, Türkiye; and Medical Faculty, Clinical and Experimental Medicine, University of Modena and Reggio Emilia, Modena, Italy
Tommaso Trenti, Bianalisi Group Monza, Roma, Italy
Brian McMillan, Centre of Primary Care and Health Services Research, University of Manchester, Manchester, UK
Christopher R. Lowe, Trinity College, University of Cambridge, Cambridge, UK
Jochen Lennerz, BostonGene, Waltham, MA, USA
Elizabeth Macintyre, Onco-Hematology Laboratory, Necker Hospital and Université Paris Cité, Paris, France
Carlo Gabelli, Research Centre for Brain Aging (CRIC), University Hospital of Padua, Padova, Italy
Sverre Sandberg, Noklus, Haraldsplass Deaconess Hospital, Bergen, Norway
Andrea Padoan, Department of Medicine, University of Padova, Padova, Italy; and Laboratory Medicine Unit, University-Hospital of Padova, Padova, Italy
Joesph R. Wiencek, Department of Pathology, Microbiology, and Immunology, Vanderbilt School of Medicine, Nashville, TN, USA
Giuseppe Banfi, IRCCS Galeazzi Sant'Ambrogio, Milan, Italy; and University Vita e Salute San Raffaele, Milan, Italy
Ira M. Lubin, Division of Laboratory Systems, Center for Laboratory Systems and Response, Centers for Disease Control and Prevention, Atlanta, GA, USA
Matthias Orth, Medical Faculty of Mannheim, Vinzenz von Paul Kliniken gGmbH, Stuttgart, Germany; and Heidelberg University, Heidelberg, Germany
Anna Carobene, Laboratory Medicine, IRCCS San Raffaele Scientific Institute, Milan, Italy
Tomáš Zima, Institute of Medical Biochemistry and Laboratory Diagnostics, 1st Faculty of Medicine, Charles University and General University Hospital, Prague, Czech Republic
Christa M. Cobbaert, Department of Clinical Chemistry and Laboratory Medicine, Leiden University Medical Center, Leiden, The Netherlands; and EFLM Committee on European Regulatory Affairs and EFLM Liaison to BioMed Alliance in Europe, Brussels, Belgium
Ron H.N. van Schaik, Department of Clinical Chemistry, Erasmus MC University Medical Center, Rotterdam, The Netherlands
Giuseppe Lippi, Section of Clinical Biochemistry, University of Verona, Verona, Italy. https://orcid.org/0000-0001-9523-9054

provide a comprehensive overview of value-based laboratory medicine, projecting the profession into a more clinically effective and sustainable future.

Keywords: laboratory medicine; technology; home testing; value

The value of laboratory information: navigating between quality and errors

The concepts of value-based medicine and value-based laboratory medicine are not new, but the coronavirus disease 2019 (COVID-19) pandemic has highlighted the need to change clinical practice, including clinical laboratory activities, to improve the overall quality, safety and sustainability of healthcare and clinical laboratories. Efforts to reduce costs, economies of scale and maximize revenue led to the trap described by Porter: "The more you focus on reducing costs, the more costs have gone up", as better health is inherently less expensive than poor health.

In recent decades, clinical laboratories have faced the same difficulties as they adopted management approaches that allowed consolidation, merger and downsizing, to achieve economies of scale and reduce cost per test while increasing productivity [1]. However, laboratory medicine is well positioned to support the transition to value-based healthcare as it helps improve clinical outcomes and healthcare sustainability by reducing time to diagnosis, increasing diagnostic accuracy, providing effective guidance on tailored therapies and monitoring, and supporting screening and wellness. An article published in 2007 proposed four seminal principles for implementation of value-based laboratory medicine, namely that, (i) the goal should be the value for patients and public health; (ii) laboratory services must be based on medical conditions and cycles of care; (iii) clinical and economic outcomes must be measured; and (iv) competition between different laboratories must be based on the best possible quality and benefit for patient care [2]. If it is true that the performance of a laboratory can be judged by the indices of its products, there is no doubt that the worst result of a laboratory test is an incorrect result/information, which can lead to diagnostic errors and jeopardize patient safety. Therefore, laboratory processes and procedures should primarily aim to avoid any risk of vulnerability throughout the total testing process, especially errors with higher risk for patient health [3].

This collective opinion paper, composed of summaries from presentations given at the 2-day European Federation of Laboratory Medicine (EFLM) Strategic Conference "A vision to the future: value-based laboratory medicine" (Padova, Italy; September 23–24, 2024) (Table 1), aims to provide a comprehensive overview of value-based laboratory medicine, projecting the profession into a more clinically effective and sustainable future.

Demand management for appropriate test requesting and clinical laboratory stewardship

The correct processing of laboratory requests is crucial for improving patient care. Clinical Laboratory Stewardship (CLS) and Demand Management (DM) are possible approaches to achieve these goals. Key strategies include educational initiatives, removal of certain tests from laboratory ordering profiles (LOP), gatekeeping, automated notifications from computerized physician order entry (CPOE) systems, and several others. These strategies are useful when it comes to reducing overuse. However, when targeting the underuse with the right tests for the individual patient, laboratory diagnostic pathways need to be applied, which are the closest to CLS of all approaches.

A key element in understanding overuse is the relationship between availability and demand, as Mrazek et al. demonstrated using examples from some European laboratories [4]. The ease with which laboratory tests can be ordered, combined with the lack of clinical information at the time of ordering and the subsequent inability of the laboratory to assess the need for these tests for the patient, has triggered an increased demand in most hospitals.

Sometimes very simple procedures can lead to astonishing results, as described in the study by Keppel et al. [5]. The authors collaborated with the cardiology department and identified several LOPs that included high-sensitivity (hs)-cardiac troponin T and N-terminal pro b-type natriuretic peptide (NT-proBNP). After removing these parameters from all LOPs, orders for hs-cardiac troponin T and NT-proBNP dropped by 66.1 ± 7.6 % and 75.8 ± 8.0 %, respectively, with no negative impact on the 30-day readmission rate or length of stay.

