Opinion paper

Leveraging the real value of laboratory medicine with the value proposition

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A B S T R A C T
Improving quality and patient safety, containing costs and delivering value-for-money are the key drivers of change in the delivery of healthcare and have stimulated a shift from an activity-based service to a service based on patient-outcomes [2]. These developments occur in an environment emphasising the need for a patient-centred focus of healthcare as well as providing a more integrated approach to health and social care [3]. While such aspirations and drivers are rightly focused on individual patients and the requirements of the wider population, it is also important to recognise that they are shared with, and relevant to, a number of stakeholders representing the various clinical disciplines as well as the various individuals and organisations involved in policymaking, purchasing and delivering healthcare (Fig. 1). The complexity of providing healthcare services in relation to the expectations of each stakeholder, with particular attention to the contribution by laboratory medicine, is summarised in Appendix 1 of this document.

Currently the business models involved in the delivery of healthcare, including laboratory medicine, are primarily designed, managed, and executed in individual units or silos. Such units are driven by activity in their respective disciplines, as well as being managed according to performance metrics that match these disciplines – rather than the product of the clinical pathway, and the contribution of the stakeholders. Thus, in the case of laboratory medicine there is, primarily, a focus on the quality of analytical performance, volume of activity and cost of delivery. However, the central role of the laboratory medicine service is to deliver the results of investigations that enable clinicians and other stakeholders to make better decisions. Consequently, the real value of the laboratory medicine service is found in other silos, with the benefits appreciated by other stakeholders. More recently this approach has been explored with the more advanced diagnostic tests (e.g. molecular and genetic tests) with a trend from a volume based- to a more outcomes based approach to laboratory medicine [4].

In order to deliver an outcomes-based healthcare agenda the real value of the laboratory medicine service to all stakeholders has to be understood, effectively defined, communicated, and applied. This will only be fully appreciated through service delivery based on the adoption of a value proposition for laboratory medicine [5]. The content of this document has been endorsed by the Executive Board of the International...
Federation of Clinical Chemistry and Laboratory Medicine (IFCC) and the Bureau of the World Association of Societies of Pathology and Laboratory Medicine (WASPaLM).

1.1. Background: making the case for a value proposition

Many clinical decisions made in caring for individual patients are facilitated by the results from laboratory medicine investigations. They can impact on the clinical outcome for patients, on the operational efficiency of the process of care, and the resources required for the delivery of that care. However, these objectives are compromised by a limited evidence base that demonstrates the utility and benefits of such investigations, as well as paying insufficient attention to ensuring that the laboratory medicine services are fully integrated into the care pathway – and consequently utilised efficiently.

Quality improvement in laboratory medicine embraces a number of activities, including (i) quality control and external quality assurance, (ii) audit, (iii) performance management, and (iv) strategic planning at both the service purchasing and service provision levels. However, quality improvement tends to focus on the analytical aspects of the laboratory service rather than considering the whole patient care pathway including the pre- and post-analytical phases. This focus may, in part, help explain the higher prevalence of pre- and post-analytical errors compared to analytical errors that is commonly reported [6]. Other quality improvement initiatives include analysis of frequency of testing [7], adherence to guidelines [8], and consensus guidance on appropriateness of laboratory test utilisation [9]. However, few of these initiatives have investigated the use of the test result in relation to patient outcome or operational and resource utilisation metrics. Resolution of many of the pre- and post-analytical problems and accepting greater accountability within the patient care pathway and outcome will only be achieved by working as a member of the clinical team.

Quality improvement also embraces innovation and it is recognised that there are often barriers to adoption of new technologies in healthcare. They include (i) poor understanding of the problem or unmet need, (ii) limited evidence of clinical and/or cost effectiveness, (iii) financial reimbursement, (iv) disinvestment in redundant procedures following adoption of new technology and/or process, and (vi) lack of planning – a symptom of the lack of an innovation culture [10]. Successful innovation is disruptive, involves change and should be patient-centred [11].

The laboratory medicine service is presently an example of the fee-for-service (or cost-per-test) business model [12]. Laboratory medicine can only contribute to the outcome- and value-based agendas through adoption of the concept of a value proposition for individual test utilities, embedded in the overall healthcare service specification. This should be developed on the basis of evidence of impact on clinical, operational and resource outcomes, and in the context of a patient-centred care pathway.

