Laboratory medicine is a medical specialty at the centre of healthcare. When used optimally laboratory medicine generates knowledge that can facilitate patient safety, improve patient outcomes, shorten patient journeys and lead to more cost-effective healthcare. Optimal use of laboratory medicine relies on dynamic and authoritative leadership outside as well as inside the laboratory. The first responsibility of the head of a clinical laboratory is to ensure the provision of a high quality service across a wide range of parameters culminating in laboratory accreditation against an international standard, such as ISO 15189. From that essential baseline the leadership of laboratory medicine at local, national and international level needs to ‘add value’ to ensure the optimal delivery, use, development and evaluation of the services provided for individuals and for groups of patients. A convenient tool to illustrate added value is use of the mnemonic ‘SCIENCE’. This tool allows added value to be considered in seven domains: standardisation and harmonisation; clinical effectiveness; innovation; evidence-based practice; novel applications; cost-effectiveness; and education of others. The assessment of added value in laboratory medicine may be considered against a framework that comprises three dimensions: operational efficiency; patient management; and patient behaviours. The profession and the patient will benefit from sharing examples of adding value to laboratory medicine. Laboratory medicine data informs a high percentage of clinical decisions in healthcare. The percentage is often quoted as being approximately 70%, although a more recent assessment suggests that the impact of laboratory medicine varies with the clinical specialty and application. What is beyond doubt is that laboratory medicine is an essential element of the healthcare system providing users with pivotal information for the prevention, diagnosis, treatment and management of health and disease. The global laboratory medicine market represents < 5% of total healthcare expenditure. This central role of laboratory medicine in healthcare means that the leadership of the discipline has a responsibility to ensure that it is used optimally to the benefit of the patient and the healthcare system. In this context leadership must include the director of local laboratory medicine services and also those in learned professional societies and other specialist laboratory medicine organisations at a national and international level. (1)

Ministries of Health as well as hospital chief executive officers, department heads, and medical directors from a wide range of hospital types consistently rate quality care and value-for-money as key priorities. The role of the laboratory is changing across the healthcare continuum and new laboratory diagnostics are coming to market at an ever-increasing rate. There is a need to better define, measure, and evaluate the value of laboratory diagnostics. Significant changes in the healthcare environment and the laboratory testing process are requiring hospital and government leaders to continually assess the value of laboratory diagnostics relative to other health system investments. Health leaders are faced with rising demand and cost increases which are projected to worsen. Current cost challenges include the management of chronic age-related diseases, the prevalence of which will grow as the population ages. The increase in healthcare costs related to these conditions has created the need for innovative technology that provides faster and more specific, accurate, and affordable information to enable a shift to disease prevention. It is likely
that the laboratory will play a central role in this process. Cost containment and constraints are reflected in recent healthcare reform recommendations including:

- identifying and reducing resource utilization in high-impact, high-cost areas;
- reducing hospital and physician wait times;
- reducing re-hospitalization rates;
- implementation of patient-based payment systems for healthcare providers;
- incentives for quality, efficiency, and improved patient outcomes.

Laboratory tests have a significant impact on clinical decision making and provide healthcare professionals with information to aid in disease prevention, diagnosis and personalized treatment. As much as 70% of clinical decisions may be informed by data from the medical laboratory, although data are lacking on the precise number. Despite this influence, the total healthcare expenditure dedicated to laboratory medicine is reported to be less than 5%, as already said. The contributions of laboratory medicine to healthcare delivery are, arguably, under-recognized. The paucity of evidence demonstrating the impact of laboratory medicine on costs and outcomes may contribute to this perception. This market growth is driven largely by the need for innovative technology to meet the growing demand for quality healthcare within constrained budgets. Low perceived value coupled with the lack of outcomes evidence has resulted in reimbursement and uptake challenges for laboratory diagnostics. Laboratory diagnostics are typically reimbursed at the Ministry of Health or hospital and laboratory levels. With competing health care priorities and new innovative diagnostics entering the market at an ever-increasing pace, there will be a need to better define, measure, and evaluate their value to aid in decision-making. To date, the value of laboratory diagnostics has largely been ill-defined in that the literature is not only dispersed but focuses on one aspect of value or another (eg, efficiencies gained in the laboratory, vs patient effects, vs patient and hospital outcomes and costs). This is likely reflected by the lack of a coordinated response by the various stakeholders (eg, laboratory scientists, physicians, academics, industry). (2)

A key question about the accuracy of a diagnostic test/biomarker is whether that test improves the diagnostic workup beyond already available diagnostic test results. The reporting on the relative increase in discrimination and disease classification is relevant to obtain insight into the incremental value of a diagnostic test or biomarker (3).