In all of these efforts to improve the use of laboratory testing, close collaboration with the clinicians involved is essential. In addition, recommendations or automated implementation of test profiles or laboratory diagnostic pathways must be based on current evidence. Ibarz et al. conducted a survey of laboratory specialists and clinicians from nine European countries to obtain information on clinicians' attitudes towards supporting laboratory specialists

Table 1: Program of the European Federation of Laboratory Medicine (EFLM) strategic conference – a vision to the future: value-based laboratory medicine, Padova (Italy), 23–24 September 2024.

First session: creating value for users	
8.45	Opening remarks, M. Plebani (Padova, Italy)
9.00–9.30	The value of laboratory information: navigating between quality and errors. M. Plebani (Padova, Italy)
9.30–9.50	Demand management for appropriate test requesting and clinical laboratory stewardship. J. Cadamuro (Salzburg, Austria)
9.50–10.10	Transforming laboratory data into clinical information. P. Vermeersch (Leuven, Belgium)
10.10–10.30	Process and outcomes measurement. S. Jovicic (Belgrade, Serbia)
11.00–11.20	Sustainable laboratory medicine (Green and smart clinical laboratories). T. Ozben (Antalya, Turkiye)
11.20–11.40	Development of new reimbursement models. T. Trenti (Modena, Italy)
11.40–12.00	Patient empowerment. B. McMillan (Manchester, UK)
Second session: changing the organization	
14.00–14.30	Integration – overcoming silos in health care. C. Lowe (Cambridge, UK)
14.30–14.50	Integrated diagnostics. J. Lennerz (Boston, USA)
14.50–15.10	Integrated diagnostics in hematological cancers. E. Macintyre (Paris, France)
15.10–15.30	Networking, decentralized laboratory testing and point-of-care. S. Sandberg (Bergen, Norway)
16.00–16.20	Home testing, wearables and remote patient monitoring. G. Lippi (Verona, Italy)
16.20–16.40	Clinical diagnostic and therapeutic pathways. C. Gabelli (Padova, Italy)
16.40–17.00	Information technology, digitalization and health electronic record. A. Padoan (Padova, Italy)
Third session: ethical aspects in laboratory medicine	
9.00–9.20	Ethical challenges in laboratory medicine (covering big data). G. Banfi (Milan, Italy)
9.20–9.40	Ethics in scientific research and publication. J. Wiencek (Vanderbilt, USA)
9.40–10.00	Challenges to the brain-to-brain loop. I. Lubin (Atlanta, USA)
10.00–10.20	Direct-to-consumer laboratory testing. M. Orth (Stuttgart, Germany)
10.20–10.40	The role and ethical aspects of artificial intelligence in value-based laboratory medicine. A. Carobene (Milan, Italy)
10.40–11.00	Disruptive innovations: between fakes and value for users. T. Hankemeier (Leiden, The Netherlands)
Fourth session: the future of laboratory professionals	
13.30–13.50	Changing education and training of laboratory medicine professionals. T. Zima (Prague, Czech Republic)
13.50–14.10	The new *in vitro* diagnostic regulation (IVDR). C. Cobbaert (Leiden, The Netherlands)
Fourth session: the future of laboratory professionals	
14.10–14.30	Forecast of the diagnostic market. J. Rueda Rodríguez (Brussels, Belgium)
14.30–14.50	Biomarkers and personalized medicine. R. van Schaik (Rotterdam, The Netherlands)
14.50–15.20	Future duties and responsibility of laboratory professionals: the role of EFLM in sustaining value-based laboratory medicine. M. Plebani (Padova, Italy)

in test selection and interpretation [6]. They found that 85.6 % of respondents felt that measures to ensure appropriate use of tests were necessary, and that 100 % of respondents were interested in advice/information on their indication.

In summary, demand management and stewardship in the clinical laboratory are essential for optimizing test use, improving patient care and reducing healthcare costs. In addition, developing tailored strategies for local setting in collaboration with clinicians will bring laboratories closer to the patient, demonstrate the added value of laboratory specialists' expertise, and thus counteract attempts to outsource laboratory services.

Transforming laboratory data into clinical information

In the era of precision medicine and personalized therapy, high-quality healthcare requires the integration of all the available clinical data. Laboratory medicine as a medical specialty is the largest producer of structured data and plays an essential role in healthcare. Although laboratory testing accounts for less than 5 % of the healthcare budget in the United States and Europe, laboratory results influence up to 50 % of clinical decisions.

Clinical data can be unstructured (e.g. physician notes) and structured (e.g. laboratory database). As laboratory professionals, we need to ensure that laboratory data is understandable and well structured. The data contained in the laboratory report must be clear and easy to understand, not only for healthcare providers, but also for the final recipient, i.e., the patient. Misinterpretation of diagnostic test results is one of the main causes of diagnostic errors. The structure of laboratory data must also correspond to well-defined fields in relational databases that enable fast electronic searches and efficient data management. In addition, the structure should allow access by healthcare

professionals and patients from outside the healthcare facility, and allow data sharing for diagnostic, epidemiological and research purposes.

Structured data is also a promising means of enhancing the ability of clinical decision support (CDS) systems to improve patient safety, quality of care and patient outcome. A major problem with current CDS systems, which typically rely on a limited volume of structured data such as age, gender and ward, is the large number of inadequate and clinically inconsistent alerts, which reduce their effectiveness due to alert fatigue and distraction. Incorporating clinical information into CDS systems is essential to translate laboratory data into clinically relevant information, could significantly reduce the number of inconsistent alerts and improve the quality of rules and algorithms.

One of the challenges for the coming years is the comprehensive standardized coding of laboratory results, to enable electronic data exchange both nationally and internationally. The transmission of test results between countries for routine patient care using different national databases and different languages, as envisaged by the European Health Data Space, poses a particular challenge. While there are coding standards for the exchange of analytical test results (e.g. Logical Observation Identifiers Names and Codes [LOINC]), this does not apply to non-conformities (e.g. hemolysis and other sources of errors) and comments (e.g. suspected interference) and their impact on laboratory test results. Without comprehensive standardized coding, essential information could be lost in translation.

