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Opinion Paper

Graham H. Beastall*

Adding value to laboratory medicine: a professional responsibility

Abstract

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.

Keywords: adding value; clinical outcomes; professional leadership.

*Corresponding author: **Graham H. Beastall**, President, International Federation of Clinical Chemistry and Laboratory Medicine, IFCC Office, Via Carlo Farini 81, 20159 Milan, Italy; and University of Glasgow, Glasgow, UK, Phone: +39 02 66809912, Fax: +39 02 60781646, E-mail: president@ifcc.org

Introduction

Laboratory medicine data informs a high percentage of clinical decisions in healthcare. The percentage is often quoted as being approximately 70% [1], although a more recent assessment suggests that the impact of laboratory medicine varies with the clinical specialty and application [2]. 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 [3]. The global laboratory medicine market is expected to reach USD 52 billion in 2013 [4] and, although this is a large sum, it represents <5% of total healthcare expenditure [5].

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.

Assuring quality in laboratory medicine

The provision of a high quality laboratory medicine service is the primary responsibility of every professional working in the discipline. There are many definitions of a high quality laboratory medicine service; there is a vast literature on the subject; and there are organisations dedicated to its practice and continuous development. One simple definition is 'the establishment of conditions such that the quality of all tests performed in laboratory medicine assists clinicians in practising good medicine' [6].

Figure 1 summarises the components required to deliver a high quality laboratory medicine service. On the left hand side of this figure are the factors required to assure the quality of an individual test result or

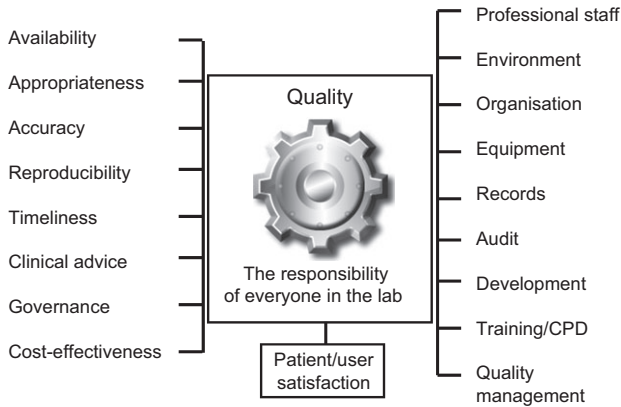


Figure 1 Assuring quality in laboratory medicine. Parameters listed on the left of figure relate to the properties required of a test or investigation and the use of the result obtained. Parameters listed on the right relate to the requirements that need to be in place in order for a clinical laboratory to deliver a quality service. CPD, continuing professional development.

investigation. On the right hand side are the parameters required by the laboratory to assure the quality of the supporting infrastructure in the present and into the future. Central to the quality service is that it meets the needs of users as assessed through surveys of user satisfaction. The figure also reinforces that quality in laboratory medicine is the responsibility of everyone, not just of the laboratory director or quality manager. Finally, the central cog signifies that high quality laboratory medicine is the essential engine to enable a value added service.

The most comprehensive measure of quality in laboratory medicine is currently laboratory accreditation against an international standard. In Europe the current standard of choice is ISO 15189-2007 'Medical laboratories – particular requirements for quality and competence' [7]. Accreditation of laboratories offering laboratory medicine services is now widespread across Europe although it is mandatory in only one country [8]. Laboratory accreditation encompasses the 'end to end' process from selecting and requesting an investigation to receiving a validated laboratory report that includes information to assist with interpretation and knowledge that may be applied to individuals or to groups of patients. It is worthy of note that the very few errors that do occur in the laboratory medicine process are usually in either the preanalytical or postanalytical phases of the process [9] where the laboratory medicine specialist traditionally has had least influence. This important observation provides a valuable pointer to future role of laboratory medicine being increasingly outside the laboratory, adding value to the quality product produced within the laboratory.

Understanding added value in laboratory medicine

The concept of 'added value' in Laboratory Medicine has existed for many years. The growing need for 'clinical laboratory consultants to add value and medical relevance to the healthcare system to earn and maintain their roles in an era of managed care' was described in 1995 [10]. This visionary publication focussed on a range of opportunities that look beyond the generation of an authorised laboratory report in order to ensure that the laboratory medicine service achieves optimal clinical relevance for users and that it takes advantage of rapid advances in technology and our understanding of the disease process and treatment opportunities. Panteghini concluded that 'the importance and true impact of laboratory medicine can only be achieved by adding value to laboratory tests, represented by their effectiveness in influencing the management of patients and related clinical outcomes' [11].

