



## Editorial

## A manifesto for the future of laboratory medicine professionals



## ARTICLE INFO

## Keywords:

Laboratory medicine  
Diagnosis  
Quality  
Safety

## ABSTRACT

Laboratory medicine plays an increasingly essential role in modern healthcare systems, since it is integral to most care pathways and plays an essential role for optimizing patient flow, harmonizing procedures before and after analysis, improving harmonization and containing unnecessary testing. Nevertheless, recent changes in the nature of laboratory services, promoted by innovation and introduction of more complex tests in emerging diagnostic fields, more advanced diagnostics along with other “internal” and “external” drivers, will promote a paradigmatic transformation of current scenarios. The future of laboratory professionals remains hence uncertain, and it seems obvious that the role and figure of laboratory scientists and professionals shall evolve. We are hence proposing this 10-point “manifesto”, which is aimed to encourage a new vision of the future of this discipline and should help supporting the development of a new generation of laboratory professionals and leaders, who shall be able to integrate specific technical and administrative skills with a broader vision of health care and patients needs.

## 1. Introduction

Laboratory medicine plays an increasingly essential role in modern healthcare systems, since *in vitro* diagnostic tests are now used in virtually each step of the managed care. Laboratory tests are, in fact, requested for a) predicting susceptibility to diseases, b) preventing diseases, through identification of risk factors, c) diagnosing many pathological conditions, often at early stages, d) prognosticating, e) monitoring disease progression and f) personalizing treatments for achieving the best possible outcomes [1].

In the last decades, technical and organizational advancement in laboratory testing have progressed in parallel with both improved knowledge of the pathophysiology of human diseases and changes of healthcare deliverance, thus supporting a paradigm shift from diagnosing and monitoring advanced diseases, to an equally pervasive predictive and preventative approach [2]. Most organ diseases (e.g., liver, kidney and thyroid pathologies) can only be identified with support of laboratory testing. Many of these conditions are asymptomatic during the early stages, and are hence unlikely to be clinically detected. Early identification of asymptomatic diseases should allowed an improved disease management and a lower erosion of public and private (i.e., the so-called out of pocket expenditure) economic healthcare resources. Some laboratory biomarkers (e.g., cardiac troponins, glycated hemoglobin, anti-transglutaminase antibodies) have been developed and introduced into clinical practice exactly for this reason. For most infectious diseases, including hepatitis, HIV, malaria and tuberculosis, both diagnosis of causative agents and detection of antimicrobial resistance necessitate microbiology/virology testing [3]. Even more interestingly, a progressive shift towards predictive medicine and personalized health monitoring has occurred over recent years. Thanks to remarkable advancements in genomic, transcriptomic and proteomic techniques, this innovative strategy is now strongly

based on results of laboratory testing. Rapid “near patient” and “point-of-care” tests have also been developed for measuring common analytes, for analyzing many other diagnostic biomarkers and for diagnosing infectious and genetic diseases. These tests have a paramount potential for improving clinical outcomes, both inside and outside the hospital environment, and this can be achieved by increasing efficiency of care, lowering the risk of referral and ultimately reducing the complexity of many care pathways [4]. Laboratory professionals intersect with all major medical specialties, assisting clinicians in selecting the right test for the right patient at the right time, and cooperating with them for facilitating an appropriate interpretation and use of laboratory information. This concept is now identified with the term “clinical laboratory stewardship”, and encompasses a substantial revolution in various steps of the total testing process, including test ordering, analysis and results reporting [5,6].

Clinical laboratories are integral to most care pathways and play an essential role for optimizing patient flow, harmonizing procedures before and after analysis, improving harmonization and containing unnecessary testing. Delayed transmission of inpatient test results exceeding the recommended turnaround times (TAT) may extend the hospital length of stay and increase patient dissatisfaction. Poor organization of care pathways may also trigger unnecessary consultations when laboratory tests are requested without an appropriate time schedule, or are not integrated with other diagnostic investigations [7]. Recent data shows that inappropriate requests, errors in patient/sample identification, inaccurate laboratory results, as well as delays in communication and inaccurate interpretation, may increase the risk of generating diagnostic errors, thus pinpointing the ever growing pivotal role of laboratory information in clinical reasoning and managed care on one side, and the compelling need of reducing the risk of errors throughout the total testing process on the other [8]. For example, patient and sample misidentification still represents a challenging issue,