Process and outcomes measurement

Although quality in laboratory medicine has so far only been considered in an analytical context and in terms of efficiency, the vulnerability of the extra-analytical phases and the lack of attention to the patient have been clearly demonstrated. Therefore, starting from the classical or so-called “internal” indicators of analytical quality, considerable efforts should be made to expand this area to include indicators of total quality, clinical effectiveness and patient outcomes [7]. Therefore, quality in laboratory medicine may be considered as bi-dimensional. The “internal dimension”, which relates to the laboratory environment, ensures efficiency and implies accuracy and reliability of analytical results and their timely release and communication. The “external dimension” includes diagnostic accuracy, value in test-treatment pathways, impact on clinical and economic outcomes and, most importantly, patient safety. The latter dimension combined with timely and appropriate intervention based on a laboratory result provides valuable outcomes for the patient.

To provide an optimal laboratory service that improves patient care, the quality of laboratory processes should encompass the pre-analytical and post-analytical phases. By identifying reliable quality indicators for monitoring all steps of the testing process, especially the extra-analytical phases, and by establishing appropriate performance specifications, laboratory performance can be effectively improved and the error rate reduced. At the same time, the assessment of the quality of laboratory services must be more patient-centered. Therefore, process and outcome quality indicators are effective tools to measure and improve laboratory services by stimulating a competition based on intra- and extra-analytical performance specifications, intermediate outcomes and customer satisfaction [8]. Their implementation will promote value-based laboratory medicine, ensuring more effective, safer and patient-centered clinical diagnostic and therapeutic strategies [3].

Sustainable laboratory medicine (green and smart clinical laboratories)

Laboratory medicine should contribute to a sustainable healthcare system that ensures efficient use of resources from environmental, social and economic perspectives, while providing high-quality services to patients and physicians. Achieving sustainable operations will be a challenge for clinical laboratories, which consume more energy and water than offices, and generate large amounts of hazardous and non-hazardous waste each year. Clinical laboratories can limit their impact on the environment and provide sustainable laboratory services by reducing energy and water consumption, waste production and use of hazardous chemicals in four key areas [9]. By setting sustainable development goals and applying various measures to reduce these key areas, the environmental impact could be substantially attenuated. By considering the environmental impact of everyday actions in a laboratory, and taking steps to minimize the use of energy, water, hazardous chemicals and waste, a clinical laboratory can be transformed into a safer and more sustainable environment. Thus, sustainability measures should be key features in the rapidly changing healthcare environment to reduce the negative impact on environment and economy [10]. The laboratory medicine community should lead the transition to carbon

neutrality by reducing its harmful impact on the environment and implementing effective approaches to combat the effects of climate change and pollution, without compromising the quality of healthcare. In order to provide high-quality, effective and safe healthcare services, sustainable healthcare systems need to overcome major economic and social challenges. Despite the initial capital costs, there is potential for long-term cost savings through more efficient use of energy and other resources in healthcare systems. Nevertheless, there is still a long way to go before environmentally friendly hospitals, healthcare structures and clinical laboratories become the norm. Good collaboration between healthcare systems and a shared vision for future action would help to achieve such goals [11].

Development of new reimbursement models

Reimbursement models have a considerable influence on the behavior of players and providers in the healthcare system and thus also on the quality of care. The most common reimbursement methods in healthcare, including diagnostic laboratory services, are the fee-for-service model, reference pricing and diagnosis-related groups. To promote patient outcomes and overall value of care, and not just the number of tests performed, healthcare payers are exploring new methods such as bundled payments or value-based reimbursement. These models are designed to promote cost-effective, high-quality laboratory testing to improve patient health outcomes. Value-based healthcare, for example, focuses on optimizing outcomes and costs, while value-based payment models encourage reimbursement based on the value of care provided rather than the volume of services rendered. This view can be a strategic theme for laboratory medicine to emphasize its central role [3, 12].

It is essential to develop an agenda to promote value-based healthcare and value-based reimbursement in laboratory medicine in an integrated framework [13]. The first step is based on the principles of evidence-based laboratory medicine to define health outcomes. Theoretically, this process should be adopted by national or international healthcare institutions that are able to manage and ensure resource allocation, involving all stakeholders such as interest groups, patients and experts. The spread of value-based approaches is accelerating worldwide with the adoption of interoperable information technology systems that support value-based assessment of healthcare services. The second step is to support the link between the diagnostic accuracy of tests and key outcomes in downstream patient management. The dynamic integration of available data can enable ever-increasing expertise and identify the most effective services linked to the right economic value.

The final step consists of the traditionally assessed areas, considering the total cost of production testing, but based on analytical performance specifications and quality indicators to ensure the entire diagnostic process, as proposed by EFLM and International Federation of Clinical Chemistry and Laboratory medicine (IFCC). This is in line with the European Commission's (EC) report, in which value-based healthcare is organized into four value pillars: care to achieve patients' personal goals, achieving the best possible outcomes, distributing resources across all patient groups and collective value.

Patient empowerment in the context of laboratory testing

Historically, blood test results have been viewed by clinicians, with patients often receiving only a brief summary (if any). However, since November 1, 2023, General Practices (GPs) in England have been contractually obliged to provide all adult patients with prospective access to their primary care electronic health record (EHR) via online services such as the National Health Service (NHS) 'App' [14]. This includes access to test results for investigations requested in primary care, and some hospital results.

We describe here a program of work aimed at: (i) ascertaining patients, carers, and primary care staff views and experiences of patients being able to access their blood test results online, (ii) identifying benefits and drawbacks of online access to results, and (iii) developing improvements to clinical practice that will enhance patients' experiences of accessing their test results and mitigate potential drawbacks for staff. Following extensive patient and public involvement and engagement work, across four separate studies, we conducted interviews and focus groups with 53 patients and carers, and 43 members of primary care staff in England. We also conducted a survey of 400 GPs working in England [15]. The results are as follows.

Enabling online access to blood test results has both advantages and disadvantages. Advantages include convenience, patient empowerment, and potential reductions in some types of GP workload (fewer patients calling to request their results). Disadvantages include causing patients distress or confusion, widening health inequalities, and increases of other forms of GP workload (more patients calling to discuss their results). The solutions basically included changes to software systems (e.g., facilitating clinician

comments, or improved presentation of results to patients), training for clinicians, and building algorithms that enable patients to interact with test results in a more meaningful way.

