COMMENTARY

Appl Health Econ Health Policy 2012; 10 (5): 295-297
1175-5652/12/0005-0295/$49.95/0

NICE Medical Technologies Guidance

A Novel and Rigorous Methodology to Address a New Health Technology Assessment Challenge

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This issue of *Applied Health Economics and Health Policy* includes a detailed description of the National Institute for Health and Clinical Excellence (NICE) guidance, and of its development, on the adoption into practice of the 'PleurX peritoneal catheter drainage system for vacuum-assisted drainage of treatment-resistant, recurrent malignant ascites'.[1] This is the ninth piece of Medical Technologies Guidance on a diverse range of devices and diagnostics (table I).

The aim of this Commentary is to provide some background to the NICE Medical Technologies Evaluation Programme (MTEP), and to why the assessment reports – which will be summarized in this journal – are vital to its methodology.

1. Background and Principles of Operation

In 2009, NICE was given responsibility for establishing a system to identify and, subject to evaluation, encourage adoption of new or novel medical devices and diagnostic technologies with potential to improve the experience and outcomes of patients and/or to drive efficiencies in the use of health-service resources.

The NICE Medical Technologies Programme, and the specialist Diagnostic Assessment Programme, were constructed through a wide-ranging series of discussions with many interested parties – industry, clinicians, commissioners, health-service

Table I. Published Medical Technologies Guidance (MTG)

MTG	Title	Date issued
MTG1	SeQuent Please balloon catheter for in-stent coronary restenosis	Dec 2010
MTG2	MoorLDI2 Burns Imager a laser Doppler blood flow imager for the assessment of burn wounds	Mar 2011
MTG3	CardioQ-ODM (oesophageal Doppler monitor)	Mar 2011
MTG4	BRAHMS copeptin assay to rule out myocardial infarction in patients with acute chest pain	Jun 2011
MTG5	MIST Therapy system for the promotion of wound healing in chronic and acute wounds	Jul 2011
MTG6	Ambulight photodynamic therapy for the treatment of non-melanoma skin cancer	Jul 2011
MTG7	Inditherm patient warming mattress for the prevention of inadvertent hypothermia	Aug 2011
MTG8	The VeriQ system for assessing graft flow during coronary artery bypass graft surgery	Nov 2011
MTG9	PleurX peritoneal catheter drainage system for vacuum assisted drainage of treatment-resistant recurrent malignant ascites	Mar 2012
MTG10	Pipeline embolisation device for the treatment of complex intracranial aneurysms	May 2012

managers, academics, scientists and patients. The result is a programme where the following principles of operation reflect the distinct characteristics of innovative medical technologies.

- All forms of evidence (published and unpublished and with no design or quality threshold) are considered, reflecting the often sparse evidence base for medical technologies.
- The evaluation timeline is as short as possible to reflect the often rapid pace of development of technologies.
- The initial assessment of a technology is based on the claims made for a single product: to simulate the decision making in health systems and ensure that guidance is as relevant as possible. During evaluation, the guidance is based on a sponsor's submission, including cost modelling (on a template specified by NICE). Clear and explicit value propositions about all aspects of introducing technologies in place of 'current management' are central to evaluations.
- System benefits are given equal prominence to patient benefits and sustainability benefits are identified and actively considered.
- Technologies are notified to NICE by innovators (usually a commercial sponsor, i.e. manufacturer or distributor) so that the full range of medical technology products is considered.
- Products which are novel but not new can be notified and may be evaluated if there is evidence that they have plausible claimed benefits and are not being routinely adopted.
- Medical Technologies Guidances specifically examine products which are plausibly resource-releasing. The economic method used is cost-consequences analysis where the inputs and outcomes are costs rather than any patient-based outcome such as quality-adjusted life-years.