<https://doi.org/10.1016/j.cca.2018.11.021>

Received 9 November 2018; Accepted 12 November 2018

Available online 13 November 2018

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with a concerning prevalence (up to 2.25% defect rate in some institutions), thus emphasizing the poor availability and/or compliance with standard operating procedures [9]. This, in turn, may lead to poor outcomes and unsatisfactory quality of care, as it was estimated that 17% of specimen misidentification defects may then trigger incorrect therapies, and almost 6% results may generate adverse events [10]. The link between poor quality of laboratory information and diagnostic errors is now unquestionably proven [11].

Laboratory diagnostics, a cornerstone of modern medicine, has undergone monumental changes in recent years, which have led to a substantial transformation of the conventional landscape of their environment and activities. In particular, laboratory investigations have evolved from simple tests used for making clinical diagnoses, to more sophisticated and pathognomonic analyses, which can be useful for stratifying the risk of certain diseases, for achieving earlier diagnoses, and for promoting the path towards personalized medicine. Laboratory organization has consistency evolved from simple analytical techniques carried out by medical doctors in small rooms close to or into the wards, to large, automated, sophisticated and consolidated facilities, often located far from hospitals and patient care, organized as individual units or “silos”, and managed according to performance metrics resembling industrial models rather than be centered on clinical pathways [12]. Although the cycle of laboratory testing develops as a brain-to-brain loop, starting with appropriate test request and finishing with appropriate use of laboratory information [13,14], the focus on volume of activity, cost of delivery, throughput and analytical quality has contributed to generate a misleading picture of laboratory services, seen as simple commodities, based on scale economy models which overshadow medical aims to economic purposes. This model was strongly influenced by the nature of the “traditional” laboratory tests been performed until the last decade, mostly entailing methods aimed to measuring analytes well known to practicing physicians, who were (and still are) capable to correctly interpret their values [15]. Changes in the nature of laboratory services, promoted by innovation and introduction of more complex tests in emerging diagnostic fields (e.g., autoimmunity, allergy, hemostasis, early cancer detection), more advanced diagnostics (e.g., molecular and genetic testing) and other “internal” and “external” drivers, will hence promote a paradigmatic transformation of the current scenarios. This “manifesto” is hence based on 10 point, as follows (See Table 1).

- 1) Laboratory results “can no longer be tossed over the fence” to clinicians. Several lines of evidence now attest that errors still occur for inaccurate interpretation and for lack of confidence of practicing physicians in understanding test limitations, including a poor knowledge of the inherent risk of false positive and/or negative test results. Even the Washington Post has recently published an article highlighting this issue (What the tests don't show) [16]. Some recent surveys clearly demonstrate that practicing physicians have challenges and poor confidence in ordering and interpreting many laboratory tests, along with their hope for a provision of

mechanisms expected to establish simple and effective strategies for consultation on laboratory tests selection and interpretation [17]. The ever growing availability of Direct-to-consumer (DTC) tests should not underestimate the evidence that laboratory “results” need to be correctly interpreted in the context of the clinical status, and patients will continue to depend on their physicians and laboratory professionals for expert advice in “converting numbers and short verbal reports in reliable (clinical) information”.