In conclusion, enabling online access to test results presents both opportunities and challenges. Whilst patients generally prefer being able to see their results online, they are conflicted about whether this should be before or after a clinician review. Primary care staff are generally supportive of patients being able to access their results online and see the potential to reduce workload, but are also concerned that the opposite may occur, especially if systems are not in place to ensure that patients can adequately understand the implications of their results [16]. Algorithms that enable patients to interact with their blood test results (e.g., to explore how they might reduce their risk of developing certain conditions though behavior changes) have the potential to improve public health.

Integration – overcoming silos in health care

The term “silo” is used to describe both physical and non-physical boundaries created by divisional knowledge, personnel or data units within a healthcare system. Silo mentality refers to individual or group lexicon or beliefs that may create barriers to communication and the emergence of disjointed work processes. There are drivers and technologies contributing to the changing world of preventative, diagnostic, curative and digital healthcare, which are building new barriers to healthcare provision. Suggestions can be made as to why understanding these silos is important, what are their consequences and how their potentially detrimental effects on patient safety might be mitigated.

Integrated diagnostics

Integrated diagnostics synergizes imaging, pathology, laboratory tests, pharmacy, revenue cycle management, and advanced information technology (IT) to enhance disease diagnosis and patient care [17, 18]. We outline a workflow, which has proven effective for hundreds of patients, and provide a practical blueprint for health care professionals [18, 19].

We propose here a strategy for implementing integrated diagnostics consisting of three components: (i) disease-specific care pathways with standardized diagnostic criteria, (ii) functional administrative alignment to integrate these workups into the broader health care ecosystem, and (iii) leveraging multidisciplinary artificial intelligence (AI) and regulatory sciences for rapid therapy initiation. The workflow has been implemented at Massachusetts General Hospital in 2020. Performance assessment included 222 cancer patients, involving 30 process steps across interventional radiology, surgical pathology, molecular diagnostics, specialty pharmacy, and revenue cycle management.

Implementing a coherent care pathway through administrative alignment significantly shortened the time from diagnosis to therapy initiation, reducing the mean time from 12.6 to 2.7 days ($p<0.001$) [17]. Notably, we demonstrate non-inferiority of reimbursement and several payor incentive programs.

Integrated diagnostics represents a cohesive approach to disease-specific diagnostic pathways, improving patient outcomes and operational efficiency. Key recommendations for transitioning to an integrated diagnostics practice include selecting high-impact conditions, fostering interdisciplinary collaboration, and maintaining a commitment to patient care. This administrative alignment enhances care coordination, reduces costs, and optimizes service delivery. Future directions include integrating real-world data into payor negotiations for further optimization in multisite healthcare networks.

Integrated diagnostics in hematological cancers

Hematology has always been a mixed diagnostic/therapeutic specialty, in which trainee hematologists learn to both diagnose and treat patients with benign and malignant blood disorders. The increasing diagnostic and therapeutic complexity have led to a progressive specialization within hematology, both at the professional level and at the level of disease subtypes. Different European countries have implemented this specialization in different ways.

In short, the subtyping of diseases has led to an increasing separation of malignant hematology from non-malignant hematology, with a further subdivision of the latter into hemostasis/thrombosis and red blood cell disorders. On a technical level, the addition of immunophenotypic and various molecular analyses to morphological (cell or tissue) assessment has revolutionized cancer diagnosis and classification, with a tendency towards multidisciplinary diagnostics shared between pathology, genetics, hematology and immunology. Similar considerations apply to non-malignant hematology, which will not be addressed here.

The hematology community in most European countries defends the maintenance of training in both diagnosis and therapy, with increasing acceptance of variable, progressive differentiation/specialization. These considerations have a profound impact on European harmonization, which in turn affects intra-European mobility. The current variability in Member States needs to be assessed in order to identify constructive initiatives and avoid specific difficulties. The diagnosis of hematologic malignancies requires both medical and scientific expertise that goes beyond MD/PhD training. Shared training and concerted professional practice between pathology, genetics and laboratory medicine are required for optimal patient care and resource utilization. As diagnostics become increasingly costly, it is important to develop appropriate health technology assessment (HTA), which traditionally evaluates therapeutic rather than diagnostic interventions. Diagnostic specialties need to identify optimal training pathways and advocate for their implementation and appropriate reimbursement with equal access across Europe.

Home testing, wearables and remote patient monitoring

Home testing, wearables and remote patient monitoring are now an integral part of modern healthcare, revolutionizing the way people manage their health and interact with the healthcare system [20]. Home testing is essentially the concept of allowing patients to perform a wide range of laboratory tests at home, ideally without direct supervision by healthcare providers. Most tests developed so far are used to monitor diseases such as diabetes, cardiovascular pathologies and infectious diseases. Thanks to recent technological advances, home tests are now accurate, convenient, accessible and sustainable, allowing patients to plan proactive measures to better manage their health [20].

Although home testing in most cases takes the form of wearable devices such as smartwatches or fitness trackers equipped with sensors to measure various health metrics in real time, home testing for specific laboratory analysis is essentially performed using specialized instruments, an increasing proportion of which are now available as wearable devices that incorporate electrochemical and optical biosensing approaches. For example, wearable devices based on biosensing can continuously monitor specific biomarkers in body fluids such as interstitial fluid, sweat or even blood [21]. The most common example is the measurement of blood glucose levels in diabetics, which allows real-time monitoring of blood glucose and provides immediate feedback and alerts for insulin dose management and dietary choices. Other analytes that could be measured relatively frequently are creatinine for monitoring chronic kidney damage and pulse oximetry for monitoring respiratory function, but many others are also being developed and clinically validated, such as hemoglobin, bilirubin, international normalized ratio (INR), thyroid stimulating hormone (TSH), cardiac troponin, procalcitonin, etc. [21].

Wearable/portable devices could either perform the analysis directly or the patient could collect personal samples used for testing on another device. These devices would thus enable remote monitoring of patients, which is essentially understood as the use of technology to monitor health status outside of traditional healthcare settings such as hospitals and clinics. It would enable continuous monitoring of some laboratory parameters remotely, allowing healthcare providers to monitor the patient's condition and plan specific interventions when needed. Remote patient monitoring has proven to be particularly useful in chronic disease management, post-operative recovery and elderly care, as it improves patient outcomes and may even reduce healthcare costs. Overall, these technologies would enable greater individual empowerment and better health monitoring by facilitating and accelerating detection and management of health deterioration, allowing healthcare professionals to provide more personalized and proactive care. Importantly, wearable devices for monitoring laboratory tests can be integrated with laboratory information systems (LIS), allowing seamless data sharing and even integration with electronic health records. However, all that glitters is not gold, as there are also some critical aspects to consider before thoughtfully relying on this technology, spanning throughout the total testing process, and thus including preanalytical, analytical and postanalytical issues [22].

