



COCIR position paper

Assessing the value of Medical Imaging and Health ICT

The role of Health Technology Assessment (HTA)

COCIR started its efforts a long time ago in the field of Health Technology Assessment and issued a first [position paper](#) in October 2010 where we were putting focus on the importance of assessing the entire process rather than the technology itself, as we are moving into more integrated care solutions. While maturing on this key matter, we decided this year to go further into our industry's recommendations towards HTA agencies which are put forward in this new position paper.

Executive Summary

Health Technology Assessment (HTA)¹ is increasingly used as an additional requirement for market access after safety and efficacy for regulatory approval. The framework and methods of HTA for vaccines and pharmaceuticals are now well-established. **It is however recognised that there are important differences between medical technologies that must be considered if appropriate assessments are to be conducted.**

A collaborative effort across medical technology industries (medical devices, medical imaging, health ICT, IVD/diagnostics) is required to develop and propose appropriate HTA methods for assessing each respective healthcare technology. COCIR believes that current HTA methodologies do not, in most cases, assess the true value of medical imaging and health ICT optimally and manufacturers should be proactive in driving change in how their products and technologies are assessed.

COCIR key recommendations to HTA agencies concerning HTA processes

COCIR recommends that HTA agencies should align their processes with the following key elements to optimise the assessment of medical technologies:

- 1. Flexibility and pragmatism combined with acceptance of different types of evidence**
 - Adopt different methodologies to assess whole healthcare system benefits appropriate to the medical technology and the need that is being addressed (e.g. clinical application, productivity, access)
 - Recognise that different levels of benefit/risk exist for medical technologies and adopt a pragmatic approach to incorporate different types of evidence into effectiveness assessments
- 2. Timeline**
 - Streamline processes to enable more timely technology assessment and encourage early (and controlled/monitored) dissemination of promising solutions to benefit patients
- 3. Broad scope of benefits considered**
 - Recognise healthcare system benefits as well as patient benefits; actively encourage input of different perspectives from multiple stakeholders (patients, carers, clinicians, payers, *et al*)
 - Develop mechanisms for facilitating recommendations for further research - both through early dialogue activities before HTA to develop appropriate evidence, and following an HTA to develop study protocols to fill evidence gaps
- 4. Implementation support**
 - Put processes and mechanisms in place that support healthcare providers to implement recommendations by providing tools and practical guides to facilitate rapid technology

adoption

DETAILED BRIEFING

Key factors and differentiators for assessment of medical technologies¹

A. Main factors

- Medical technologies do not necessarily themselves produce a clinical outcome. For instance, the value of improved diagnostic information is intrinsically linked to the subsequent diagnosis and treatment; diagnostic tests are frequently performed in conjunction with other tests or measurements to produce a composite picture that supports clinical decision making.
- Medical technologies require outcomes data. However, randomised controlled trials (RCTs) are not practicable and blinding in clinical studies is more difficult with the risk of introducing bias. RCTs to demonstrate impact in medical practice and longer-term effectiveness are not currently required to comply with regulatory requirements.
- Implementation and full effectiveness of new medical technology may have wider organisational and thus economic implications, e.g. training requirements, alteration of workflows and patient pathways; the impact of medical technology on patient outcomes may not be captured in traditional metrics, e.g. diagnostic information may create medical value (informing medical treatment), treatment decision making (patient preferences) and improved quality of care (patient satisfaction).
- Medical imaging systems can be used for multiple clinical applications such that the overall benefit of the technology is some weighted average of its use across all applications.

¹ Drummond et al *Economic Assessment of devices and drugs - same or different?* *VinH*; 12(4): 402 (2009); Gazelle et al *Radiology*; 261(3): 692 (2011); Lee et al *VinH*; 13(2): 310 (2010)



- Medical technologies prices are more likely to change over time because of new market entrants and the different procurement mechanisms.

B. Additional factors

An additional factor is intellectual property, meaning that medical technology manufacturers seldom have applications exclusivity. Hence investing heavily to generate evidence to substantiate impact on outcomes that can be considered as a “class effect” is commercially unattractive – especially before a product is introduced. An allied factor is that life cycles for medical technologies are often much shorter (than pharmaceuticals) hence by the time evidence of impact on outcomes is available a technology has been superseded.

A number of HTA bodies have developed assessment processes for non-drug technologies e.g. NICE, HAS, IQWiG, etc. For the purposes of this document, we have focussed on the approach taken by NICE² in the UK that has developed a complete suite of programmes to support healthcare providers to adopt clinical and cost-effective technologies more rapidly and consistently. NICE provides early dialogue opportunities for manufacturers to get scientific advice on evidence generation through its technology assessment programmes, research recommendations, protocol development and implementation programmes to maximise uptake of cost-effective healthcare interventions to benefit patients. More details of the NICE processes are given in the Appendix.

COCIR actions to further develop tailored HTA for medical technologies

A key challenge for COCIR members is often how to go about generating appropriate and robust evidence to support the clinical and economic advantages of (new) medical technologies.