1.2. The value proposition for laboratory medicine

Value has been described as “the regard that something is held to deserve” [13]. In healthcare it is described as “outcomes relative to costs” [14]. While this is an economic perspective, and its use is most appropriate for the policymaker as the patient’s advocate, it hides the fact that healthcare is delivered through the work of a team of stakeholders each of whom have their own responsibilities (and accountabilities) with regard to outcomes and costs.

The value proposition of any product or service is the link between the provider and the needs of the customer. It describes the utility of the product or service in terms of benefit to the customer. The value proposition comprises (i) the unmet clinical need, (ii) the nature of the service, (iii) the potential benefits of the product or service, and (iv) the evidence to demonstrate that the benefit claimed can be achieved [5]. It is complemented by an implementation plan and performance management programme.

The customer values the resolution of a problem or the service provided to meet an unmet need, which can be defined in terms of clinical, operational and economic (resource) outcomes. In healthcare, while the patient is the ultimate and most important customer, all stakeholders can also be considered as customers (Fig. 1). Thus while laboratory medicine may provide a service that directly impacts a patient, typically it offers benefits to other stakeholders as well, e.g., carers, healthcare providers, those purchasing healthcare services and policymakers. Typically, the delivery of a laboratory test result, of itself, will not deliver any benefit; the value of laboratory medicine can only be considered in the context of the element of the care pathway in which the test is used. In other words, a particular action has to be taken on receipt of the result.

Therefore, the value proposition for laboratory medicine (whether it be overall service or individual test utility) is expressed in terms of contributions to guide decision making in clinical care, the process of the care delivered and the resource required to deliver that care. It is a comprehensive and practical tool for the application of Evidence-Based Laboratory Medicine (EBLM) [15,16].

A key aspect of the value proposition is taking into consideration the expectations of all stakeholders. Such teamwork can be described in terms of a customer-client relationship matrix involving each stakeholder with regard to what they expect to deliver and what they expect to receive (Fig. 1). It has been argued that focussing on value may be the most effective approach to bring stakeholders together and may provide the greatest opportunity for laboratory medicine to truly join the clinical team [17].

The framework of a value proposition provides the core business case that drives a number of key activities in the evolution and maintenance of high quality healthcare from research that stimulates the innovation cycle through to adoption and quality improvement in an established service – from problem to solution. A method for developing the value proposition is presented in Appendix 2 to this paper. The early steps in the framework reflect the EBLM cycle [15].

2. Conclusions

If one accepts the arguments for the need to move towards a more outcome-based and value-based approach to healthcare, then the value of all contributors to healthcare needs to be demonstrated and recognised, as well as becoming the basis on which healthcare is resourced, organised and delivered. The key objective of laboratory medicine is to contribute to guiding decision making that ensures the...
best health outcome for the individual patient, while minimising the risk, and at reasonable cost. Adoption of a value proposition in healthcare, including that for laboratory medicine, carries with it significant implications for all stakeholders. The clinical and cost effectiveness to be gained from the appropriate utilisation of laboratory medicine can deliver clinical, operational and/or economic benefits spread across the whole care pathway, thereby addressing the interests – and responsibilities - of all stakeholders.

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Appendix 1

Stakeholders in the provision of healthcare and their expectations from the contribution of laboratory medicine.

1.1. Patients

A great deal has been written about patient expectations in the healthcare literature which attempts to articulate the patient’s needs and expectations, and which can help to inform the actions of all healthcare stakeholders. They cover the care pathway from understanding the problem, (the patient’s unmet need) through to diagnosis and treatment, the patient’s experience, expected outcomes and the role that the patient plays in the clinical pathway. Thus in the case of laboratory medicine the patient will expect the right test to be performed, at the right time, of the right analytical quality, with the right decision being made on the result and the right action taken. The patient will be part of this “test-and-treat” cycle and in certain circumstances may perform the test and manage the treatment change, for example as in the case of warfarin management.

1.2. Carers

Carers represent a wide spectrum of individuals including friends and family, clinicians together with a range of health and social care professionals. Their expectations will undoubtedly vary but, at their core, will be access to the services that help them manage the individual patient – including access to laboratory medicine. The carers are expected to make the right decision and take the right action with the diagnostic information available to them to meet the expectation of the patient as well as the providers and purchasers of these healthcare services.

