Evaluating the cost-effectiveness of diagnostic tests

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Overview

• A brief description of how (and why) cost-effectiveness analyses are applied

• A brief overview of the analyses required to model diagnostic tests in sepsis

• A very brief description of the reasons why diagnostic evaluations are more difficult than pharmaceutical evaluations
Cost-effectiveness analyses

In the last 10 years there has been a considerable increase in the importance of cost-effectiveness analyses.

This was due to the relatively fixed budget and a combination of ageing populations and emerging expensive interventions.

This has led to the formation of funding agencies in England and Wales, Scotland, Australia and Canada.
Does a diagnostic test represent value for money?

Diagnostic tests with high prices may be cost-effective (i.e. a worthwhile use of a limited budget). Conversely, diagnostic tests with low prices may not be cost-effective.

The ‘gold standard’ approach for determining whether the price of a diagnostic test is justified is through an economic evaluation, or cost-effectiveness analysis.
Cost-effectiveness analyses

The goal of funding agencies is to provide the greatest amount of health for society within the budget, and thus opportunity cost is a key principle. That is, what health would be lost if money was diverted from one intervention in order to fund another.

The process is typically to estimate the cost-effectiveness of an intervention through modelling, and comparing this result with a value assumed to represent opportunity cost.
Previous Diagnostic evaluations

Whilst the majority of evaluations undertaken relate to pharmaceuticals, evaluations of diagnostic tests have been conducted:

- Carotid Artery Imaging - Wardlow et al. HTA
- Thrombophilia Testing - Simpson et al. HTA
- BMD Scanning (Strontium Ranelate) – Stevenson et al HTA
- Diagnostic strategies for DVT – Goodacre et al HTA
- Diagnostic pathways for minor head injuries – Pandor et al. HTA
- Non-Invasive Liver Testing – Stevenson et al HTA (in press)
Methods for evaluating diagnostic tests

There have been, for some time, clear methods guide for undertaking evaluation of pharmaceutical interventions.

Recently NICE has set up a Diagnostic Assessment Programme which has issues an interim statement of the methods it expects to be followed in evaluating diagnostics.

http://www.nice.org.uk/media/164/3C/DAPInterimMethodsStatementProgramme.pdf
Simplified Overview of the modelling required

The following slides discuss the steps that would be required to generate an estimate of the cost-effectiveness of a diagnostic test (or series of diagnostic tests).

The overview is a simplification. More detailed discussion is provided in the previously listed HTA reports (all free to download) and the Diagnostic Methods statement.
Estimating Test Accuracy

The sensitivity and specificity of a diagnostic test must be estimated.

These values would be combined with the estimated prevalence of the condition being tested for, to form an expectation of the number of true positives, true negatives, false positives and false negatives generated by the diagnostic test.
Modelling the patient experience

For each of the four groups defined, an estimation of the events that would occur to the patient must be modelled. These may differ due to underlying risks and the chosen medical management.

The modelling would include factors such as the risks of mortality, risk of morbidity, length of stay within hospital, costs for initial and subsequent care, treatment-related adverse-events and the quality of life for patients in each potential health state.
Modelling the patient experience

Ultimately, an estimation of the life years, quality adjusted life years (QALYs*) and costs can be attributed to each of the four groups.

These can be weighted by the proportions in each group to form a total cost and total QALY for patients post diagnosis. The costs of the diagnostic tests performed are then added.

* The QALY is a combination of life years and patient utility. A person living for 10 years at a utility of 0.5 would gain 5 QALYs; a person living for 4 years at a utility of 0.75 would gain 3 QALYs
Calculating an ICER*

Assume that post diagnosis, an average patient was expected to gain 10 QALYs at a cost of £20,000 under current best practice. These values became 11 QALYs at a cost of £18,000 following a new diagnostic test, which costs £4,000 per patient.

In this instance the increase in cost is £2,000 (£18,000 - £20,000 + £4,000)

The increase in QALYs is 1. \(11 - 10\)

* An Incremental Cost Effectiveness Ratio.
Calculating an ICER

In this example, the ICER would be £2,000 per QALY gained (£2,000 / 1)

This would be compared with an estimation of the cost of gaining a QALY in interventions that are likely to be replaced.*

Thus if this were the result from a real technology appraisal the diagnostic test would be likely to be recommended for use.

* NICE has estimated this to be in the region of £20,000-£30,000
Implications for diagnostic pricing.

Where a new diagnostic test has a large impact on mortality or on the utility of a patient, then the QALY gained over the current diagnostic will be greater.

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\text{ICER} = \frac{\Delta \text{Cost}}{\Delta \text{QALY}}
\]

Thus, for a constant ICER, such a test would be able to command a higher price than a test with a smaller QALY gain.
Sequences and subgroups

Note that sequences of tests and only incorporating tests on a subgroup of the population are possible.

The following slide shows the predicted optimal strategy for diagnosing whether a patient has deep vein thrombosis. The costs of diagnostic tests, the risks of death, morbidity, recurrence, treatment-related adverse-events and the costs of treating future events were all considered in the model.
Example of diagnostic algorithm

Taken from Goodacre et al. QJM 2006; 99:377–388
Returning to the example of sepsis

Current gold standard is blood culture, but this has poor sensitivity.

A new test is available (SeptiFast©) which has higher accuracy than blood culture tests, but is relatively expensive. The price may preclude use in all patients with suspected sepsis.

A decision support system is also available, (Treat ©) which can categorise patients into high, medium and low risk. This may allow SeptiFast© to be used more efficiently.
Estimating the cost-effectiveness of a Treat© and SeptiFast© diagnostic strategy

For each Treat© category, the patient experience must be modelled taking into account true positives, false positives, true negatives and false negatives. This will incorporate (amongst others)

- Risks of mortality
- Risks of post-infection sequelae
- Length of stay in hospital

These variables are expected to be lower where there is appropriate management of a patient with sepsis.
Thus there will be a QALY gain (and cost reduction) associated with the new diagnostic tests. It is expected that these will be greatest in those patients denoted high risk.

Factoring in the costs of the diagnostic (Treat© for all patients, SeptiFast© for the groups being evaluated) will allow the cost-effectiveness of diagnostic strategies to be evaluated.
Additional complications with evaluating diagnostic tests

There are reasons why evaluating diagnostic tests are more difficult than evaluating pharmaceuticals.

Due to time restrictions these will be mentioned very briefly under broad headings.
Complicating Issues

1) The need to understand the patient pathway
2) Data reporting
3) Missing and unobtainable data
4) Meta-analyses
5) Correlation between tests
6) Imperfect gold standards
7) Required operator skill
8) Spectrum bias
9) Incidental findings
10) Estimating the costs of diagnostic tests