COCIR members will need to proactively address the increasing evidence requirements. This could be done through the following actions:

- Engage in active dialogue with HTA bodies to develop recommendations on the types and design of studies that will enable more efficient evidence generation and that can be translated into outcomes (e.g. how to make best use of modelling approaches, observational studies, registries, etc)
- Support evidence generation needs across the technology lifecycle from early product development to post-marketing studies
- Where appropriate, engage in collective evidence generation to support key technologies with joint studies
- Work with HTA bodies to develop/define incentives for manufacturers to invest in evidence generation that benefits multiple manufacturers (e.g. coverage with evidence development)

² See appendix hereafter



ⁱ EUnetHTA definition of HTA: Health Technology Assessment (HTA) is a multidisciplinary process that assesses evidence about medical, social, economic and ethical issues related to the use of a health technology in a systematic, transparent, unbiased, robust manner. Its aim is to inform the formulation of safe, effective health policies that are patient focused and seek to achieve best value.



APPENDIX

The purpose of this appendix is to describe the approach taken by NICE in the UK for assessing medical technologies.

UK – NICE

Principles of NICE guidance [From: <http://guidance.nice.org.uk/>]

- designed to promote good health and prevent ill health
- produced by the people affected by the work, including health and social care professionals, patients and the public
- based on the best evidence
- transparent in its development, consistent, reliable and based on a rigorous development process
- good value for money, weighing up the cost and benefits of treatments
- internationally recognised for its excellence.

NICE has developed an holistic approach to support the NHS in adopting clinical and cost-effective technologies more rapidly and consistently from providing early dialogue opportunities for manufacturers to get scientific advice on evidence generation through its technology assessment programmes, research recommendation protocol development and implementation programmes to optimise appropriate adoption and use of evidence and guidance.

Topics are selected on the basis of a number of factors, including the burden of disease, the impact on NHS resources, and whether there is inappropriate variation in practice across the country.

Guidance is then created by independent and unbiased advisory committees. NICE also recognises the importance of proactively engaging with and involving multiple stakeholders in the assessment process (from manufacturers to clinicians to patients). During the development of recommendations NICE encourages the input of qualitative evidence related to the experiences of patients, carers and clinical experts who have used the technology.

NICE has developed bespoke processes and methods for the assessment of different types of medical technologies, interventions and therapies. The four key processes that are relevant for medical technologies are the Diagnostics Assessment programme (DAP), Medical Technologies Evaluation Programme (MTEP), the Interventional Procedures Guidance (IPG), and clinical best practice guidelines.

Medical Technologies and Diagnostics

The Medical Technology Evaluation Programme at NICE has been developed such that the following principles of operation reflect the distinct characteristics of innovative medical technologies (*taken from Campbell & Campbell, 2012*).

- All forms of evidence are considered (published and unpublished and with no design or quality threshold), reflecting the often sparse evidence base for medical technologies.
- The assessment timeline is as short as possible to reflect the rapid pace of development of some medical 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).
- Products that 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 Guidance specifically examines products which are plausibly resource releasing.
- The economic evaluation used is cost-consequence analysis costs are considered opposite consequences – usually some measure of effectiveness rather than any patient-based outcome such as quality-adjusted life-years.

The Diagnostics Assessment Programme is designed to evaluate complex decisions problems relating to diagnostic technologies and whose economic methods include cost-utility analysis.

Cost-utility of diagnostics is complex as the main patient benefits usually arise from the subsequent treatment rather than from the diagnostic procedure itself. Often there is limited direct evidence of long-term outcomes. This means that modelling is often used to link intermediate outcomes (such as diagnostic accuracy) to patient outcomes (e.g. length or quality of life). Modelling by its nature is highly dependent on the available data and assumptions used that in turn rely on expert clinical opinion³.

Differences between the NICE Diagnostics Assessment Programme (DAP) and the Technology Evaluation Programme (MTEP)⁴

The DAP evaluates diagnostic technologies using cost-utility analysis but it differs in various significant ways from the NICE Technology Appraisal Programme for drugs, which also uses cost-utility analysis. The differences are outlined below:

