Review Article

Navigating between technology and professionalism: key points for the future of clinical laboratories

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Abstract: In the last few decades, monumental changes have been made to the landscape of clinical laboratories. Laboratory medicine has always been influenced by a broad range of trends affecting technological development, the healthcare system organization, medical practice and patient empowerment. In the coming decade, disruptions will intersect, interact, and overlap with these trends, and with the existing set of laboratory practices; combinatorial innovation will make it of critical importance for leaders to prepare for a future with the understanding of possible collisions between linear trends and nonlinear external forces. The aim of the present paper is to discuss the future of clinical laboratories according to two different approaches: technological and professional. In particular, a description is given of a revised version of a 'ten points' manifesto for the future of laboratory professionals, with a focus on the main drivers and efforts made to demonstrate the added value and true role of laboratory medicine in modern health care systems. The main goal of this manifesto is to emphasize the centrality of the contribution of clinical laboratories and their professionals to improved health care.

Keywords: Future; laboratory medicine; quality; laboratory stewardship; technological developments; professionalism

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Introduction

In the last few decades, laboratory medicine has undergone monumental changes and the landscape of clinical laboratories continues to evolve. Currently, laboratory services are an integral part of health care systems as laboratory tests play a major role in clinical care, providing practitioners with prognostic tools and establishing effective preventative measures, diagnosing diseases, especially at an early stage, making reliable prognoses and undertaking patient monitoring, as well as personalizing therapy and improving outcome (1). Innovative molecular diagnostic techniques, advances in precision disease treatments, and population-based screening programmes for disease detection have made laboratory medicine an even more important part of modern medicine and health care. The diagnosis of many infectious diseases and the assessment of antimicrobial resistance are now mainly based on *in vitro* diagnostic testing (2), and technological innovations have enhanced the scope, quality, and sophistication of laboratory services, to the real benefit of health professionals and patients alike. Laboratory testing is now performed not only in traditional centralized clinical laboratories, but also in other decentralized settings, including the home (3,4). Efficient near-patient and point-of-care (POC) devices have been developed for enabling the prompt bedside diagnosis of many conditions, including genetic and infectious disorders (5). Integration of laboratory tests to care pathways, however, 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 (6). In the late 1960s, as a precursor of the medical industrial complex, for-profit corporations entered the clinical laboratory field advocating the adoption of industrial management techniques and

aggressive sales strategies to deliver huge numbers and varieties of laboratory tests. The paradigm shift in the past 50 years has, therefore, led to a gap between laboratory and clinic as well as to the consolidation of analytical work in focused factories and megastructures whose main aim is to achieve ever greater turnovers, decrease cost per test thus generating a vision of laboratory services as mere commodities (7). Although we are currently witnessing an explosion of innovative technologies, including "omics" and biomarkers, the prediction of the future of clinical laboratories and laboratory professionals remains a challenging issue.

Key questions on the future of laboratory medicine

Some recently published papers discuss the future of clinical laboratories along two different lines: technological and professional. According to the technological viewpoint, the prerequisites for future SMART (Speed Metrics Automation Remote Technologies) are automation, the use of drones for sample transportation, integration of big data and real-time data management, novel human-machine interfaces, robots, 3D-printing, internet of things and sensors (8). This prediction is based on the evidence of the trend to the consolidation of laboratories, the evolution into integrated care networks, increasing consumerism and direct-to-consumer testing (DTC). A major concern regarding this view is the brain-to-brain loop concept, which emphasizes the fundamental role of clinical laboratories only in the central process of analytical and post-analytical decisions, with little influence on both the pre-pre-analytical and post-post-analytical components. Indeed, it is stressed that with the advent of DCT and home-based collection the location of testing and interpretation of results is likely to fall increasingly outside the realm of laboratory professionals (8). If this is true, laboratory medicine will no longer be an academic discipline and a profession, and laboratory tests will be requested, performed and interpreted by consumers and/or clinicians. The "current brain-to-brain-loop" concept described highlights the scant influence of laboratory professionals on fundamental components of the testing cycle (appropriateness in test requesting and results interpretation/utilization), thus reflecting and consolidating a major concern in the current underestimation of the value of laboratory medicine, and its role in modern medicine. Regarding the pre-pre-analytical phase, Graves and Colleagues highlight the current emphasis on direct-to-consumer testing (DTC), particularly in relation to genetic testing, and the general trend towards "consumerization" of laboratory testing (8). However, while the clinician-centric traditional model of test requesting and results interpretation is switching to a model underpinned by empowered consumers, increasing attention is being paid to potential risks to patient safety related to this model. In fact, the overuse of testing may translate into overtreatment and potential patient harm. The recently introduced so-called hybrid laboratory model (9) is central to both the consumer and the clinician, in that hybrid laboratories facilitate consumer access, but a clinician (who may be the consumer's regular physician, a physician provided by the laboratory or a laboratory professional) orders the tests and returns the results to users. Potential benefits of hybrid model are greater access to testing for the consumer, particularly when the test is not covered by insurance and/or the consumer does not have a regular clinician or refuses to authorize the regular clinician to order testing, but wishes to obviate the risk related to self-interpretation of results, preclude underestimation of the quality of laboratory services and do not compromise the continuity of care. According to this innovative model, the clinical laboratory should be requested to provide an effective stewardship both in improving test request appropriateness, and result interpretation (10,11), thus directly involving laboratory professionals in patient management and care. This in turn, may yield effective tools to rebut current accusations of inappropriateness in test requesting and over-testing, while promoting the rational utilization of laboratory information.

