Innovation – what's it worth?

First experiences of setting up an economic value assessment of medical device innovations with healthcare decision-makers using a spreadsheet tool. By **M. P. Craven, S. P. Morgan, J. A. Crowe and B. Lu**

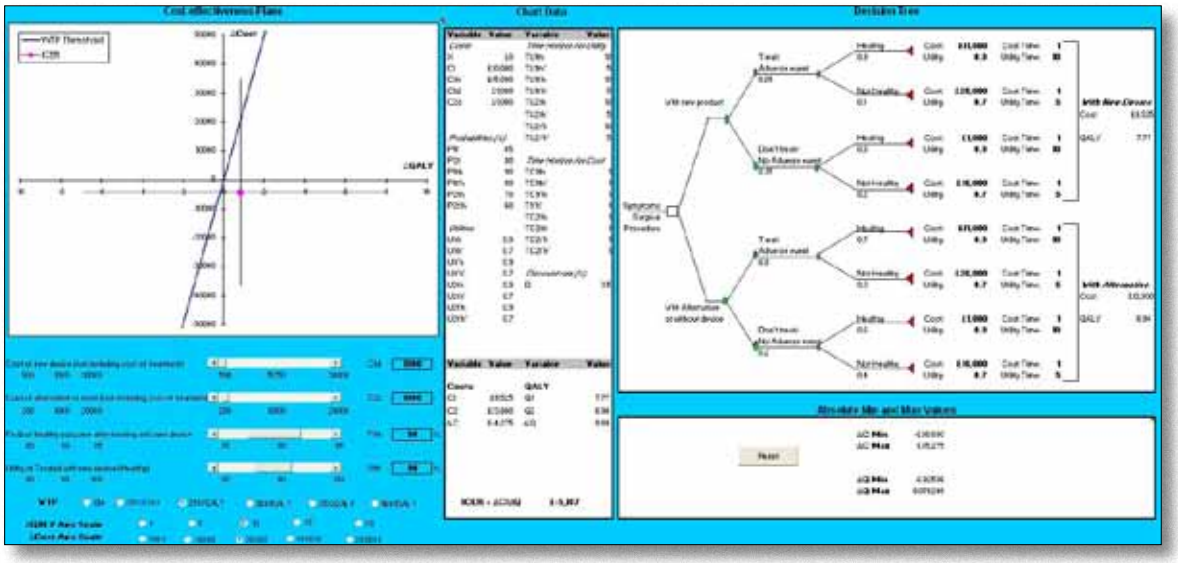
Early stage evaluation of medical device innovations is important for healthcare decision-makers as much as for manufacturers, meaning that a wider application of a basic cost-effectiveness analysis is becoming necessary outside the usual expert base of health technology assessment specialists.

Resulting from an academic-industry-healthcare professional collaboration, a spreadsheet tool is described that was designed to be accessible both to professionals in healthcare delivery organisations and to innovators in the healthcare technology industry who are non-experts in the field of health economics. The tool enables a basic cost-effectiveness analysis to be carried out, using a simplified decision-tree model to compare costs and patient benefit for a new device-related procedure with that of standard care employing an incumbent device or other alternative. Such a tool is useful to:

- Healthcare professionals – because it enables them to rapidly elucidate the cost-effectiveness of heterogeneous innovations by means of the standard quality adjusted life year (QALY) measure of clinical outcome, which is intended to be broadly comparable across treatments.
- Innovator or manufacturer – it helps them focus on what is required for future stages of development, in order to fill gaps in the input data and so further strengthen their case from a health economics perspective.

Results are presented of first experiences from deploying the tool on three medical device exemplars, in face-to-face meetings of the NHS National Innovation Centre (NIC) along with the innovator or clinical champion. The results show that mapping of device-related innovations to the tool is achievable in a short meeting between the NIC and the innovator using expected costs, outcomes data from the literature and estimates of ranges for unknown input data.

Whilst the result of a simplified analysis is not expected to be definitive, the process of reasoning is found to be illuminating for the parties involved, enabling innovators to articulate the benefits of their innovations and for all



parties to highlight gaps in data and evidence that will be required to take the innovation forward. The partnership model of the authors' organisation supports the kind of co-operative design approach that is necessary to produce the kind of tool described.

Economic evaluation is commonplace in the assessment of therapies involving drugs and medical devices. In the UK, in the National Health Service (NHS) context, a cost-effectiveness analysis (CEA) is an important component of health technology assessments of treatments that are carried out for organisations such as the National Institute for Health and Clinical Excellence (NICE) of England and Wales, Quality Improvement Scotland (QIS) and the Department of Health, Social Services and Public Safety Northern Ireland (DHSSPNI).

The need for increased capacity in the NHS to assess value through consideration of both costs and benefits is growing. At the local level, primary and acute hospital trusts are already tasked to demonstrate the quality of care through value indicators[1]. Acting on the outcomes of the Healthcare Industries Task Force (HITF)[2,3], the Purchasing and Supply Agency (PASA) is now carrying out its own reviews and analysis of economic evidence of products through the Centre for Evidence-based Purchasing (CEP).

Furthermore, the launch of the National Innovation Centre (NIC), another HITF initiative, has made pertinent the need for accessible tools to enable decision-makers to assess new healthcare technologies that are disclosed to them. The NIC aims to speed up the development of pre-commercial technologies likely to benefit the NHS, and has already produced a set of web-based tools to help innovators.