- 2) Data on diagnostic errors, evidence that many errors are due to failure in requesting “the right test at the right time” without guidance from laboratory-based experts, along with failure of timely acknowledging, interpreting and correctly using laboratory information, should actually catalyze a narrowed interaction between laboratory professionals and physicians, thus facilitating the establishment of an effective teamwork throughout the diagnostic process, which should also include active patients' involvement in this partnership [18].
- 3) Diagnostic stewardship, which implies modifying the process of ordering, performing and reporting laboratory test results, has emerged as a willingness to improve clinical care, by decreasing the rate of false-positive test results and thus mitigating the risk of overdiagnosis [5]. As clinical laboratories generally serve large populations of patients and provide ample test menus, the potential benefits may be broader than for traditional antimicrobial stewardship, which is mostly focused on tailored treatments.
- 4) Laboratory professionals are now using efficient instrumentation and technologies for providing effective answers to the increasing request of laboratory tests, for allowing timely data reporting, as well as for improving standardization and analytical quality. Some tasks originally performed manually by laboratory professionals (e.g., cell counts, urinalysis, typing and screening of blood) have then been automated, thus allowing requalification of professionals towards more complex diagnostic activities. Even radiologists have dramatically modified their professionalism, and they are now considered “information specialists”, focused on medical imaging. Since laboratory professionals and radiologists share a similar history and a common destiny, it has been speculated that their specialties should be perhaps merged into a single entity, the “information specialist,” whose responsibility will not be limited to extract clinical information from images and laboratory data, but will also manage information elaborated by artificial intelligence in the clinical context of the patient [19]. 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 seen as a major goal for the future of laboratory medicine [20]. The contribution to better understand and interpret laboratory results is certainly recognized as an emerging duty of laboratory professionals, who should be considered “information specialist of laboratory tests”. The integration of different sub-disciplines data (e.g., clinical biochemistry, hematology, hemostasis, molecular diagnostics) is an essential step for improving the quality of laboratory information and for providing a unique, coordinate and clear laboratory report, which shall be suited for improving clinical decision making and patient management.
- 5) While the definition of “normal” values for common laboratory tests is a mainstay for diagnosis, treatment and managed care, limited systematic analyses of baseline variation across demographically different population strata (e.g., race, ancestry, gender, sex, age and socioeconomic status) are available. After decades of routine use, reference intervals and decision limits should be reconsidered, since unquestionable evidence has now been gardened that tests results may be classified as “normal” with one analytical system, but can be classified as “abnormal” with others [21]. This aspect highlights the limited importance often attributed to post-analytical issues (namely result reporting and interpretation),

**Table 1**

Laboratory professionals: what should do now and in the future.

- 1) Convert results in clinical information
- 2) Cooperate in reducing the risk of diagnostic errors
- 3) Implement a reliable laboratory medicine stewardship
- 4) Combine data of all laboratory subspecialties and diagnostic imaging in the same report
- 5) Establish reliable reference ranges and decision limits
- 6) Facilitate more effective teamwork and be actively involved in interdisciplinary teams
- 7) Promote the shift from volume-based reimbursement models to clinical value
- 8) Improve and update the way laboratory medicine is taught
- 9) Do not neglect administrative competences and duties
- 10) Promote the value of the profession

which instead play an essential role for enhancing the clinical value of laboratory information.

- 6) The progressive transition from the so-called “silos” models to more integrated and patient-centered systems (i.e., more focused on patient journey) in clinical medicine has been earlier suggested by Michael E Porter, who emphasized the need to deliver value in patient care, where value has been defined as “the health outcomes achieved per dollar spent” [22]. 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” [23]. Therefore, laboratory professionals shall be educated to be part of interdisciplinary teams and more effective teamwork should be promoted, in accordance with the Goal 1 of the National Academies of Sciences, Engineering, and Medicine [18].
- 7) Health care systems are generally evolving from a model designed around reimbursement according to the volume of services, to a fee-for-service environment with bundled payment, oriented to reimbursement of comprehensive diagnostic and therapeutic pathways in inpatient settings according to the diagnosis-related group (DRG) system [24]. Even for outpatients, the scenario is evolving from a model based on volumes and cost per test, to a system more focused on effectiveness and value of laboratory information. This, in turn, should revolutionize the delivery of laboratory services, thus emphasizing the value of laboratory information in clinical pathways and patient outcomes instead than volumes and cost-per test [15].
- 8) Along with closer collaboration and cooperation between laboratory professionals, clinicians and patients, several lines of evidence highlight the importance revolutionizing the approach to teaching laboratory medicine in medical schools [25] and post-graduate courses [26]. Competent professionals are central to delivery of high-quality health care services, especially in an era of rapid and monumental advancements of both medical knowledge and technologies. More information on the real value of laboratory services should also be made available to patients and other stakeholders.
- 9) Several surveys have recently described the growing complexity of the activities performed by laboratory professionals and, in particular, by laboratory managers. Along with clinical activities (e.g., directing interpretative services and performing specific tests), laboratory professionals are now involved in many administrative activities heading for optimizing test menus, discontinuing obsolete tests, ensuring adequate training and education to the staff, discussing budgeted, resources and technological innovations [27]. The large majority of these activities require clinical expertise and scientific/technical training, whilst other tasks need administrative skills.
- 10) The evolution of the “clinical pathologist”, who should be better defined “laboratory professional”, has been recently summarized by Steven H Kroft with the following statements: “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*” [28]. This well represents the job description of laboratory professionals which has become dramatically more complex in the last decades.