The professional viewpoint

The professional viewpoint highlights the need for a better integration of laboratory tests in care pathways as the only possible way of guaranteeing that laboratory medicine and laboratorians have the right value and visibility, and that quality and patient safety are assured. This view is based on a re-evaluation of the key principles of the brain-to-brain-loop (12) and on the fundamental recognition of the need to assure close and effective interconnection and interrelation between the different phases of the testing cycle, thus promoting effective clinical laboratory stewardship (13). The authors of the manifesto, who describe ten points that should be adhered to by laboratory professional now and in the future, focus on the importance of clinical laboratory professionals in effectively collaborating with

Table 1 Laboratory professionals: what should be done now and in the future (14)

(I)	Convert results into clinical information
(II)	Cooperate in reducing the risk of diagnostic errors
(III)	Implement a reliable laboratory medicine stewardship
(IV)	Combine data of all laboratory subspecialties and diagnostic imaging in the same report
(V)	Establish reliable reference ranges and decision limits
(VI)	Facilitate more effective teamwork and be actively involved in interdisciplinary teams
(VII)	Promote the shift from volume-based reimbursement models to clinical value
(VIII)	Improve and update the way laboratory medicine is taught
(IX)	Do not neglect administrative competences and duties
(X)	Promote the value of the profession

Table 2 Laboratory stewardship: main areas of improvement

(I)	Test requesting (misordering tests)
(II)	Results interpretation (misinterpreting test results)
(III)	Laboratory data utilization (failure to acknowledge and act on test results)
(IV)	Efficiency/effectiveness of laboratory services (avoiding unnecessary costs)

physicians in order to achieve optimal value in healthcare (14,15). A central theme of the manifesto is cooperation and optimization in the workflow, the brain-to-brain loop, first described in 1981 by Lundberg, being implemented by clinical care providers and laboratory medicine experts (16). The ten points list is shown in *Table 1*.

As underlined by Miller and Plebani in their letter to the Editor commenting on the Manifesto points, harmonization and standardization of the laboratory testing process are essential in achieving high quality laboratory service and should, therefore, be considered a pre-requisite for any further strategy designed to promote the value of laboratory medicine (17). The key to avoiding misunderstanding and misinterpretation of test results is harmonization of pre-examination components such as patient preparation, test ordering and sample procurement as well as the post-examination components such as reporting units, reference intervals and interpretive information. Harmonization of the laboratory test results themselves is critically important in realizing several points in the manifesto (18-20). Therefore, first and foremost, laboratory professionals should promote the comparability of laboratory information in the same laboratory over time (serial results), and between different laboratories. The accuracy and interchangeability of laboratory information are fundamental prerequisites for assuring reliability of the electronic patient record (EHR), adopting expert systems, machine learning and artificial intelligence to improve test ordering and result interpretation. Therefore, this should be the first point of the new manifesto. The second point, "*Convert results into clinical information*", emphasizes the need to consider laboratory testing part of diagnostic and treatment pathways, stressing the evidence that only an appropriate test request and interpretation, in addition to analytical accuracy, can assure benefit to patients and valuable clinical and economical outcomes. In the post-analytical phase, further efforts should be made to assure the right measurement units, the right reference intervals/decision limits, and the right interpretative comments (18). Only in this way should analytical results become reliable laboratory information to be used in diagnostic/therapeutic pathways (6,21). The third point, "*Implement a reliable laboratory medicine stewardship*", is strictly related to previous points since the goal is to assure valuable laboratory information for patient diagnosis and treatment. Laboratory stewardship gives evidence-based guidance and decisional support to providers ordering laboratory testing and interpreting results (22,23). Current evidence highlights the unacceptably high rates of diagnostic errors related to mistakes in test requesting and result interpretation, as well as the scarce confidence of physicians in interpreting complex laboratory tests (e.g., coagulation, autoimmunology, allergy) (24). The contribution of laboratory professionals therefore aims to improve upon the areas reported in *Table 2*.