Clinical diagnostic and therapeutic pathways

Neurocognitive disorders affect 57 million people worldwide. Ten million new cases are diagnosed every year and the number of people living with dementia is expected to rise to 139 million by 2050. Alzheimer's disease (AD) is the leading cause of neurocognitive disorders, and the advent of disease-modifying drugs requires a reconceptualization of AD as a clinical and biological construct. From clinical, symptom-focused diagnosis and management, we need to shift to the next-generation pathways that include biomarker-driven and digitally-assisted decision-making algorithms for risk stratification, early detection, timely diagnosis and therapeutic

intervention. The state of the art in the use of liquid biomarkers in various fields is summarized below.

After a slow beginning, the use of cerebrospinal fluid (CSF) biomarkers is now an established diagnostic criterion within the so-called "AT(N)" paradigm. The quantification of the 42/40 ratio of beta-amyloid peptides in CSF allows the assessment of brain amyloid burden, while the determination of total tau and the p-tau-181 protein concentration in CSF is associated with neurodegeneration and tau pathology, respectively. In March 2024, the Alzheimer's Association published the revised criteria for diagnosis and staging of AD [23]. Core biomarkers are now categorized (core 1 and 2) and plasma biomarkers are included. According to this view, diagnosis is no longer based on clinical observations but solely on biological hallmarks of disease, even in the asymptomatic stage.

The emergence of blood-based biomarkers represents another breakthrough, as they offer a less invasive and scalable diagnostic tool and have further improved the possibility to identify at-risk individuals and detect disease hallmarks at a very early in the AD continuum, even in primary care [24]. P-tau 217 is one of the most interesting plasma biomarkers that will be included in next generation clinical pathways along with neurofilament light chain (NFL) and beta-amyloid 42/40 ratio. The definition of an appropriate methodology and cut-off value as well as validation in a real-world clinical setting are necessary to fully include this type of approach in the pathways.

In summary, there is an urgent need to incorporate new fluid biomarkers into the diagnosis, staging and treatment outcome evaluation of people with NCDs. However, we need to invest in healthcare professionals, infrastructure and appropriate funding to enable the introduction of new technologies.

Networking, decentralized laboratory testing and point-of-care (outside hospitals)

Point-of-care testing (POCT) is the most rapidly growing area in laboratory medicine. With increasing technological and analytical possibilities, an increasing number of analyses can now be performed with POCT devices. Although the cost of devices is lower than hospital instruments, the number of users of POCT is much greater, ranging from hospital wards in the hospitals, general practitioner (GP) offices, nursing homes and home care. The ultimate goal of using POCT devices is that they improve outcomes for patients and/or that they are more cost-effective than using traditional laboratory testing. To achieve this, the role of POCT in the different clinical settings and the responsibility for the introduction and management of the instruments and their use should be clearly defined. To build a POCT network, it is important to form alliances between key stakeholders. In most countries, these include professional associations in laboratory medicine, general practice, community medicine as well as the government and/or insurance companies. A POCT organization should deal with the following questions [25]: (i) which constituents shall be analyzed at the GP-office, in nursing homes etc.? (ii) which POCT devices should be used in primary care? (iii) how to secure analytically correct (enough) results? (iv) how to perform correct interpretations of the results?

The main reason for using a POCT instrument is that a rapid result is more useful than waiting for a result from a central laboratory. A key question is therefore: how can we ensure the quality of these instruments and their use [25–27]? Quality control is a well-established routine in laboratory medicine. As POCT is performed in a different environment with different users and often with different performance specifications and other types of built-in controls, we need to re-evaluate how and what types of quality controls we should use. There is little evidence on how often internal and external quality controls should be performed for POCT instruments and what performance specifications should be established [26, 27]. The Norwegian Organization for Quality Improvement of Laboratory Examinations (NOKLUS), which serves about 3,400 POCT units, has established a system for both internal and external quality control of POCT instruments over the course of 30 years and has established many educational courses [25–27]. The performance specifications for POCT instruments may differ from those of instruments in a central laboratory as they are often used in different ways [27].

Information technology, digitalization and health electronic record

Clinical laboratories have recently made incredible advances in various technological tools and instruments. LISs have evolved from results management and reporting support software to sophisticated tools capable of retrieving and exchanging information with various instrumental middlewares [28] and regional or national health records. In addition to demographic information and laboratory test results, LIS typically records the name of the test, the time of blood collection, changes in the test pathway, technical or

medical validations, and the sources of requests, such as inpatient departments or outpatient general practitioners. In addition, some modern LISs are able to capture data from the laboratory quality system, including external and internal quality controls, as well as information on verification and validation of analytical methods. Thus, LIS can record data obtained throughout the total testing process, including the pre-analytical, analytical and post-analytical phases of the so-called "brain-to-brain loop".

Apart from the main information generated by clinical laboratories (test results), the other types of data (attributable to the total testing process) could be ascribed to different data types, e.g., metadata. Interestingly, some of this information is usually not captured by LIS, and, thus, part of the daily generated data is often inevitably lost. The use of information to describe data (e.g., metadata) is essential for digitization processes in the sense of findability, accessibility, interoperability, and reusability (FAIR) approach. This is central to ensuring that healthcare data is not only relevant to the specific context of their collection, but can also be used for research purposes and the generation of AI algorithms for clinical and research applications, thereby extending its practical utility beyond its original scope. This approach can also facilitate the development of new technologies such as creation of synthetic electronic health records.