## 2. Conclusions

The future of laboratory medicine seems bright. Innovative biomarkers, advances in molecular diagnostics for identifying risk factors, for early diagnosing, guiding treatment and personalizing treatments,

have enormously contributed to revolutionize modern medicine, and will continue to change and improve the quality of care for the single patient and for the general population. Nevertheless, the future of laboratory professionals remains uncertain, and it seems obvious that the role and figure of laboratory scientists and professionals shall evolve. In particular, perpetuation of the “silo approach” for delivering laboratory services should be challenged, whilst reinforced interaction with other elements of the diagnostic and therapeutic networks should be promoted, thus improving patient-center and end-to-end support in clinical pathways and patient journey. The current perception of major changes in the way laboratory services are delivered mainly originates from the clinical world. Many articles have recently been published, which emphasized the need that clinicians shall more committed to a better use of diagnostic testing, “considering timing, sequencing, proper performance, errors in sample collection, analysis and interpretation” as well as disease prevalence and prior probability in order to share the process of “diagnostic decision making” [29,30]. Others have also advocated the concept of “diagnostic calibration”, which has been defined as the relationship between diagnostic accuracy and physician confidence in that accuracy, aimed at reducing errors and improving quality of care [31]. Laboratory activity is essentially based on titrating methods against standards. This concept should hence be translated into clinical practice, more actively supporting clinicians for improving clinical reasoning and decision making. The growing availability of DTC tests, which now encompass a vast array of laboratory and genetic analyses, shall not underestimate the evidence that patients will continue to depend on physicians and laboratory professionals for counseling, procedural expertise, and access to reliable diagnosis and treatment [32]. Although the compelling need to improve these essential processes has been somehow overlooked in laboratory medicine, the time has come to take a step forward towards a new vision of the future of this discipline. The development of a new generation of laboratory professionals and leaders shall be encouraged, who will be able to integrate specific technical and administrative skills with a broader vision of health care and patients needs.

## References

- [1] M. Plebani, G. Lippi, Improving diagnosis and reducing diagnostic errors: the next frontier of laboratory medicine, *Clin. Chem. Lab. Med.* 54 (2016) 1117–1118.
- [2] T. Walley, Evaluating laboratory diagnostic tests, *BMJ* 336 (2008) 569–570.
- [3] Wilson ML, Fleming KA, Kuti MA, Looi LM, Lago N, Ru K, Access to pathology and laboratory medicine services: a crucial gap, *Lancet* 391 (2018) 1927–1938.
- [4] I.V. Jani, T.F. Peter, How point-of-care testing could drive innovation in global health, *N. Engl. J. Med.* 368 (2013) 2319–2324.
- [5] D.J. Morgan, P. Malani, D.J. Diekema, Diagnostic stewardship-leveraging the laboratory to improve antimicrobial use, *JAMA* 318 (2017) 607–608.
- [6] M. Plebani, Quality and future of clinical laboratories: the Vico's whole cyclical theory of the recurring cycles, *Clin. Chem. Lab. Med.* 56 (2018) 901–908.
- [7] M.J. Misialek, Valuing value. The changing role of pathologists, *Am. J. Clin. Pathol.* 142 (2014) 584–585.
- [8] M. Plebani, Laboratory-associated and diagnostic errors: a neglected link, *Diagnosis (Berl)* 1 (2014) 89–94.
- [9] R. D'Angelo, O. Mejabi, Getting it right for patient safety: specimen collection process improvement from operating room to pathology, *Am. J. Clin. Pathol.* 146 (2016) 8–17.
- [10] P.N. Valenstein, S.S. Raab, M.K. Walsh, Identification errors involving clinical laboratories: a College of American Pathologists Q-Probes study of patient and specimen identification errors at 120 institutions, *Arch. Pathol. Lab. Med.* 130 (2006) 1106–1113.
- [11] M. Plebani, System-related and cognitive errors in laboratory medicine, *Diagnosis (Berl)* (2018 Sep 28), <https://doi.org/10.1515/dx-2018-0085> (Epub ahead of print).
- [12] C.P. Price, A.S. John, R. Christenson, V. Scharnhorst, M. Oellerich, P. Jones, et al., Leveraging the real value of laboratory medicine with the value proposition, *Clin. Chim. Acta* 462 (2016) 183–186.
- [13] G.D. Lundberg, Acting on significant laboratory results [editorial], *JAMA* 24 (1981) 1762–1763.
- [14] M. Plebani, M. Laposata, G.D. Lundberg, The brain-to-brain loop concept for laboratory testing 40 years after its introduction, *Am. J. Clin. Pathol.* 136 (2011) 829–833.
- [15] M. Plebani, Clinical laboratories: production industry or medical services? *Clin. Chem. Lab. Med.* 53 (2015) 995–1004.
- [16] Washington Post, Doctors are surprisingly bad at reading lab results. It's putting us