All who work in laboratory medicine have anecdotal evidence of the value of laboratory medicine in delivering safe and effective patient care and improving individual patient outcomes by enabling faster, more accurate diagnosis and effective treatment. However, systematic evidence of the contribution of laboratory medicine to the clinical process has been much harder to obtain – understandably so, in view of the multitude of factors that are involved in reaching a diagnosis or planning treatment for an individual. Laboratory medicine has also had a broader impact upstream of diagnosis and management, playing a key role in areas such as risk assessment and screening of healthy subjects for latent disease. These areas are becoming increasingly important with the recognition that early diagnosis and intervention reduces overall healthcare costs for a wide range of common diseases. The so-called “70% claim” is commonly cited to indicate the value of laboratory medicine. It occurs in various forms, most commonly that “Laboratory medicine data influences 70% of clinical decisions”, or minor variations around this figure. Unfortunately, the data on which this claim was based represents unpublished studies and anecdotal observations,
and cannot now be objectively verified. We need more specific and evidence-based measures of the added value of laboratory medicine, which in turn require better designed studies and better use of existing biomarkers. A recently published paper, however, shows that in the US and Germany, in more than 66% of the cases, laboratory information is essential in achieving a clinical diagnosis in cardiology and oncology. According to the data published in this study, in vitro diagnostic (IVD) costs account for 2.3% and 1.4% of total healthcare expenditures (HCE) in the US and Germany, respectively (4). In addition to this evidence, further studies emphasize the increasingly important role of laboratory tests, particularly in improving the diagnostic process and reducing diagnostic errors (5). Laboratory doctors and scientists of the future must be involved in producing guidelines for investigation, advising clinical staff on the best strategy for individual clinical presentations and the further tests needed to confirm a diagnosis, and ensuring that results are not misinterpreted or missed and that resources (human, technical and financial) are used to do the right test on the right person at the right time. (6)

While the frequency of laboratory errors varies greatly, depending on the study design and steps of the total testing process (TTP) investigated, a series of papers published in the last two decades drew the attention of laboratory professionals to the pre- and post-analytical phases, which currently appear to be more vulnerable to errors than the analytical phase. In particular, a high frequency of errors and risk of errors that could harm patients has been described in both the pre-pre- and post-post-analytical steps of the cycle that usually are not under the laboratory control. A further step in the journey towards improved understanding of the issue is the recent demonstration that errors in laboratory medicine are part of a much wider issue, commonly known as “diagnostic error”, thus definitively linking laboratory-associated errors to patient safety problems. The current awareness of the nature of laboratory testing associated errors, in particular the link between appropriate test ordering and result interpretation/utilization, and their potential in reducing diagnostic errors, should herald a change in the old paradigm which was focused only on errors detected within the laboratory walls. Evidence-based quality indicators represent a formidable tool for improving quality and decreasing the risk of errors in the total testing process. During the past decade, after the publication of the Institute of Medicine (IOM) report, To Err Is Human, patient safety has finally become the object of medical and public attention. Compared with other types of medical error, however, errors in laboratory medicine have received little attention. The reasons for this neglect are complex, but the difficulties largely arise from the number of steps and the time lapse which separate laboratory testing, physicians’ actions and patient outcomes. Moreover, usually only the analytical phase falls under laboratory control, while the pre- and post-analytic phases are the responsibility of stakeholders other than the laboratory such as the clinician, the nurse, the patient and others involved in patient identification, data entry, specimen collection and transport. In addition, most of the many different terms used in the literature to define errors in laboratory medicine (e.g. mistakes, blunders, defects, outliers, unacceptable results, quality failure) have negative connotations involving blame, individual failure and culpability and, even worse, pertain to studies focusing on a limited number of total testing process (TTP) steps. Taken together these are the “reasons for neglect” for errors in laboratory medicine, and should explain why the patient-centered viewpoint has been taken into account only in recent years. According to recent data from malpractice claims, diagnostic errors appear to be the most common, most costly and most dangerous of medical mistakes both in inpatients and outpatients. Failure in the ordering of appropriate laboratory test and the application of laboratory test results are major contributors to diagnostic errors, along with residual problems in test performances (analytical errors). Therefore, the main message is the need to improve the quality of laboratory services, avoiding errors and improving patient safety, employing a global approach across the TTP, according to the seminal concept of
the brain-to-brain loop. The use of a consensually-defined list of evidence-based QIs to be applied in the accreditation programs of clinical laboratories according to the current International Standard (ISO 15189:2012) is an effective tool for improving quality, decreasing the risk of errors and increasing patient safety. (5)