The rate of change in the scope, configuration, delivery and application of laboratory medicine has never been greater. Demand for laboratory medicine services is growing rapidly [1]. This change and increased demand is happening at a time of financial pressure in healthcare across the developed world. Consequently, laboratory medicine specialists face the growing challenge of delivering a modern service that is both clinically efficient and cost-effective. This can only be addressed by 'working smarter' – which includes eliminating waste, targeting clinical priorities, adopting automation and communication technology, altering the staff skill mix, networking services and sharing the costs with users. It is neither reasonable nor desirable for laboratory medicine specialists to expect the users of the service to understand how to make the most effective use of a changing service. Therefore, it must be the role of leaders in laboratory medicine to take responsibility for this process of knowledge management, education and support. This process constitutes 'adding value' to laboratory medicine. It is a process that should occur at local level between every laboratory medicine service and its users. It should also occur at a regional, national and international level to ensure that policy makers and those responsible for commissioning clinical services understand the pivotal role that laboratory medicine should play in a modern health service. Against this background this article seeks to provide a contemporary definition for 'added value' and to introduce a tool that will help laboratory medicine specialists appreciate where and how they can add value to the service that they provide.

The following definition of adding value to laboratory medicine is recommended: ‘The addition of value to laboratory medicine services is the responsibility of leadership in the speciality. It comprises working with users of the service and those responsible for defining and commissioning clinical services to ensure that the available high quality laboratory medicine services:

- Develop in line with contemporary knowledge and modern technology
- Are evidence-based
- Are cost-effective in the context of the patient journey and local targets
- Facilitate improved clinical outcomes
- Contribute to increasing patient safety
- Are better understood by users, patients, the media and the wider public.’

Adding value to laboratory medicine through the appliance of ‘SCIENCE’

As the previous paragraph reveals the addition of value comprises several related dimensions. A simple tool has been developed to simplify understanding (Figure 2).

The mnemonic ‘SCIENCE’ may be used to consider adding value in each of seven domains. Each of these domains will be considered in turn. It should be stressed that at the centre of this tool is the essential requirement for a high quality laboratory service, consistent with that delivered by an accredited laboratory.

Standardisation and harmonisation

Patients and the public are increasingly mobile and their clinical records may be accessed from wherever they are based. Therefore, laboratory medicine records should provide a consistent and coherent message. This is a matter of patient safety [12]. Standardisation addresses the issue through conformance to an agreed standard. Harmonisation addresses the issue through consensus agreement where no standard exists. Within laboratory medicine there are active initiatives to standardise/harmonise both practices and methods.

Laboratory medicine practices that may be standardised include nomenclature and units of measurement [13]. Practices that may be harmonised include reference intervals and action limits [14]. Further harmonisation of investigative protocols is evidenced through the growing availability of laboratory practice and clinical practice guidelines. Results from point of care testing (POCT) devices should be harmonised with those used by the central laboratory.

The standardisation and harmonisation of laboratory methods is an international partnership initiative involving laboratory medicine specialists together with scientists from the in vitro diagnostics industry. Method standardisation is a formal process that requires adherence to metrological traceability [15]. This has only been achieved for a relatively small number of biomarkers, which are listed by the Joint Committee for Traceability in Laboratory Medicine [16]. A new international project has been proposed to address a co-ordinated approach to the harmonisation of the many methods that cannot meet the requirements of standardisation [17].

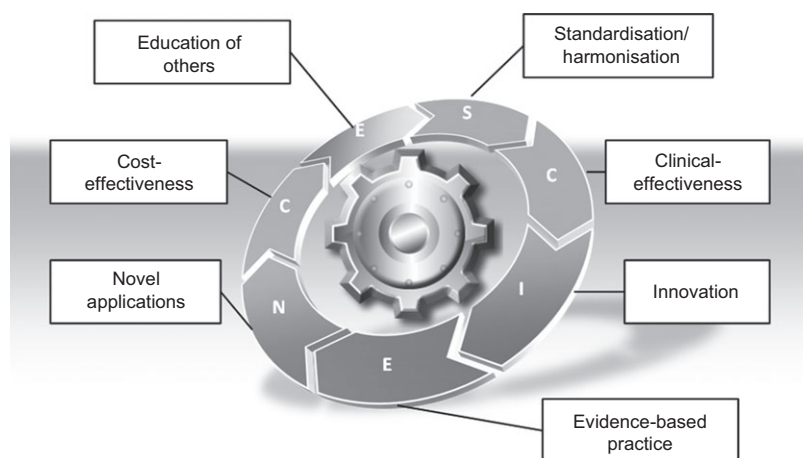


Figure 2 Adding value to laboratory medicine through the appliance of ‘SCIENCE’.

The mnemonic ‘SCIENCE’ describes the seven domains in which value can be added to a quality laboratory medicine service. The central cog refers to the high quality laboratory medicine service from Figure 1 that is necessary to drive added value.

