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IM - POINT OF VIEW

Driving the route of laboratory medicine: a manifesto for the future

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Abstract
The role of laboratory medicine is essential in healthcare, since in vitro diagnostic testing represents now an unavoidable part of reasoning and clinical decision making. Laboratory tests are an essential part of most care pathways, aimed at optimizing resource utilization and improving patient outcome. The activity of laboratory professionals is interconnected with all medical disciplines, and provides a crucial support for ordering the right test, for the right patient and at the right time, but also helps interpreting and using laboratory data. Although recent advancement in laboratory medicine, catalyzed by technical innovations and development of innovative tests, have promoted a substantial revolution in the organization of clinical laboratories, the future of this profession seems still ambiguous. We have hence developed a "manifesto" of laboratory medicine, meant to promote an innovative prospect of our discipline and encouraging the establishment of a new generation of laboratory professionals and managers.

Keywords Laboratory medicine · Diagnosis · Quality · Safety

The contribution of laboratory medicine is essential in modern healthcare, since in vitro diagnostic testing plays a pivotal role for predicting disease susceptibility, for establishing effective preventative measures, for making diagnoses, especially at an early stage, but also for prognosticating and monitoring diseases, as well as for personalizing therapies and improving outcomes [1]. Early identification of diseases, especially in asymptomatic patients, enables better management and use of both public and private economic resources [2]. The diagnosis of many infectious diseases and the assessment of antimicrobial resistance are now substantially based on in vitro diagnostic testing [3]. Predictive and personalized (precision) medicine is now also straightforwardly emerging, and fast and efficient point of care (POC) devices have been developed for enabling rapid bedside diagnosis of many pathological conditions, including genetic and infectious disorders [4].

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The activity of laboratory professionals is interconnected with all medical disciplines, and provides a crucial support for ordering the right test, for the right patient and at the right time, but also helps interpreting and using laboratory data. The recently coined definition "clinical laboratory stewardship" provides a brilliant representation of the irreplaceable role of laboratory medicine in improving appropriateness of test ordering and enhancing total quality in the testing process, from sample collection to test results interpretation [5–7], thus lowering the risk of diagnostic errors and harms to the patients [8]. Patient and/or sample misidentification is a paradigmatic example. The prevalence of identification errors during or immediately after blood sampling is still relatively high in healthcare (i.e., frequently around 2%), and is often caused by limited accessibility to, or compliance with, guidelines, recommendations and standard operating procedures (SOPs) [9]. The consequences of these errors are frequently detrimental, since approximately 20% of sample identification errors might then be associated with inappropriate treatment and unfavorable clinical events [10]. This evidence clearly reflects the strict connection between inadequate quality throughout the total testing process and magnified risk of generating diagnostic errors [11].

Laboratory medicine, which should hence be regarded as irreplaceable in modern clinical medicine, has consistently changed over the past decades. The organization of

Table 1 The evolving role of laboratory professionals

1. Transform laboratory data in clinical information
2. Establish an effective interaction with clinicians for lowering the risk of diagnostic errors
3. Develop laboratory medicine stewardship
4. Combine results of laboratory and imaging investigations in a unique report
5. Develop and continuously update reference ranges and decision thresholds
6. Establish interdisciplinary teams and be engaged in effective teamwork
7. Encourage a paradigm shift from models based on cost-per-test reimbursement to those based on the value of laboratory information
8. Improve teaching in laboratory medicine
9. Do not discount the importance of administrative tasks
10. Reinforce the value of laboratory medicine in healthcare

clinical laboratories has progressed from performance of easy analytical assays in small physicians' offices, to huge and highly automated facilities, which are frequently set aside from hospitals and patients. These new services are now structured more or less like "silos", whose management resembles that of industrial facilities, no longer focused on clinical pathways [12]. The increasing commitment on testing volumes, low costs and high throughput has hence promoted the development of an ambiguous perception, according to which laboratory services are now regarded as scale economy-based "commodities", in which the economic revenue often outshines clinical objectives. Nevertheless, many "internal" and "external" forces are now upholding a paradigm shift, thus re-establishing the antique role of laboratory medicine as an essential part of healthcare. These important drivers have persuaded as to develop a 10-point "manifesto" of laboratory medicine, meant to promote an innovative prospect of our discipline and encouraging the establishment of a new generation of laboratory professionals and managers (Table 1).

