Opinion Piece

A call for a value based approach to laboratory medicine funding☆

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ABSTRACT

All areas of healthcare, including pathology, are being challenged by the reality that the days of ever increasing budgets are over and the key debate is about how to provide value for money. As originally described by Porter and Teisberg, value-based healthcare is defined as maximising outcomes over cost by moving away from fee for service models to ones that reward providers on the basis of outcomes [1]. While production efficiencies will continue to evolve, the opportunities for future stepwise improvements in production costs are likely to have diminished. The focus now is on delivering improved testing outcomes in a relatively cost neutral or at least cost effective way. This brings pathology into line with other health services that focus on value for money for payers, and maximising health outcomes for consumers. This would signal a break from the existing pathology funding model, which does not directly recognise or reward the contribution of pathology towards improved health outcomes, or seek to decommission tests that offer little clinical value. Pathology has a direct impact on clinical and economic outcomes that extend from testing and it is important to garner support for a new approach to funding that incentivises improvements of the overall quality and contribution of the pathology service.

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1. Introduction

All areas of healthcare, including laboratory medicine, or pathology as it is more commonly called in Australia, are being challenged by the reality that the days of ever increasing budgets are over and the key debate is about how to provide value for money. As originally described by Porter and Teisberg, value-based healthcare is defined as maximising outcomes over cost by moving away from fee for service models to ones that reward providers on the basis of outcomes [1].

In Australia the dominant model of pathology funding is fee for service, which has focussed payers on costs, and by extension focused pathology practices on cost minimisation. The past decade or more has seen an era of ‘commodification’ of laboratory tests, with large scale automation and market concentration to achieve economies of scale and scope.

The efficiencies that laboratories have been able to achieve have largely been passed onto payers with a long term decline in reimbursement as indicated by medical rebates for pathology falling by 7.6% from 2000 to 2013 compared to the consumer price index which has increased by 43% over the same period [2].

While production efficiencies will continue to evolve, the opportunities for future stepwise improvements in production costs are likely to have diminished. The focus now is on delivering improved testing outcomes in a relatively cost neutral or at least cost effective way. This brings pathology into line with other health services that focus on value for money for payers, and maximising health outcomes for consumers.

This would signal a break from the existing pathology funding model, which does not directly recognise or reward the contribution of pathology towards improved health outcomes, or seek to decommission tests that offer little clinical value. Pathology has a direct impact on clinical and economic outcomes that extend from testing and it is important to garner support for a new approach to funding that incentivises improvements of the overall quality and contribution of the pathology service.

This means promoting appropriate and efficient test selection, avoiding pathology testing that adds no value, and building better relationships and information sharing with referrers to achieve these goals.

Promoting the “value” of pathology is a key focus of the Health Economics Working Group of the Australasian Association of Clinical Biochemists (AACB), which is assembling existing, and encouraging
the future development of, health economic evidence for pathology testing, and how to use that evidence to develop models that demonstrate the value of pathology.

This initial paper presents the underlying issues and an outline of initial proposals for future work.

2. Underlying issues

2.1. Strategic vision for pathology

It is critical that the pathology sector and government (payers) come together to offer a long term strategic vision about how pathology should develop in Australia, in addition to the underlying goal of minimising costs to the health system. Some areas where a longer term and more strategic focus on value would generate better testing and health outcomes include genetic services and point-of-care testing (POCT).

Genetics is an area that is rapidly changing in terms of automated technology and with considerable potential to impact patient outcomes. Scale economies are more difficult to achieve but partnered with a tailored approach to therapy selection and treatment, it offers enormous potential to avoid ineffective interventions and achieve better patient outcomes. The volume of testing is increasing more strongly than any other test type, and consumers have demonstrated a willingness to privately pay for genetic tests, both within Australia and overseas, to enable access to tailored treatment.

POCT is another area where scale economies are less evident but patient convenience, result timeliness, and ultimately patient outcomes can all benefit. For example the provision of central pathology services to rural and remote Australia is a challenge but using POCT to provide critical analytes such as troponin provides a feasible alternative that has been shown to be clinically effective [3]. POCT is also being adopted abroad with countries such as the UK looking to incorporate POCT as part of a greater use of telehealth applications to deliver more care in the home [4].