The comparability of test results between different laboratories could also be improved by using algorithms to harmonize results obtained with the same analytical systems from different instruments. Recently, digital twins (DTs) have also been proposed as transformative tools that offer opportunities for diagnosis, prognosis, real-time monitoring of patients, and evaluation of the precision of medical devices and clinical facilities [29]. Improving the capabilities of the LIS by changing the type of data recorded, reducing data silos, and enhancing data integration can lead to advances in laboratory technology. These improvements ultimately improve patient care and enable the generation of customized actionable results for patients.

Ethical challenges in laboratory medicine

Ethical issues are particularly important in modern laboratory medicine. The topic is demanding, because the ethical challenges are fundamental to the definition, management and organization of most of the classical sections of laboratory medicine. The need for a specific ethics culture for laboratory professionals is crucial to ensure the best scientific and practical approach to laboratory investigations, whether by observational or perspective.

Ethics committee experts should be familiar with the specific protocols commonly published and applied by laboratories, such as the possible use of residual biological material and reuse of pseudonymized data. The ethical issue is one of the points required for complete HTA, so it is crucial to know and apply the ethical aspects when introducing new products, new instruments and new procedures in clinical laboratories. The evaluation of ethical aspects in the laboratory could be based on the classical four arguments: autonomy, beneficence, non-maleficence, justice. In general, these arguments are discussed in relation to the outcomes of the laboratory, i.e. the impact of laboratory methods and the corresponding data on patient/citizen, but in some cases the arguments can also be evaluated for the professionals when methods and procedures are used outside the competence of the laboratory professionals [12].

Clinical laboratory professionals should be aware that the use of methods and the corresponding data can be unethical and potentially dangerous for the patient. This is the case of POCT, where the methods and procedures used for data collection are often not supervised and controlled by laboratory professionals. The proliferation of POCT outside of laboratories and healthcare services, often delivered by AI-based algorithms for interpretation of test results, requires ethical evaluation considering the potential inaccuracy of results and incorrectness of interpretation, leading to a cascade of negative processes for the patient and additional costs for the third-party payer.

Ethical challenges for laboratory medicine include several aspects, as detailed below [30, 31]: (i) direct release of laboratory data to the patient before or even without delivery to clinician or physician; this is a particular challenge for some data, such as genetic or infectious tests, but in general the unmediated relationship between laboratory and patient could be properly assessed; (ii) reference ranges, as the use of different reference ranges, mostly due to differences between laboratory techniques, is an obvious ethical standardization issue and (or) homogenization; despite publication of international standards to harmonize methods and results, laboratory data are often different even when methods are correctly standardized. This is an ethical challenge as different results for a standardized method may lead to a different classification of the patient (presence or absence of disease) or to different treatment (result above or below a defined threshold); and (iii) appropriateness of tests; the ethical challenge lies here in the correct use of newly proposed assays and tests, in elimination of tests with lower sensitivity and specificity and in correct evaluation of tests, not only in terms of analytical characteristics but for the actual impact on diagnosis and prognosis, according to the concept of value-based healthcare [30, 31].

Ethics in scientific research and publication

Publication ethics are at the foundation of scientific inquiry. Articles with data fabrication, errors, plagiarism, duplication and other ethical violations left unidentified can spread misinformation. Once detected, retracted papers are visibly branded indefinitely. Crossref Retraction Watch Database was recently made available to the public, that collates retracted articles or other articles of concern reported from participating journals. This study was performed to characterize articles reported to the database from medical technology journals in clinical medicine.

Clarivate Journal Citation Reports was used to identify all medical technology journals under clinical medicine, their impact factors and total citations reported in 2023. Crossref Retraction Watch Database was used to further characterize all reported articles from this list of indexed journals. Crossref provided all articles ever reported from the journal and respective author(s), retraction reason(s) or concern(s), publication and retraction dates and country codes. PubMed was used to categorize total number of citation(s) and publisher websites were reviewed to classify adherence to internationally recognized Committee of Publication Ethics (COPE) standards for prospective authors.

A total of 34 reported articles were identified from 50 % of the journals listed in the medical technology journal category (15/30) representing 78 % (11/14) of the unique publishers studied. Journal impact factors for 2023 ranged from 0.4 to 7.1 with 139,610 total citations (individual journal total citations range 111–23,544). Of the reported database articles, 31 were retracted, 2 corrected and 1 was expressed as an article of concern. Most retracted articles were original research (n=27) followed by review articles (n=3) and conference abstract (n=1). There were 13 countries represented with China (n=8), United States (n=6) and Canada (n=5) displaying the highest frequency rates of reported articles. Article errors (n=10) and duplications (n=8) were the most common reasons reported. Once an article was published, it took a mean of 39 (range 0–233) months until it was retracted. There were 803 total citations (range 0–191) from the reported articles. COPE standards were available on 78 % of the publisher (11/14) websites.

In conclusion, retracted articles exist in common laboratory medicine journals. Some articles took approximately 3 years before being labeled as retracted, which could have led to an increased citation rate and spread of misinformation. Although many publishers provided information on adhering to COPE standards, this study demonstrates a need to reduce time to retraction.

Challenges to the brain-to-brain loop

The brain-to-brain loop, first presented in a publication by Lundberg in 1981, described a nine-step process that supports the performance of any laboratory test. Lundberg also addressed the perceived challenge that clinical laboratories were solely responsible for providing “prompt and perfect” test results.

Lundberg emphasized that this was not the case as the testing process takes place both in patient care and in the clinical laboratory. Plebani and colleagues revisited the concept of the brain-to-brain loop in a 2011 publication [32], commenting on contemporary challenges associated with technological advances, automation, workforce shortages, and increasing isolation of clinical laboratories from patient care functions in providing services that best serve the patient. At this time, it was recognized that most testing errors occur in the pre- and post-examination phases of testing [33]. Since these realizations, there have been increasing efforts to incorporate the clinical laboratory into a more comprehensive strategy to ensure quality testing, focusing on a data-driven, multidisciplinary approach to optimize each step of the brain-to-brain loop.

An extended representation of the brain-to-brain loop, otherwise referred to as the total testing process, was published by Lubin and colleagues in 2023 [34]. This revised model recognizes increasing engagement of the clinical laboratory with patients and clinicians, advances in data collection and utilization for continuous quality improvement, the importance of a competent workforce, and other elements within an 11-step testing workflow. The detection of blood culture contamination and the use of next generation sequencing for the diagnosis of critically ill newborns are used to describe and address today’s persistent and new challenges in clinical laboratory practice within the context of the total testing process.