Successful management of laboratory test utilization requires the entire laboratory team to use their skills and knowledge to identify utilization issues, implement a program that will achieve more effective testing and establish appropriate processes from the beginning to the end of the test cycle. (7)

The World Health Organization–World Alliance for Patient Safety has identified patient identification and test result management as priority areas. While the right identification of the patient and his/her samples is absolutely essential to assure not only safety and quality, but also efficiency to the entire test cycle, the end of the cycle requires higher concern. Poor test result follow-up can have major consequences for the quality of care, including missed diagnoses and suboptimal patient outcomes. Information technology (IT) has the potential to enhance the performance and safety of test result management processes. Effective solutions must engage all stakeholders, including consumers, in arriving at decisions about who needs to receive results, how and when they are communicated, and how they are acknowledged and acted upon and the documentation of these actions. Meeting these challenges requires the establishment and maintenance of resilient governance approaches and a culture dedicated to ensuring the reliability and safety of patient care. Failure to follow up laboratory test results is a significant concern and a priority patient safety area. The issue of missed test results is multi-dimensional, and involves a number of interconnected issues encompassing both test result management practices and the systems involved in the process. An examination of existing research has revealed a lack of consistency in how test results are managed in the post-analytic laboratory testing phase, including variations and ambiguity in policies regarding result notification procedures, identification of critical results, timeliness of results reporting, and acknowledgement of result receipt. Improving the safety of test result management through IT initiatives involves the establishment of a fully integrated electronic system that is implemented as a component of the solution alongside appropriate clinical and organizational governance elements. The success of IT interventions is intrinsically linked to resilient management arrangements, attention to clinical governance and commitment to robust evaluation practices which address issues with laboratory test management work practices and guidelines at the post-analytic testing phase. The empowerment and engagement of consumers in the management of their own healthcare data will further the move towards a culture which delivers reliable and safe patient care. (8)

The ultimate goal of diagnostic testing is to guide disease management in order to improve patient outcomes and patient well-being. The relative spend on diagnostics compared with pharmaceuticals indicates that diagnostic tests are underappreciated in relation to the medical and economic value that they deliver. Clinical laboratory diagnostics should be viewed as a pivotal part of the healthcare system and valued accordingly. The skills available in clinical laboratories around the world should be harnessed to ensure the continued development of accurate tests that inform the healthcare community with respect to the pathophysiology of disease and facilitate the screening, diagnosis, appropriate treatment and monitoring of patients. Laboratory medicine will need to form alliances with clinicians, healthcare managers and insurers, as well as the general public, and gain these stakeholders as advocates for valuing laboratory medicine according to the information it delivers to facilitate optimum clinical care. (9)
In conclusion as already published in 2007 “The mission of clinical laboratory medicine is to improve patient care by improving laboratory testing. If the discipline wants to be positioned strategically for the future, it must enhance efficiency by consolidation, formation of alliances or partnerships, and (horizontal and vertical) integration. Efficiency is a prerequisite for success, but not a guarantee. The relevant standard is value. To add value, the core competency of laboratory professionals must be refocused on providing additional knowledge services related to in vitro diagnostic services.” (10)

References

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