In particular, the NIC's Scorecard tool[4] provides an automatically generated self-assessment and also allows the innovation to be submitted for review by NIC experts if necessary. Scorecard is therefore a gateway to the innovation's detailed assessment, such that if a submission meets an NIC priority, an innovator may be offered a deeper due-diligence service (covering IP, legal, commercial and financial aspects) with the aim of building a full business case. As a measure of the take-up of such tools, in August 2008 the NHS National Innovation Centre had received 151 submissions of an idea to its Scorecard tool and 500 out of the 939 registered individuals had used it for their own use without submitting it to NIC.

Resulting from this focus on accelerating the adoption of innovations into the NHS, technology businesses that are developing new medical devices for sale in the NHS are being encouraged to think about cost-effectiveness analysis at an ever earlier stage in the innovation process. To assist with this, the UK-based research programme Multidisciplinary Assessment of Technology Centre for Healthcare (MATCH)[5] is collaborating with the NIC to develop and validate a new tool that is intended to be suitable for non-expert health economists to carry out, with minimal assistance, a basic cost-effectiveness assessment of their innovation.

The prototype tool was developed within the MATCH programme and has recently been made available to all its partners with an expectation for wider dissemination. The tool we describe is aimed at early stage cost-effectiveness which would ideally be applied after the NIC's Scorecard gateway. The following sections will describe the function of the tool, and present the results of research with three examples where it has been used to determine an estimate of cost effectiveness during meetings of

MATCH and the NIC together with the participation of the innovator or clinical champion.

With an increasing need to identify additional spending with metrics of patient benefit, the wider application of basic cost-effectiveness analysis has become necessary outside the usual expert base of health technology assessment specialists. In the context of the findings of the UK Health Industries Task Force, that a better assessment of value is required to bring new health technologies into the National Health Service, the tool described is seen to be facilitating a common understanding of value between healthcare decision-makers and medical device developers or clinician "champions" who are amongst the first adopters of newly marketed devices.

Further exemplar work is needed to examine the generalisability of the tool in terms of number and depth of decision-tree branches, balanced with a requirement to keep the model simple for non-expert use, and in the knowledge that data for a more complex model will be limited at the early stage of an innovation's development or deployment. As stated repeatedly, the tool is not intended to replace the need for a full NICE appraisal using a more complete data set, accepting that limited data will be the norm for early stage decisions. However more work needs to be done to examine the sensitivity to estimated data ranges and especially to research the effect on decisions from the making of optimistic or pessimistic estimates.

Conducting these exemplar studies with the tool on real users during its development prompted discussion about the "percentage cost modifier parameter". The rationale for inclusion of the feature was based on an example of a diagnostic device designed to assess burns by means of blood-flow measurement, where the treatment is a skin graft. If the innovation resulted in better assessment of the area in need of grafting, it was argued that this could be modelled as an efficiency saving in the treatment and therefore cost of treatment could be reduced accordingly. However, for general use it is perhaps too tempting to use it as a "fudge factor" to reduce the relative cost of the innovation. We have now decided to remove the feature and the user should enter cost savings to treatments directly.

A major lesson learnt from the exemplar work is that lack of hard data is not a barrier to mutual understanding of value at the early stage of development or deployment of a medical technology innovation. We also found that data may exist but not be readily available, which suggests that wider deployment of the tool would ideally be supported by an accessible repository of data for the purposes of health economics evaluation. Most importantly the tool was developed in close partnership with its users. The close academic-industry-healthcare professional linkage facilitated by MATCH supports and actively promotes this kind of co-operative design approach.

All of the focused evaluation meetings were carried out over a half-day period. However, some preparation is needed by all parties. Since conducting these exemplars, and after further consultations with partners in the medical devices industry, we have identified that an introduction to health economics, data sources and some hands-on training with the tool prior to the evaluation meeting would be beneficial. MATCH therefore decided to launch a series of tool workshops through the UK-wide Medilink network which brings together medical manufacturing and distribution companies, hospitals and universities to stimulate innovation on a regional basis. This is taking place alongside a new phase of exemplar studies with both NIC and PASA.

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MATCH

For more information about this tool and other tools and methods developed by the Innovative Manufacturing Research Centre MATCH for use by Medical Device manufacturers, or for information about the benefits of becoming a MATCH Partner, please visit www.match.ac.uk or contact elizabeth.deadman@brunel.ac.uk

1 NHS Institute for Innovation and Improvement, "Better Care, Better Value Indicators", http://www.productivity.nhs.uk (accessed September 2008).

2 Healthcare Industries Task Force (HITF) "Better health through partnership: A programme for action", 17 November 2004, http://www.advisorybodies.doh.gov.uk/hitf/ (accessed August 2007).

3 Strategic Implementation Group (SIG), Healthcare Industries Taskforce, Innovation for health: making a difference, 6 March 2007, http://www.advisorybodies.doh.gov.uk/hitf/ (accessed August 2007).

4 NHS National Innovation Centre, Scorecard, http://www.nic.nhs.uk/Scorecard/Pages/Scorecard.aspx (accessed October 2007)

5 Craven M., Crowe J., Botterill N., Morgan S. and Williams H., MATCH (2004): A multidisciplinary approach to the advancement of Health Technology Assessment, Proceedings of the Institute of Physics and Engineering in Medicine (IPEM) 11th Annual Scientific Meeting, York, 6-8 September 2004, p;41, ISBN 1-9036-1323-X. First appeared in the Journal of Management & Marketing in Healthcare. VOL. 2 NO. 3. PP 1–15. MONTH 2009