1.3. Provider organisations

Provider organisations are primarily concerned with providing the infrastructure required to support the delivery of high quality healthcare. The infrastructure will include the necessary estate, support services and management required to deliver the quality of healthcare expected by the purchasers, carers and patients. For their part the provider organisations will expect to be supported with contracts from purchasers (including the necessary reimbursement), as well as regulatory support for professional standards and regulations. Importantly, in relation to earlier observations on unit (silo) organisation and management, the call for a more integrated approach to care – both at an intra- as well as an inter-organisational level, it is here that the focus on the integration of the clinical team is most critical. It is also at this level that benefits should be measured in relation to clinical, process and economic outcomes. Further, it is at this level that the impact of laboratory medicine is best defined and explained.

1.4. Purchasers of healthcare services

Those purchasing healthcare services including government departments and insurers (depending on the health system) are primarily responsible for obtaining the best quality of care for communities and patients. They will define their expectations required of providers for their patients and communities including quality, informed by requirements defined by the policymakers and their available resources. The challenging features of the current dialogue between purchasers and providers are (i) improving the quality of care, (ii) containing the rising cost of care, and (iii) providing care closer to home. These high level objectives impact on laboratory medicine, while providing opportunities for developing laboratory medicine strategies for supporting care services closer to home.

1.5. Policymakers

The responsibility of policymakers is to ensure that the best quality of healthcare is available, accessible and affordable to the community, whether it be a country, state or region. This responsibility will extend to health and wellbeing initiatives, screening programmes as well as research, education and training required to support these services. They will invariably be challenged on how to make the best use of new technologies, e.g. communication technology, point-of-care technologies, advanced molecular diagnostics, as well as new treatments. This is where laboratory medicine has an opportunity to demonstrate the value of new investigational technologies at this level.

1.6. Laboratory medicine specialists

There are five main responsibilities for laboratory medicine professionals in the adoption of a value proposition; (i) demonstrate how their service benefits patients and all of those stakeholders that contribute to patient care, including an evidence-based indication for tests to avoid overuse, as well as managing implementation of innovation, (ii) deliver the quality of service to meet those objectives, (iii) make all stakeholders aware of how the laboratory service meets their individual needs, and (iv) make all stakeholders aware of how the benefits are best delivered, and (v) with all of the stakeholder groups, ensure that all of the benefits are delivered. These initiatives address the key issues relating to working as a clinical team, quality improvement and change management across the care pathway. These responsibilities are relevant both at a service-wide as well as individual test level.

Appendix 2

The framework of a value proposition for laboratory medicine:

1. The unmet clinical need; this represents a definition of the problem and is complemented by the impact on clinical, operational and economic outcomes.
2. Patient population that will benefit: this will include gender, age and setting in which problem arises, including in the home, primary care, paramedical vehicle, emergency department, and other hospital settings, e.g. intensive care.
3. Identity of the test and its properties: this will include the name of the test and a statement of the basic pathology with which it is associated, reference intervals or clinical decision cut-off values, biological variation and expected analytical performance.
4. Test intervention utility: screening, diagnosis, prognosis, risk stratification and/or monitoring.
5. Expected outcomes: clinical, process and/or resource utilisation.
6. Location where test is performed: laboratory and/or point of care setting, e.g. home, primary care, ambulatory hospital clinic, paramedical vehicle, hospital department.

7. Quality of evidence available: results from formal trials, observational studies, systematic review and meta-analysis.

8. Part(s) of the care pathway in which the test will be used: linked with utility.

9. Stakeholders involved in delivering and receiving the care identified in the care pathway; the potential beneficiaries.

10. Benefits to each stakeholder in relation to the outcomes identified above; again clinical, operational and/or economic linked with the stated outcome measures.

11. Potential limitations and risks associated that might be associated with introduction of the test, and a proposed mitigation strategy: this could be relevant to all of the beneficiary stakeholders and may cover clinical, operational and economic outcomes.

12. Resource/activity contributed by each of the service lines involved in the care pathway with and without the test intervention.

13. Statement of the reimbursement received for delivering the care pathway with and without (before and after) the test intervention.

14. A proposed implementation plan including the metrics for monitoring appropriate adoption.

15. Summary of the value proposition in two sentences; the executive summary/key messages.

References