The programme has a dual function: first, to select the most promising technologies from those notified and route them to the most appropriate NICE programme. Second, to carry out evaluations which are published as Medical Technologies Guidance. Thus, topics such as the PleurX peritoneal drainage system are 'self-referred'. The selection process is designed to ensure that only new or novel products with plausible promise are routed for evaluation. The option to route to the most appropriate NICE programme ensures flexibility in enabling a wide range of products, with different value propositions, to be handled. A particularly important routing option is to the NICE Diagnostics Assessment Programme which was launched in 2010. This is a specialist programme designed to evaluate complex decision problems relating to diagnostic technologies and whose economic methods include cost-effectiveness analysis.

In summary, the purpose of the programmes is to encourage early uptake of technologies which offer advantages for patients and for the UK National Health Service (NHS), compared with current methods of management. The NICE MTEP has been identified as the central source of guidance on medical technologies in the report: *Innovation, Health and Wealth* by the NHS Chief Executive.[2]

2. Process and Methods

The MTEP draws on the core principles of all NICE guidance. It is based on the best evidence available; uses and values input from experts, patients and carers; involves decision making by independent advisory committees, genuine consultation and regular review; and has open and transparent processes. The Programme's Process and Methods Guides were published in April 2011 following public consultation and are available on the NICE web site (www.nice.org.uk/mt).

For products notified and selected for development of Medical Technologies Guidance, NICE first develops and publishes a scope. The next important step is production of a submission by the sponsor. This includes the clinical evidence and cost modelling which specifically supports the claimed benefits in the sponsor's case for adoption. The submission is critically reviewed by an external academic group with expertise and experience in health technology assessment of medical technologies. The submission and this critique are the key evidence used by the independent Medical Technologies Advisory Committee in its decision making. A particular blend of skills and experience are required for health technology assessment of medical devices and diagnostics.

Based on an innovative service specification, and after a public procurement process, NICE now contracts with four external assessment centres (EACs), including the Cedar group which has published the article in this edition of the journal, to provide this expertise.

The key output from the EAC during the development of Medical Technologies Guidance is the assessment report. This report draws together the EAC's critique of the sponsor's submission, including:

- the literature search strategy;
- the quality and relevance of the clinical evidence;
- the choice of comparator;
- the quality of the economic model, including the assumptions made, and any scenario or sensitivity analysis carried out. The EAC may carry out further analyses where the original submission is inadequate.

During the preparation of the assessment report, the EAC will consult with the sponsor and with clinical and patient experts, particularly when there are uncertainties.

3. Resolving Uncertainties

When all of the analytical work is complete, and the Advisory Committee is considering the technology, uncertainties frequently arise on which the EAC is able to provide expertise and insights from their work. For example, there may turn out to be an unexpected paucity of good evidence; certain assumptions used for cost modelling which are not plausible; expert opinions which call into question the likelihood that the technology will fit into care pathways or produce the clinical benefits which are claimed. In addition, it is unusual for the published evidence to provide clear answers about all the clinical utility issues. These uncertainties mean that debate is often difficult and complex, but the Committee needs to decide whether, on balance, the evidence is sufficient to support the case for adoption of the technology by the NHS (perhaps for defined indications).

Sometimes a technology is judged to have real promise but aspects of the available evidence are insufficient. In these circumstances, the committee can make recommendations for further research. In such cases, NICE now has a mechanism for facilitating such research, through the EACs.

In conclusion, the NICE MTEP is a novel health technology assessment initiative which incorporates world-leading clinical, scientific and academic support in its processes and methods. Its Medical Technologies Guidance offers a valuable aid for NHS decision makers. The guidance states whether the available evidence supports the case for adopting a technology as an alternative to current (clearly described) management. It describes the advantages of doing so for patients and for the service; and outlines changes to care pathways that introducing the technology would require. It presents the cost consequences, calculated over an appropriate length of time. This kind of recommendation and explicit description of likely outcomes ought to furnish commissioners and providers with all the information they need to make decisions about developing their services through the purchase of new technologies. It should assist clinicians who want to introduce technologies and may influence those who are uncertain; and it may provide a useful tool for patients who are keen to gain access to new technologies which will help them.

Acknowledgements

Potential conflict of interest: Bruce Campbell is the Chair of the NICE Medical Technologies Advisory Committee.

Reference

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