- all at risk, Available at: <https://www.washingtonpost.com/news/posteverything/wp/2018/10/05/feature/doctors-are-surprisingly-bad-at-reading-lab-results-its-putting-us-all-at-risk/> Last accessed, 27 October 2018.
- [17] M.B. Marques, J. Anastasi, E. Ashwood, B. Baron, R. Fitzgerald, M. Fung, et al., The clinical pathologist as consultant, *Am. J. Clin. Pathol.* 135 (2011) 11–12.
- [18] National Academies of Sciences, Engineering, and Medicine, *Improving Diagnosis in Health Care*, The National Academies Press, Washington, DC, 2015, <https://doi.org/10.17226/21794>.
- [19] S. Jha, E.J. Topol, Adapting to artificial intelligence, *JAMA* (22) (2016) 2353–2354.
- [20] M.L. Wilson, The future of pathology and laboratory medicine-again, *Am. J. Clin. Pathol.* 150 (2018) 93–95.
- [21] A.K. Manrai, C.J. Patel, J.P.A. Ioannidis, In the era of precision medicine and big data, who is normal? *JAMA* 319 (2018) 1981–1982.
- [22] M.E. Porter, What is value in health care? *N. Engl. J. Med.* 363 (2010) 2477–2481.
- [23] M. Plebani, Charting the course of medical laboratories in a changing environment, *Clin. Chim. Acta* 319 (2002) 87–100.
- [24] D. Srinivasan, N.R. Desai, The impact of the transition from value to value on heart failure care: implications of novel payment models and quality improvement initiatives, *J. Card. Fail.* 23 (2017) 615–620.
- [25] M. Laposata, Insufficient teaching of laboratory medicine in US medical schools, *Acad. Pathol.* 3 (2016) 1–2.
- [26] E.I. Peerschke, Y. Agrawal, C.B. Alexander, E. Bovill, M. Laposata, Proposed research training guidelines for residents in laboratory medicine, *Clin. Lab. Med.* 27 (2007) 241–253.
- [27] J.A. Branda, A.S. Dighe, W. Dzik, M.J. Ferraro, J. Flood, Lee-Lewandrowski, et al., The practice of clinical pathology: a quantitative description of laboratory director activities at a large academic medical center, *Am. J. Clin. Pathol.* 142 (2014) 144–149.
- [28] S.H. Kroft, The Evolution of the Clinical Pathologist, *Am. J. Clin. Pathol.* (2018 Aug 24), <https://doi.org/10.1093/ajcp/aqy119> (Epub ahead of print).
- [29] G.D. Schiff, S.A. Martin, D. Eidelman, L. Volk, E. Ruan, C. Cassel, et al., Ten principles for more conservative, care-full diagnosis, *Ann. Intern. Med.* (2018 Oct 2), <https://doi.org/10.7326/M18-1468> (Epub ahead of print).
- [30] J.E. Brush, J.M. Brophy, Sharing the process of diagnostic decision making, *JAMA Intern. Med.* 177 (2017) 1245–1246.
- [31] A.S. Cifu, Diagnostic errors and diagnostic calibration, *JAMA* 318 (2017) 905–906.
- [32] M.K. Kilbride, S. Joffe, The new age of patient autonomy, *JAMA* (2018 Oct 15), <https://doi.org/10.1001/jama.2018.14382> (Epub ahead of print).

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