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Developing a value proposition for high-sensitivity troponin testing

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ABSTRACT

Laboratories are looking for ways that they can identify and deliver value through their service rather than just provide high quality test results. One way to demonstrate value has been described in the form of a value proposition where the application of a laboratory test is described explicitly in terms of the process of care and the patient outcomes. We have applied this concept to the use of high sensitivity troponin assays for the assessment of patients with suspected acute coronary syndrome. From a previously described framework we use a checklist to describe the various steps in the complete intervention or clinical pathway, demonstrating how the test should be used, highlighting key evidence in the literature that supports the intervention and list some of the measures which can be used to assess how well the intervention is being adopted and implemented. While the value proposition concept is based on the foundations of evidence based medicine it also requires collaboration between the laboratory and other stakeholders including clinicians to ensure that appropriate resources are applied across the complete clinical pathway in order to ensure its effectiveness.

1. Introduction

A major discussion is proceeding in healthcare about how to improve the value of services by changing the management from activity-based to one that is outcome or value-based [1]. Such value-based discussions have now reached the laboratory where for several decades, the focus of activities has been one of expanding test capacity and reducing costs. This has had several consequences including the introduction of new tests without necessarily a good evidence base. It is not surprising, therefore, that there is a wide variation in the adoption of tests (even where there are established guidelines) [2], as well as evidence of both under- and over-utilisation of tests [3]. In addition the adoption of new tests is known to be slow [4]. Furthermore there appears to be little effort made to ensure that tests are employed correctly – particularly across pathways, including limited dialogue between laboratory professionals and other stakeholders. Maximising the value of laboratory investigations offers an opportunity for laboratory professionals to drive laboratory medicine toward a more value - and outcomes-based service, that is more appreciated by all stakeholders [5,6].

To address these issues the concept of a value proposition for laboratory medicine has been proposed, as a means to better demonstrate the value provided by laboratory testing [7,8]. Expressed simply this value proposition is: *The provision of information to enable clinicians and other stakeholders to make better decisions about the care of individual patients*. The purpose of the value proposition is to inform the stakeholders involved in the delivery of care, e.g. a care pathway, of the benefits expected from the introduction of a new test intervention on the outcomes. The outcomes can be described in clinical, process and structure (resource utilisation) dimensions according to the individual stakeholders. This accords with the approach of Donabedian when considering quality assurance and system redesign in healthcare, of which a new care pathway and test adoption is a prime example [9].

Using this approach allows the laboratory test to be more clearly identified as an intervention. Tests are rarely interventions on their own, which is one of the reasons why the evidence base for testing is relatively poor. But a significant number of tests, alone or more often, in combination with clinical signs and symptoms, do play a key role in, and some might even say drive, the clinical care provided to patients. Consequently, there is the potential for the laboratory to play a much greater role in the adoption and ongoing management of clinical pathways, and in particular to show how the laboratory brings value to the healthcare process [7]. Furthermore the value proposition can be employed to (i) present the business case for a new test, (ii) inform the implementation plan for the adoption of a new test, and (iii) validate the adoption of a new test and associated ongoing quality improvement.

The objective of the exercise reported in this paper was to evaluate

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the value proposition framework for the adoption of high-sensitivity troponin (hsTn) assays in the management of patients with suspected acute coronary syndrome (ACS). Our choice of troponin is for several reasons. First it is a rapidly evolving area as the development and availability of more sensitive troponin assays changes the way they can be utilised in clinical care including the use of accelerated assessment strategies or protocols to rule-out or rule-in ACS in the Emergency Department (ED) [10]. Second the test plays a crucial role in the differential diagnosis of patients with chest pain [11–13]. Third it is a test associated with a care pathway which impacts on a number of different stakeholders, the considerations of which are important to determining both the effectiveness and the efficiency of the test and the resulting process of care. Last, at the present time there are recognised pressures on the work of the Emergency Department, and rapid triage and early discharge of patients presenting with suspected ACS may help to ease these pressures.

2. Methods

In the absence of a systematic review and meta-analysis of studies investigating the clinical and cost effectiveness of a high sensitivity troponin I test we have drawn on various observational studies of accelerated diagnostic pathways (ADPs) which are cited below in more detail and which are summarised in the review of Hollander et al. [10]. In addition, our value proposition is informed by the recent economic modelling study of Jülicher et al. [14].

Data for each element of the framework was extracted from the relevant studies of the use of a high sensitivity TnI assay, compared with current practice, and the potential changes (to clinical, process and economic outcomes) that could result from the adoption of a high sensitivity assay. The value proposition framework requires initial consideration of the current clinical problem, the revised clinical pathway that will address this problem, the stakeholders involved in the clinical pathway and the desired outcomes of these stakeholders.

We briefly describe below how each component of the value proposition framework as shown in the Box 1 below relates to the use of troponin testing in the particular care pathway we have chosen to describe. The intention is not to provide a comprehensive review of all the evidence relating to high sensitivity troponin assays but to identify the evidence that informs the framework of this particular value proposition, as well as the potential impact on the care pathway for all stakeholders.

3. Results

3.1. Unmet clinical need

In this value proposition, the unmet need is the timely delivery of troponin results in order to deliver a process for the safe rule out of Acute Coronary Syndrome (ACS) or Myocardial Infarction (MI) in patients presenting to Emergency Departments with signs and symptoms of myocardial infarction and without ST elevation on an ECG examination (NSTEMI).

3.2. Patient population

The population being considered for the intervention described below are those patients with possible ACS presenting to the Emergency Department, who have had at least 5 min of possible cardiac symptoms and these symptoms occurred within the previous 12 h [15].

3.3. Laboratory test intervention

The hsTnl test is a so-called high sensitivity troponin test which is reported to deliver a 99th percentile concentration of 26.2 ng/L with a corresponding coefficient of variation of $< 5\%$ and a limit of detection of 1.2 ng/L. It is used in conjunction with the ECG and a risk stratification score TIMI (Thrombolysis in Myocardial Infarction). The TIMI risk score for unstable angina or non-ST-segment elevation MI incorporates 7 predictors that are assigned a value of 1 for every positive finding [16]. The combined TIMI risk score and hsTnI results form part of an accelerated diagnostic protocol (ADP) [17].

3.4. Test intervention utility

The utility, purpose or clinical application of the hsTnI test is for the rule-out of ACS using troponin samples collected at baseline and at 2 h in conjunction with a risk prediction score (TIMI). While a number of different ADPs have been published that use this combination we are focussing on the primary diagnostic utility that rules-out ACS if the TIMI risk score is ≤ 1, the presentation ECG is non-ischaemic and the 0 and 2 h hsTnI levels are below the cut-off. This has been published as the modified ADAPT strategy [17].

Box 1

The framework of a value proposition for laboratory medicine (modified from ref. [8])

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 the 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. Benefits/disadvantages to each stakeholder involved in delivering and receiving the care identified in the care pathway; in relation to the clinical, operational and/or economic outcomes identified above.
10. 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.
11. Resource/activity contributed by each of the service lines involved in the care pathway with and without the test intervention.
12. Reimbursement required for delivering the care pathway with and without (before and after) the test intervention.
13. A proposed implementation plan including the metrics for monitoring appropriate adoption.