2.2. Information about testing outcomes and service quality

As of today there is no national database of pathology results or outcomes from testing results in Australia. While some providers have large databases these are commercially sensitive and are not typically shared. Consequently there is a lack of clarity about key performance indicators that allow for the profession, government and administrators to assess both the value of pathology and identify the impact of pathology on critical areas of healthcare in Australia. This is made more problematic by the Medicare so-called coning rules used to determine pathology billing, which prevent the recording of all the tests actually performed in each patient episode. One opportunity to address this is an initiative by the association representing diagnostics companies, IVD Australia, to determine numbers of individual tests for the key high volume tests sold to providers. This should facilitate future analysis of more valued tests, unless unless coning is removed, it will do little to identify tests that are poorly utilised and likely to be superseded.

2.3. Recognition of professional service or value adding

Pathology services are about much more than laboratory testing, although the contribution of pathology to clinical activity is poorly understood, and fails to be recognised or incentivised under the existing funding model.

Key examples of clinical activity are:

- Direct consultation (often telephone)
- Report interpretation
- Clinical education (written, lectures)
- Recall and reminder systems
- Clinical audit

Current funding mechanisms provide reimbursement only for tests reported from a laboratory. There is no direct reimbursement for clinical activities performed by clinical pathologists. National Pathology Accreditation Advisory Council (NPAAC) standards only require adequate “supervision” by pathologists. The Royal College of Pathologists of Australasia (RCPA) guidelines refer to the clinical activity but there are no requirements that should see a large laboratory with only a single pathologist fail accreditation.

There is evidence that patient-specific report interpretation impacts on physician behaviour, test utilisation and clinical outcomes (direct and indirect measures) [5] but since these are not directly remunerated there is no incentive for laboratory proprietors to invest in pathologist or other interpretative resources and provide these value-adding services. There is some level of expectation in the market (GPs) that pathologists are available for consultation, putting competitive pressure on proprietors to offer the service — but with the current level of consolidation, these competitive forces are weakened.

Thus a key question is how can “professional practice” or what might be all the other services other than generation of the analytical result such as consultation and decision support (so called value-adds), be incorporated into reimbursement? This likely requires pathology or laboratory testing to be considered as a medical consultation in a similar manner to other medical services, possibly along the lines in recent papers from the US which have discussed how clinicians can be rewarded in pay for performance schemes [6,7].

2.4. Knowledge of clinical, and in turn, economic outcomes

The difficulty of identifying the outcomes that result from the use of pathology tests is well known. Tests are often part of a complex intervention and using the conventional tools of assessment such as randomised controlled trials has proven difficult. Most importantly assessment of diagnostic accuracy is not sufficient to prove that a test will influence patient outcomes, something that is underappreciated by the profession and industry, and highlighted in the recent paper by Siontis et al. [8]. However that is changing and the Medical Services Advisory Committee (MSAC) now demands such information before a test can be placed on the Medical Benefits Schedule and worldwide, regulators are moving to demand more information about the clinical impact of tests.

2.5. The role of tests in patient care pathways

There is increasing discussion in the literature and in policy documents of the importance of defining patient care pathways and the role of tests within that pathway. This is seen as an important way to improve the utilisation of testing and therefore its value. Thus several authors discuss the importance of considering the whole test–treatment pathway when evaluating patient outcomes from the introduction of new tests, rather than just studies of diagnostic accuracy which are poor predictors of how tests will perform when used in everyday practice [9,10]. Price and St John advocate the concept of the value proposition, as used in business, to detail the benefits, costs and value of a laboratory test to its customers, be they patients, healthcare providers or the community at large. Again the emphasis is on the whole breadth of what is a complex intervention from unmet clinical need to generation of clinical, operational and economic outcomes [11].

Many different guidelines exist in relation to specific conditions such as those published by the National Institute for Health and Care Excellence (NICE) and these include interactive clinical pathways with information about the use and timing of specific tests [12]. Similarly the Map of Medicine is an organization involved in the development and maintenance of evidence-based, practice-informed care maps [13]. As new evidence becomes available including the introduction of new or modified existing tests, the maps are revised so that they can be kept up to date. In addition the care maps are accredited by a number of
organizations including professional bodies and clinical networks. The use of such care pathways based on the best available evidence, will provide the optimum use of the test and maximise patient outcomes.

2.6. Extent of over- or under-testing

Much has been written about demand management in pathology with the focus on over-testing rather than a more balanced appraisal of both under and over utilisation. Thus the continuing debate about the number of requests for vitamin D testing is probably justified in a climate of economic restraint [14]. While many of the published studies of “appropriateness” equate inappropriate testing with over-testing it should be noted that most of the studies are performed in academic teaching hospital settings, which invariably operate on a fixed budget model and hence pathology laboratories have a strong incentive to reduce costs by reducing volume. In Australia at least, most disease diagnosis occurs in the community or primary care setting and not in the tertiary care setting, so the true diagnostic value of tests should be conducted in the former. Furthermore studies in hospital settings very poorly reflect the very different clinical and demographic issues that drive pathology testing in primary care environment where the bulk of Medicare funded testing in Australia is performed.