1. *Improve results interpretation* Recent evidence clearly highlights the many challenges and the often limited confidence that physicians have in both ordering and interpreting several diagnostic investigations, a framework where laboratory professionals could provide invaluable advice and support [13].
2. *Contribute to reduce diagnostic errors* Reliable statistics attests that diagnostics errors are often caused by lack of guidance from laboratory staff in ordering "the right test, at the right time". Quality of care improvement can hence be enhanced by establishing an efficient teamwork between clinicians and laboratory professionals [14].
3. *Implement clinical laboratory stewardship* A mutual interaction between laboratory and clinical medicine is an essential part of modern healthcare deliverance. Although the extent to which laboratory testing informs the clinical decision-making remains somehow controversial, it is now undeniable that in certain areas of clinical medicine (e.g., diabetes, acute myocardial infarction and so forth), both the diagnosis and managed care cannot be efficiently developed without laboratory information. This liaison will become even more essential in the future, due to unremitting diffusion of disruptive technologies such as genomics epigenetics and proteomics, which represent the cornerstone of "personalized medicine". Clinical laboratory stewardship, which encompasses radical changes in the way laboratory tests are ordered and test results reported, holds great promise for improving managed care, by reducing the risk of both under- and over-diagnosis [5, 6]. Laboratory professionals should hence reinforce their role as "information specialist of laboratory tests". This could be achieved by establishing a proactive partnership, whereby laboratory professional should reaffirm their pivotal role of "pathologists", helping clinicians to update their knowledge on laboratory investigations, actively participating to define updated diagnostic protocols and providing expert consultancy on test results interpretation. Organization of roundtables, clinical cases discussions and joint scientific meetings are additional opportunities to improve the clinical–laboratory interaction.
4. *Support introduction of innovative technologies* Many manual laboratory techniques have now been partially or completely automated, and this has allowed requalification of laboratory professionals and major commitment to innovative technologies (i.e., the "-omics"), which represent the essential basis of personalized/precision medicine.
5. *Improve reference ranges and decision limits* The use of reference ranges and decisional thresholds is plagued by many drawbacks. Test results may be considered either "normal" or "abnormal" using different methods or different analyzers [15]. More efforts should hence be made for improving laboratory-physicians communication and for harmonizing practices

in the post-analytical phase of the total testing process (e.g., the way results are reported, critical values communication, counseling in test results interpretation).

6. *Move clinical laboratory out of the silos* The clinical effectiveness of the so-called "silos" laboratory facilities is almost certainly questionable. Laboratory services should hence be reorganized according to patient-centered care, where sustainability and clinical outcomes shall be integrated. Laboratory professionals should be more engaged in large interdisciplinary teams, where they could bring their skills and expertise for developing more efficient and effective care pathways [16].
7. *Support changing of reimbursement models* In recent years, the organization of healthcare systems has evolved from models simply based on reimbursement of services to others more comprehensively relying on diagnosis-related group (DRG), where reimbursement is increasingly based on outcomes, and hence comprehensive of both diagnostic and therapeutic pathways [17]. This evidence shall further encourage a parallel evolution of laboratory medicine services towards models based on the value of laboratory information rather than on costs [18].
8. *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 a substantial innovation of teaching laboratory medicine, in both medical schools and post-graduate courses [19].
9. *Enhance all professional tasks* The role and activities of laboratory professional have progressed in parallel with sociocultural and economic evolutionism. Laboratory managers are not solely committed to accurate and efficient analysis of biospecimens, but are now deeply involved in a vast array of administrative tasks encompassing optimization of test menus, withdrawing obsolete or redundant diagnostic investigations, providing appropriate education and training to the personnel, administering human and economic resources, managing budgets and introducing technological advancements [20].
10. *Promote the value of the profession* Steven H. Kroft has recently highlighted the substantial evolution of the role of laboratory professionals in healthcare, by affirming 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" [19]. This brilliant description symbolizes the many current responsibilities of laboratory professionals, whose complexity has enormously grown in recent times.

We sincerely hope that this clinical adaptation of the 10-point manifesto [20] will help establishing a strengthened partnership between the laboratory and the clinics, and will drive the route of laboratory medicine towards a brighter and more sustainable future.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Statement of human and animal rights This article does not contain any studies with human and animals performed by any of the authors.

Informed consent None.

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