Direct-to-consumer laboratory testing

In paternalistic medicine, the attending physician determines the indication for a medical examination according to the medical need. Recently, technological advances, self-empowerment of patients (a.k.a. “4P-medicine”), and the widespread experiences with self-testing during the COVID-19 pandemic are strong triggers for Direct-To-Consumer Testing (DTCT) [35]. In DTCT, the

consumer himself decides about the indication to test, which is performed either by the consumer himself or self-collected samples are analyzed in nonmedical or medical laboratories, the latter being named direct access testing (DAT). The clear differentiation between the setting of the testing (DTCT, DAT, POCT) can be neglected in many cases, but has an impact on quality of test results and on their potential use for medical decision making or "lifestyle modification".

Unlike true laboratory tests, DTCT is often not subjected to effective oversight by competent authorities, and the complex regulations that apply to *in vitro* diagnostics to protect patients. In many countries, DTCT is not part of the healthcare system, and patient protection – as with real laboratory tests through a complex system of national regulations and process controls – is essentially non-existent for DTCT [35].

The user of DTCT is hardly aware of the often-inadequate quality. Reasons for the lower quality are selection of unsuitable tests, unscientific test methods (such as sink testing or bogus/quacksalver technologies), inappropriate performance of pre-analytical steps, lack of quality control and poor interpretation of test results, without considering the consumer's/patient's medical history and pre-test probability. Instead, many regulations that apply in healthcare, such as strict advertising restrictions or limiting promises about the benefits of certain tests, are void in DTCT.

DTCT generally has a higher rate of false-positive test results, which leads to repeat testing and brings financial benefits to the DTCT provider. However, these false positive results are unethical as they confuse the consumer and often trigger extensive medical investigations to reassure the frightened user. It is reasonable to assume that the resources spent on DTCT (from the consumer's pocket as well as from the national health budget for follow-up procedures) are not always used efficiently, and that medicalization through DTCT calls into question the optimal use of limited healthcare resources.

Health data, such as laboratory results, is considered highly sensitive and must be protected. This privacy is often made difficult with DTCT and clients are unaware of the obvious risks associated with disclosing their health data and – particularly with genetic testing – even to their families. Medical health records could even become worthless if they are hampered by unreliable DTCT data. In summary, the ethical risks of DTCT are manifold, such as over-medicalization, waste of healthcare resources, infiltration of medical records by falsified data, and undermining the trust of patients and healthcare professionals in genuine laboratory test results [36].

The role and ethical aspects of artificial intelligence in value-based laboratory medicine

The transition from volume-centric to value-centric approaches in clinical laboratories represents a decisive development towards value-based laboratory medicine, which emphasizes patient outcomes over operational efficiency. This shift promotes an integrated model where laboratory services enhance diagnostic and therapeutic pathways, improving clinical effectiveness and patient care through the strategic use of testing.

AI brings transformative advances across three eras, each characterized by distinct capabilities and challenges [37]. Initially, AI applied symbolic and probabilistic models to tasks such as clinical decision support. With the advent of deep learning, models were able to learn from large datasets for diagnostics, including image recognition and natural language processing. Currently, generative AI, which can perform a wide range of tasks without retraining and generate new content, offers new possibilities and complexities in its application in healthcare by developing advanced diagnostic tools and simulating patient outcomes, thus improving decision-making.

Despite the potential demonstrated in numerous studies on the use of laboratory data in machine learning (ML), the practical application of AI in clinical laboratories remains underutilized, especially when compared to fields such as radiology [38]. To close this gap, targeted technology transfer and adaptation to the clinical environment is required. The underutilization of AI technologies highlights the importance of a realistic approach to integrate these tools into healthcare considering the unique complexities of laboratory data.

Three main challenges hinder the integration of AI/ML in laboratory medicine: overemphasis on basic performance metrics, validations limited to single contexts, and reliance on specialized expertise for successful integration. To effectively use AI in laboratory medicine, rigorous validation and adherence to ethical standards is essential to ensure that these technologies benefit, rather than detract from, patient care. The insufficient depth of understanding of laboratory data poses significant risks that can lead to incorrect conclusions and ethical concerns. This highlights the need for improved education and interdisciplinary collaboration to ensure that AI tools are developed in a comprehensive clinical context [38].

Moreover, the integration of AI into laboratory medicine requires careful regulation to address ethical concerns such as patient privacy, data integrity and bias. It is crucial to

establish international guidelines for the ethical use of AI, with organizations such as the IFCC promoting transparency, accountability and explainability in ML-driven decision-making [39]. In summary, the integration of AI/ML into laboratory medicine should strike a balance between innovation and ethical responsibility and ensure that it supports the goals of healthcare, i.e., improving patient outcomes and clinical effectiveness. If achieved through vigilant, multidisciplinary collaboration and strict ethical standards, AI can be an important ally in the transition to value-based laboratory medicine.

Changing education and training of laboratory medicine professionals

The education of our professionals is a critical point in all activities and developments in the laboratory [40]. Training should be divided into four stages: Undergraduate, Postgraduate, Specialization/Professional and Continuing/Lifelong Learning. Undergraduate education is organized in two stages according to the Bologna Declaration – Bachelor's and Master's degrees in various programmes that prepare our professionals with medical, scientific, pharmaceutical and other backgrounds. The core component of postgraduate/PhD programmes is the promotion of learning through original research. Professional/specialization training is designed to apply biological knowledge to clinical needs. In addition to providing a competent laboratory service, this specialist must be able to act as a consultant to clinical colleagues. The EFLM Syllabus course consists of more than 40 modules and over 300 lectures covering all four main areas of the EFLM Syllabus. Effective communication with healthcare teams and patients is increasingly recognized as critical. Problem solving skills and critical thinking are essential for laboratory professionals to solve problems and make informed decisions. The main mission of the EFLM and the national societies is continuing education and lifelong learning. The EFLM Academy, e-learning platforms and exchange programmes such as EFLMLabX support education and training, the expansion of knowledge and skills and continuous professional development.