The fourth point is "*Facilitate more effective teamwork and be actively involved in interdisciplinary teams*". An increasing body of evidence highlights the need for patient care to be managed by a multidisciplinary team in order to allow a holistic view of the patients, and their health (25). The organization of clinical laboratories is currently evolving into huge and highly automated facilities, which are frequently located apart from hospitals and patients. The structure of these new services is somewhat like that of a "silo", whose management resembles that of industrial facilities, with less of a focus on clinical pathways (26). Laboratory services should forthwith be reorganized according to patient-

centered care, where sustainability and clinical outcomes are to be integrated. Laboratory professionals should be more engaged in large interdisciplinary teams, to which they could bring their skills and expertise for developing more efficient and effective care pathways (21). Porter *et al.* advocated the progressive transition from the so-called "silo" models to more integrated and patient-centered systems (i.e., with a greater focus on patient journey) in clinical medicine, emphasizing the need to deliver value in patient care, value being defined as "the health outcomes achieved per dollar spent" (27). Unlike this approach, the value of a laboratory test "must be ascertained not only on the basis of its chemical or clinical performance characteristics, but by its impact in patient management, the only true assessment of the testing quality being quality of patient outcomes" (28). Therefore, laboratory professionals must be trained to be part of inter-disciplinary teams, and more effective teamwork should be promoted, in accordance with Goal 1 of the National Academies of Sciences, Engineering, and Medicine (25).

The fifth point, "*Cooperate in reducing the risk of diagnostic errors*" is closely related to the fourth point. Reliable statistics, in fact, attests to the fact that diagnostic errors are often caused by lack of guidance from laboratory staff in ordering "the right test at the right time" as well as in the "right interpretation of laboratory data at the right time". Quality of care improvement can thus be enhanced by ensuring efficient teamwork between clinicians and laboratory professionals (25). As members of diagnostic management teams (DMTs), laboratorians should participate in all aspects of the testing process. DMTs bring together laboratory and clinicians with a view to ensuring appropriate test requesting and utilization, thus making physicians get "the right test at the right time for the right patient".

The sixth point is "*Combine data of all disciplines of laboratory medicine and diagnostic imaging in the same report*". The integration of different sub-disciplines data (e.g., clinical bio-chemistry, hematology, hemostasis, molecular diagnostics, microbiology) is an essential step in improving the quality of laboratory information and providing a unique, coordinated and clear laboratory report, which must be suitable for improving clinical decision making and patient management. Recently, the need for a more integrated approach to diagnostic testing led to the proposal of the so-called "pathology and laboratory medicine (PALM)" services (2). The organization and integrated structure of PALM takes into account the highly complex set of medical subdisciplines that span the extent of diagnostic testing needed to support modern health care. In addition, since laboratory professionals and radiologists share a similar history and a common destiny, it has been speculated that their specialties should be perhaps merged to create a single entity, the "information specialist," whose responsibility is not to be restricted to extracting clinical information from images and laboratory data, but is also to manage information processed by artificial intelligence in the clinical context of the patient (29). The use of integrated diagnostic approaches, combining image-based analysis, molecular diagnostic testing, along with the growing use of artificial intelligence and other information technology, is considered a major goal for the future of laboratory medicine (30). In the past, laboratory medicine generated abundant time series health information with few strategies to realize the value of these data. It is time to develop a more robust decision support infrastructure capable of implementing both rule-based and machine learning-based algorithms within a clinical environment and workflow.