Several recent papers provide a more balanced view, namely that under-utilisation is as big a problem as is over-testing [15–17]. In view of these findings it is clear that more data from the primary care sector is urgently required in order to better understand the notions of appropriateness for reimbursement of testing. Such information is vital to the development of future value based reimbursement models.

2.7. Schedule based on costs not value of tests

The Medical Benefits Schedule for Pathology Tests has evolved over time and is widely acknowledged to have little relation to the true costs of performing the test or the cost of delivering service to the patient and the referrer. While the MSAC process makes a judgement on the clinical and cost effectiveness of a new test, it does not determine the fee for reimbursement. The latter is based largely on comparing the type of analytical technology used for the new test to that used for existing tests. In the case of newer genetic tests, reimbursement has been based on the cost of measurement (labour + materials) plus 15%. A review of pathology funding arrangements in six different countries including Australia conducted by PricewaterhouseCoopers in 2010, is entirely focussed on costs with no mention of the word value [18]. More recent discussions in Australia have had a focus on the rising “costs” of pathology with no concomitant attempt to measure the quality of the health services that are provided.

Rational and appropriate utilisation of pathology services, including both tests and non-test pathologist-driven activities, should be based on measures of clinical and economic value. But these measures are rarely in reviews of pathology services which tend to concentrate on the “factory” components of pathology services with no attempts to define appropriate patterns of testing or to understand the clinical value delivered by the tests and the associated clinical activities. Similarly little attention is devoted to explain or quantify the various functions and services of smaller, niche, and not-for-profit labs.

2.8. International perspectives

The challenges of defining and promoting the value of pathology are not confined to Australia nor just to the area of pathology but to diagnostic services in general. For example the radiology literature in the United States includes articles that discuss the effects of declining reimbursement upon the ability of companies to introduce new and innovative imaging technology [19–22]. Also in the States, industry groups such as Advamed have been drawing attention to the flawed reimbursement system and those in the profession have also called for changes to reimbursement such that it better reflects the value rather than the cost of tests [23]. This reinforces the importance of generating the evidence that might support a value based reimbursement system.

3. Recommendations on future activities to determine the value of pathology

3.1. Assessing and utilising existing evidence of economic outcomes

While the existing economic evidence base is small it appears to be increasing as the importance grows of measuring economic outcomes from testing [24]. This most recent review by Fang et al. only examined cost utility studies but other types of economic studies exist which may provide valuable information. Thus efforts need to be made which systematically review all the types of economic studies; grade their quality and assess their potential importance. The possibility should be considered for establishing a registry of such studies.

With greater availability to and awareness of existing evidence, efforts can then be directed to the determination of the best ways to use and apply it including the following: adding to the evidence base through design of new economic studies; guidance for future testing practice such as promotion of testing where it clearly adds value and discontinuing tests for which there is no value; and promotion both to healthcare providers and users of the health economic value of testing.

All of the above should be linked to education efforts about the importance of health economic studies and how the results of such studies can be translated into practice. The latter is particularly important because the pathology profession, providers and industry are relatively unfamiliar with the area of health economics.

3.2. Investing financial and human resources to assess new ways or models to determine the value of pathology

The need for a reimbursement system that identifies value rather than cost is seen as an essential outcome if appropriate resources are going to be invested in the future in pathology testing. This remains a difficult task but one possible approach is to determine the effects on outcomes of the various clinical or value-adding activities that may accompany a test result and were discussed previously such as consultation, commenting, decision support and auditing. Well-designed studies need to be established to measure the effects of these activities on the utilisation of pathology and patient outcomes. The results from such studies may then be used to establish reimbursement fees which reflect the relative value of these activities.

4. Conclusions

Like many other countries Australia has gone through an era of cost based funding of pathology where the overwhelming trend has been commoditisation of testing to achieve economies of scale and scope. Now there is a need for funding models which recognise the value that pathology brings to healthcare practice and reward practices which encourage testing that improves patient outcomes. The issues germane to current problems in Australia include lack of strategic vision, poor information about pathology usage, little recognition of professional service or value-adding, few studies of the economic impact of testing and anticipated pricing schemes. Some of these issues are also relevant worldwide as are the possible activities to address these problems. These include the need for more economic studies, the outcomes of which can be utilised in better funding models and the design of studies which can measure the possible impact of value-adding services such as consultation, commenting, decision support and auditing.
References