The education and training of laboratory medicine professionals continues to evolve to meet the demands of technological advances, changing healthcare systems and emerging global health issues. Training programs incorporate new emerging technologies, molecular biology techniques, digital pathology and AI to improve diagnostic accuracy and efficiency, and prepare professionals for their roles in genomic medicine and personalized healthcare. Bioinformatics, big data, statistical analysis and data science skills are becoming more central. The COVID-19 pandemic has highlighted the need for laboratory professionals to be prepared for emerging infectious diseases and we should include modules on outbreak response, biosecurity and the role of laboratories in public health. Education addresses global health challenges and the role of laboratory medicine in addressing issues such as antibiotic resistance, neglected tropical diseases and health inequalities.

ITs are innovating the educational process, offering new possibilities such as modeling, simulations, telemedicine, virtual reality and AI [41]. Online tools give everyone access to quality educational and professional content all over the world, 24 h a day and with the possibility of self-study. The digitalization of teaching improves the availability of education, the individualization of learning, increases interactivity and the effectiveness of teaching. Digital simulations, simulations of a wide range of procedures and virtual reality provide the opportunity to practice skills and perform diagnostic procedures in a safe and realistic environment. AI and robotics will increasingly find their way into healthcare, and there is a need to train professionals in this area. Despite the increase in digital and virtual learning, practical training remains crucial.

The education and training of laboratory medicine professionals are undergoing significant changes to keep pace with technological advances, healthcare demands and global health challenges. By integrating advanced technologies, emphasizing interdisciplinary collaboration, complying with regulatory requirements and promoting lifelong learning, the specialty is preparing professionals to provide high-quality, patient-centered care in a dynamic healthcare landscape.

The new *in vitro* diagnostic regulation: time to scrutinize?

With the implementation of European Unit (EU) Regulation 2017/746 on *in vitro* diagnostic medical devices (IVDR), EU market access for medical tests is governed by a vastly expanded and upgraded regulatory framework. Major regulatory changes are risk-based test classification, the generation of clinical evidence without grandfathering, compliance with the Medical Device Coordination Group guidance documents, third-party assessment by notified bodies, EU Reference Laboratories (EURLs) for batch release control of high-risk tests and advice from expert panelists for class D tests. Notably, in-house devices (IH-IVDs) are exempt from the IVDR, with the exception of compliance with Annex I and Article 5.5 [42].

The EU regulatory framework is still under development so far and <5 % of Class D tests are IVDR-compliant. While large IVD-companies are coping with the IVDR, this is far more difficult for small and medium-sized IVD-enterprises (SMEs). Because the IVDR-compliance by Notified Bodies is perceived as unpredictable, cumbersome and costly, it discourages SMEs from achieving a sufficient return on investment. As a result, there is a risk that important tests for niche and orphan (pediatric) diseases will be lost, negatively impacting patient care. On top, diagnostic laboratories face two other important challenges: (i) the provision on equivalence of tests (Article 5.5d), which imposes restrictions on the further manufacture and use of IH-IVDs once a commercial equivalent is available, and (ii) the gray area between CE-marked *in vitro* diagnostics (CE-IVDs), modified CE-IVDs, Research-Use-Only (RUO) tests, and IH-IVDs.

The results of a questionnaire on current diagnostic practice conducted by European medical societies collaborating in BioMed Alliance indicate widespread use of IH-IVDs in diagnostic laboratories across Europe and underline the need to preserve IH-IVDs for important innovations and for rapid test development during pandemics. Diagnostic equivalents of the European Reference Networks (ERNs) for rare diseases could help to ensure affordable and equitable access to specialized diagnostics across the EU. Concerted action by MedTech Europe, BioMed Alliance and Professional Societies is needed to prevent discontinuation of essential low-volume tests and to support efficient and effective implementation of IVDR, so that innovation is maintained and the quality, safety and accessibility of innovative diagnostics is ensured. Above all, critical appraisal of effectiveness of IVDR is urgently needed, as there is no evidence to date that this enormous investment in clerical paper work, even obliged for conventional tests, will improve patient management and outcome. In an era of exploding healthcare costs, it is time to think about justifying and reforming the IVDR.

Biomarkers and personalized medicine

The discovery that drug metabolism varies widely between patients, but can be predicted by DNA analysis of genes encoding drug metabolizing enzymes or drug transporters has encouraged the use of pharmacogenetics into clinical care. The initial focus was on cytochrome P450 enzymes: genotyping for *CYP2D6* (which is involved in the metabolism of 20 % of all drugs but is deficient in 5–10 % of the population) and *CYP2C19* (which is involved in the metabolism of 20 % of drugs but is deficient in 2–11 % of the population) could be useful for therapies in psychiatry, cardiology and oncology. There are currently 15–30 genes for enzymes that control drug metabolizing enzymes and drug transporters that can (and are) being used clinically to optimize personalized drug therapy as dosing recommendations and guidelines become increasingly available. Currently, the Food and Drug Administration (FDA) has included pharmacogenetic information in more than 350 drug labels. The field is growing mature as a clinical diagnostic tool, and we are seeing a shift from reactive single-gene testing to preemptive panel testing.

Future duties and responsibility of laboratory professionals: the role of EFLM in sustaining value-based laboratory medicine

The transition from volume-centric to value-centric approaches in clinical laboratories is not an easy task and requires great efforts from all scientific organizations, including the EFLM. On the one hand, all Functional Units and Committees need to develop projects and activities to implement value-based laboratory medicine, focusing on how laboratory testing can influence and improve both clinical and economic outcomes. On the other hand, there is a need to change the education and training programs for laboratory professionals through close collaboration with academia, universities and all other stakeholders [12].

An essential role in this project is to assure that the Young Scientists Functional Unit cooperate with the EFLM Executive Board and all other Functional Units to actively work on identifying future skills, tasks and competencies needed to implement value-based laboratory medicine in the real world and practice. The new competencies and tasks may range from managing decentralized testing options to implementing value-based clinical laboratory stewardship, and the ability to be part of integrated and multidisciplinary team units. Clinical laboratories have pioneered the introduction of process measures (internal quality control, external quality assurance and the model of quality indicators) to improve accuracy and reliability of laboratory test results and should now play a key role in promoting value-based laboratory medicine to ensure more effective, safe and patient-centered clinical diagnostic and therapeutic pathways [3].

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