The seventh point is "*Support new reimbursement models*". The financing of laboratory medicine was and still is a point of focus for governments and administrators. In the past, a simple evaluation of the cost per test was performed as the unique economic evaluation, and many laboratories have reasonable estimates of the per-test costs, but few laboratories have taken costing all the way to the clinical front-line by estimating the cost-per-case and its relationship with clinical outcomes. Providing data on the cost per-test, however, cannot be considered a truly reliable indicator because, rather than identifying an outcome, it merely demonstrates the provision of a test result. A more complex and thorough economic evaluation should be performed in order to gain a better understanding of the real value of a laboratory service, and this evaluation should include cost-benefit, cost-effectiveness, and cost-utility analysis since the final aim of a laboratory test is an action on the patient and the related analysis of the outcomes. In recent years, the organization of healthcare systems has evolved, the trend worldwide being to rely on reimbursement based on patient outcomes (21). This evidence shall further encourage the parallel evolution of laboratory medicine services toward models based on the value of laboratory information rather than on costs (18). Overall, healthcare systems are evolving from a model designed around reimbursement according to the volume of services, into a fee-for-service environment with bundled payment, oriented to reimbursement of comprehensive

Table 3 The 10 points of the new manifesto

(I)	Promote accuracy and comparability of laboratory information through harmonization and standardization programs
(II)	Convert results into clinical information
(III)	Implement reliable laboratory stewardship
(IV)	Facilitate more effective teamwork and promote active involvement in interdisciplinary teams
(V)	Cooperate in reducing the risk of diagnostic errors
(VI)	Combine data of all disciplines of laboratory medicine (PALM) and diagnostic imaging in a unique report
(VII)	Support new reimbursement models based on the value of laboratory information
(VIII)	Support innovation in teaching laboratory medicine
(IX)	Enhance all professional tasks
(X)	Promote the value of the profession (laboratory medicine)

diagnostic and therapeutic pathways in inpatient settings following the diagnosis-related group (DRG) system (31). Even for outpatients, the scenario is evolving from a model based on volumes and cost per test, into a system increasingly focused on effectiveness and value of laboratory information. This, in turn, should revolutionize the delivery of laboratory services, thus maximizing the value of laboratory information in clinical pathways and patient outcomes rather than volumes and cost per test (21).

The eighth point is "*Support innovation in teaching laboratory medicine*". The evolving landscape of healthcare and laboratory medicine, coupled with remarkable advancements in biology and analytical techniques, should lead to substantial innovation in the teaching of laboratory medicine, in both medical undergraduate (32) and post-graduate courses (33). Future laboratory professionals need to learn new competencies and skills enabling them to cope with the challenges of the changing healthcare landscape.

The ninth point is "*Enhance all professional tasks*": laboratory professionals are not committed solely to the accurate and efficient analysis of biospecimens, but are now deeply involved in a vast array of administrative tasks encompassing optimization of test menus, withdrawal of obsolete or redundant diagnostic investigations, provision of appropriate education and training to personnel, administration of human and economic resources, management of budgets and introduction of technological advancements (14,15,34). The large majority of these activities call for clinical expertise and scientific/technical training, whilst administrative skills are required for other tasks.

The tenth point is "*Promote the value of the profession*": Laboratory professionals and their associations must overcome their invisibility to the general public and support the substantial evolution of the role of laboratory professionals in healthcare. Usually patients receive the results of laboratory tests that can have major effects on their care, but never see or talk to the professionals responsible for those tests. Laboratory professionals and their associations, therefore, must highlight the centrality of their contribution as a clinical discipline to improved health care (35). They should not be merely perceived as "providers of tests". This concept is highlighted in the affirmation that "We are not merely generators of data, to be tossed over the fence to our clinical colleagues. We are managers of information; we are creators of knowledge. We are gatekeepers and stewards. We are builders of processes and systems. We are guardians of quality. We are business people and executives. We are team leaders and team members. We are educators and consultants. We are "*patient advocates*" (36). This statement stresses the numerous current responsibilities of laboratory professionals, whose work has recently become ever more complex. We should promote the value of the profession, making the increasingly relevant role of laboratory testing in modern healthcare more visible to patients, clinicians and other stakeholders. *Table 3* shows the following ten points in this new manifesto.

Conclusions

The time has come to take a step toward a new vision of the future of laboratory medicine, taking into consideration both technological developments and the evolving role of the profession in the modern healthcare system. It is of utmost importance to encourage the development of a new generation of laboratory professionals and leaders able to integrate specific technical and administrative skills with a broader vision of health care with an even greater focus on patients.

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