Clinical-effectiveness

Laboratory medicine can make a major contribution to improving clinical effectiveness. This can be achieved through:

- The provision of direct patient care by medically qualified laboratory medicine specialists
- The provision of rapid and accurate interpretive reports, which allow patients to be referred to the appropriate clinical team for further investigation and/or treatment, thus facilitating improved clinical outcomes
- The provision of a clinical liaison advisory service
- Participation in multidisciplinary clinical team meetings
- Participation in clinical audit projects
- The derivation and implementation of clinical practice guidelines.

There are many examples of laboratory medicine specialists taking the initiative to add value in order to deliver improved clinical effectiveness. These include the selection of clinical quality indicators [18], provision of interpretive comments on reports to primary care physicians [19], critical value reporting [20], and reflective testing [21]. In addition, the profession has introduced external quality assessment of the comments made on reports in an attempt to share good practice and achieve better agreement [22].

Innovation

Innovation has been at the heart of laboratory medicine for decades and it continues to be a dynamic driver of change. Advances in our understanding of the molecular basis of disease and the ‘omics’ revolution are leading to many candidate biomarkers. Translation of original research findings into clinical practice is challenging and a systematic approach is required to determine the accuracy and clinical utility of new biomarkers [23]. Advances in technology are meeting the demand for improved specificity (e.g., mass spectrometry), miniaturisation, more rapid turnaround and self-monitoring by patients using POCT.

Innovation is also possible in the delivery of the laboratory medicine service in an attempt to combine modernisation with improved clinical and cost-effectiveness. Examples include developments in automation and robotics, laboratory networking [24], shared technology and integrated diagnostics [25].

There is merit in coordinating innovation and in targeting translational research funding. The UK National

Health Service is supporting a number of initiatives to stimulate innovation in healthcare and transform good ideas into workable solutions.

Evidence-based practice

Evidence-based medicine comprises the distillation of research evidence, clinical expertise and patient values. The adoption of evidence-based medicine should facilitate consistent practice and improve clinical outcomes. Laboratory medicine specialists are trained to search and critically appraise the scientific and clinical literature and so are well placed to practice and contribute to the development of evidence-based laboratory medicine [26].

Every laboratory medicine specialist should ensure that current laboratory practice and clinical practice guidelines are consistent with the latest evidence from the literature. This will involve acting as ‘knowledge manager’ in discussions with users of the service. A proactive approach is required to ensure that laboratory medicine specialists are part of the multidisciplinary team that prepares new evidence-based guidelines. Supporting literature is available to assist in this process [27]. The Cochrane Library provides access to >5000 evidence-based reviews across healthcare [28]. A wide range of evidence-based clinical practice guidelines are available, many of which include laboratory medicine investigations. One reputable source is the National Institute for Health and Clinical Excellence [29].

Novel applications

Until recently medicine was reactive, being population focussed, system-based and therapeutic. The patient has been a passive partner. However, we are now facing an exciting new direction as we move to medicine that is predictive, personalised, preventive and participatory (P4 medicine) [30]. This change of direction is based on individual genome properties and so underpinned by modern molecular laboratory medicine. Pharmacogenomics is one established and growing area of P4 medicine and we are seeing the introduction of companion diagnostics in which the molecular diagnostic test is a prerequisite for selecting a patient for specific therapeutic drugs, notably in cancer [31].

The growth of P4 medicine presents a great opportunity for laboratory medicine to reinforce our central role in healthcare. We will need to think of patients as individuals and in so doing the importance of reference intervals

and population-based action limits will diminish. We will need to think of wellness and risk stratification rather than disease. We will need to embrace a new range of methods and also the bioinformatics that will be essential to interpret complex data and algorithms from individual subjects.

Cost-effectiveness

The challenges presented by the need for the laboratory to be cost-effective tend to dominate thinking and are regarded by many specialists as a barrier to implementing the other domains of added value. However, all laboratory medicine specialists have a responsibility to deliver a cost-effective service without compromising quality. There are three broad areas in which cost-effectiveness can be addressed. First, efforts can be made to contain or reduce the direct costs of running the laboratory. These include:

- The elimination of waste by using LEAN technology [32]
- Economies of scale from laboratory networking and the sharing of common equipment between laboratory specialties
- Adjusting the skill mix of the staff to match the increasing automated technology.

Second, efforts can be made to reduce unnecessary testing through demand management and test request rationalisation. This is a topic of growing importance but it can be difficult to quantify its clinical and financial impact [33]. In one well-controlled study a significant reduction in unnecessary testing was achieved through educational support for users [34].