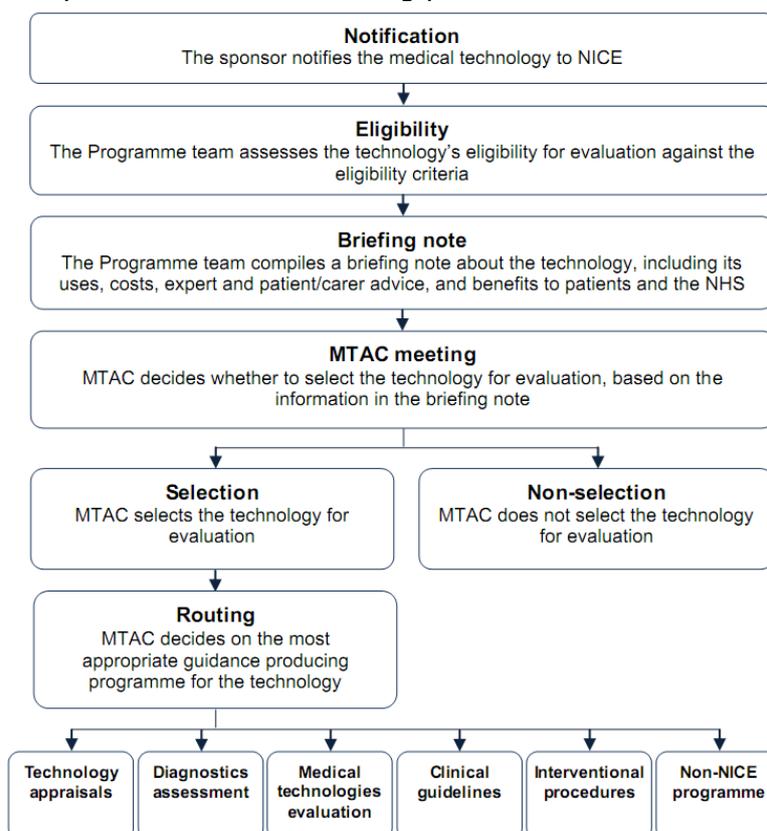
- Evidence about patient outcomes for diagnostic technologies is typically lower in quantity and quality than evidence for pharmaceutical products.
- Because most benefit to the patient arises from treatment based on the result of the diagnostic test, the value of the test or technology is best understood in the context of its effect on the pathway of care.
- Diagnostic technologies, particularly those based on electronics, often change rapidly as new methods, upgrades and capabilities are added.
- It is often not obvious where in the care pathway the diagnostic technology is best placed, so different options are evaluated.

The Medical Technology Advisory Committee (MTAC) considers whether technology should be evaluated based on cost, practice, and risk benefit impacts then routes the technology to the appropriate assessment programme (see Figure 1).

³ Campbell & Campbell. *Appl Health Econ Health Policy*; 10(5): 295 (2012); Crabb et al. *Health Pol Tech*; 1:5 (2012)

⁴ DAP manual, Dec. 2011

Figure 1 – Summary for selection and routing process of NICE MTAC



NICE. Medical Technologies Evaluation programme: Process guide. 2011

NICE has recognised that medical technologies are different from other medical interventions because:

- Technologies may be modified over time in ways that change their effectiveness.
- The clinical outcomes resulting from the use of technologies often depend on the training, competence and experience of the user (sometimes referred to as the 'learning curve').
- Clinical evidence on technologies, in particular new technologies, is often limited, especially comparative studies against appropriate methods of diagnosis or patient management.
- The healthcare system benefits of adopting medical technologies often depend on organisational factors, such as the setting in which the technology is used or the staff who use it, in addition to the clinical benefits directly related to the technology.
- When the technology is a diagnostic test, improved clinical outcomes depend on the subsequent patient management.
- Evidence of the effect of diagnostic tests on clinical outcomes may not be available because improved diagnostic accuracy may not be reflected in improved clinical or quality-of-life outcomes. Some technologies are indicated in managing or investigating a number of different medical conditions and may be used by different healthcare professionals and in a variety of healthcare settings.
- A new technology may influence resource utilisation by its effect on various aspects of the care pathway, in addition to costs directly related to the use of the technology.
- Costs of medical technologies often comprise both procurement costs (including associated infrastructure) and running costs (including maintenance and consumables).

- In general, medical technology pricing is more dynamic than that of other types of medical interventions.

Key elements of the different programmes used for medical device and diagnostics assessment within NICE are summarised in Table 1:

IPG	MTEP	DAP
Safety and efficacy	Comparative effectiveness & cost-consequence analysis [evaluate the impact of the technology on the healthcare system, alongside its clinical benefits for individual patients - the technology appears likely to achieve a similar clinical benefit at less cost or more benefit at the same cost as current practice in the NHS]	Clinical utility and cost-effectiveness (incremental cost-effectiveness ratio (ICER) expressed as £/QALY compared to threshold values.
Single procedure or intervention	Single technology	Single or multiple technologies Complex care pathways
No formal submission. Sponsor to provide all relevant data to support evaluation.	Sponsor responsible for conducting literature review & economic modelling	No formal submission. Sponsor to provide all relevant data to support the assessment.
Published evidence (RCTs, non-RCTs, case studies) & expert opinion	Published evidence. [Sponsor is responsible for a literature search that covers relevant efficacy, effectiveness, usability and safety outcomes (including intermediate clinical outcomes) and available clinical and health economic studies of any type, including non UK studies.] Cost model	Published evidence. [External Assessment Group prepares a systematic review of the clinical and health economic literature including data supplied by the manufacturer - includes RCTs, observational studies, and any qualitative evidence related to the experiences of patients, carers and clinical experts. If direct data on outcomes of the diagnostic interventions is insufficient, indirect evidence and models of the care pathway are evaluated].