Third, efforts can be made to adopt a more appropriate business model. At present laboratory medicine is often regarded as a ‘production centre’ with little or no link between output and clinical effectiveness. Inadequate reimbursement, fixed costs and silo budgeting all create an environment where it is difficult for laboratory medicine specialists to react to a rising workload and also bring in the added value that can make a difference to patients. A business model based on laboratory medicine as a ‘service centre’ would be more appropriate with funding linked to the contribution to the care pathway [35].

Educating users and others

For many years laboratory medicine could be regarded as ‘the best kept secret in healthcare’. The profession

has produced continuous quality improvement, introduced high international standards of practice and succeeded in delivering a rapidly rising workload for little or no increase in costs. However, we are taken for granted by our many of our users and peers and largely unknown to the patient and the public. We have the image of being dominated by machines, which are kept running by a few ‘boffins’ who work out of sight of the rest of the health-care team. Recently, that situation has begun to change and one of the most important functions of the laboratory medicine specialist is to look outside the laboratory and actively promote the contribution of laboratory medicine to healthcare.

There are many ways in which the contribution of laboratory medicine to healthcare may be promoted. These include:

- Providing evidence-based information in handbooks, publications and websites. ‘Lab Tests on Line™’ is a shining example of what is possible [36]
- Participating in clinical audit, in multidisciplinary clinical team meetings and in groups responsible for writing clinical practice guidelines
- Achieving greater contact with patients by visiting wards and clinics and by providing expert advice to patient organisations
- Making a coordinated effort to engage with the media and the public. The National Pathology Year 2012 in the UK is a wonderful example of what is possible [37].

A framework for assessing the value of laboratory medicine

The assessment of the added value in laboratory medicine will vary according to the perspective of the person carrying out the assessment. Thus, the healthcare manager or economist will try to answer the question ‘does it offer value for money?’ The physician will ask ‘will it improve the clinical outcome of the patient?’ The patient will consider ‘will it help to resolve my problem in a speedier or less invasive way?’ Accordingly, a framework has been proposed for the assessment of the value of any development in laboratory medicine across three dimensions [38].

Optimisation of operational efficiencies

Operational efficiency relates to the ability of a laboratory to provide rapid results and reports which may

affect the further investigation, management or discharge of the patient. Automated laboratory instruments that improve workflow, informatics solutions that allow test results to rapidly reach physicians and middleware applications that reduce medical errors and improve turnaround time are all aspects of laboratory medicine that may contribute to operational efficiencies. Criteria that may be used to assess operational efficiency include:

- Efficient patient triage
- Patient waiting times and the length of the patient journey
- The rate of re-investigation and re-admission
- Operational costs.

Optimisation of patient management

The optimisation of patient management will depend to a large extent on the laboratory providing an interpretive service that enables that laboratory information to be converted into knowledge for the benefit of the individual patient or groups of patients. The early deployment of an appropriate diagnostic test, the use of evidence-based clinical practice guidelines and the effective application of clinical audit are examples of how laboratory medicine can contribute to the optimisation of patient management. Criteria that may be used to assess operational efficiency include:

- Reduction in unnecessary investigation and treatment
- Reduction in time taken and money spent on patient investigation
- Improved patient outcome and/or improved quality of life.

Influence on patient behaviour and other effects

This dimension refers to the ability of laboratory medicine to provide information to patients that will lead them to make different lifestyle choices or change their sense of satisfaction and well-being [39]. Alteration of diet or exercise; the use of prophylactic medicines; self-monitoring; and planning for retirement may all be affected by a patient knowing the result of an investigation that highlights present or future risk of disease.

Criteria that may be used to assess operational efficiency include:

- Evidence of patient empowerment
- Information leading to a sense of satisfaction or well-being
- Evidence of lifestyle management.

Using this simple framework any value that laboratory medicine can add may be assessed. Most developments are likely to add value to more than one of these three dimensions [38]. For example, the introduction of a clinically validated new biomarker will influence patient management and if it reduces the need for other investigations it is also likely to facilitate operational efficiency. Alternatively, patient self-monitoring for chronic disease using POCT will influence patient behaviour and should lead to better patient management. Depending on the costing model in place the use of POCT may also influence operational efficiency.

Conclusions

In nations with developed healthcare systems laboratory medicine specialists have been at the forefront of delivering services of the highest quality and they have been proud to embrace external accreditation. In achieving this status they have focussed on what goes on inside the laboratory. The time is now right for laboratory medicine specialists to also look outside the laboratory as part of the multidisciplinary team that seeks to optimise clinical outcomes and patient experiences in an efficient and cost-effective way. As this article describes this process of adding value to laboratory medicine may be considered in a logical and convenient manner. A mechanism is required to share examples of added value and good practice.

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