Ascertainment of the value for money of medical devices: A European perspective

Rosanna Tarricone, PhD
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ISPOR Dublin, November 4h-XX 2013

Why is HTA different for medical devices? (1/2)

1. They are often diagnostics (e.g. diagnostic/predictive genetic tests and impact onto “personalised medicine”): challenge to measure health outcomes
2. They often only indirectly impact patients’ outcomes through better systems’ performance (e.g. ventilator in OR)
3. Experimental studies (e.g. RCTs) are more challenging (e.g. unethical, difficult, impossible): no general consensus on robust alternatives yet (e.g. registries, cohort studies), yet:
4. No general consensus on which experimental studies to be considered in HTA (e.g. comparator(s), head-to-head vs. placebo, direct vs. indirect comparisons): HTA bodies seldom agree*

Why is HTA different for medical devices? (2/2)

5. Medical devices’ performance highly depends on end-users: learning curve: i.e. what do we compare?
   • Clinical effectiveness of new program vs. current practice? Or inexperience with the new program vs. experience of the current practice?

6. Timing of assessment (i.e. Buxton Law’s “It is always too early until, unfortunately, it’s suddenly too late”): challenge to assess long-term benefits and/or spillovers vs. upfront costs

7. Medical devices have wider economic implications (e.g. organisational impact): rarely assessed*

8. Pricing strategies also depend upon country-based procurement policies: instability of ICERs vs. threshold values


HTA for medical devices in Europe: where do we stand?

1. The role of European Commission:
   - HTA Network established in EU Cross Border Healthcare Directive
   - EUnetHTA: 40 partner organisations designated by Member States + large number of regional HTA organisations
   - The promotion of good practice in HTA methods and processes (methodological guidelines for Rapid Relative Effectiveness Assessments)
   - The delivery of reliable, timely, transparent and transferable information contributing to HTAs in European countries (pilot joint assessments using the HTA Core Model)

2. NICE’s approach to medical devices appraisal

3. WHO’s HTA for “Priority Medical Devices”:
   - To develop HTA for MDs aimed at universal access and sustainability
HTA for MDs in Europe: is it an accomplished task?

• Although increasingly diffused, several challenges remain unsolved:
  – Source and quality of clinical evidence
  – Timing of assessment
  – Organisational aspects
  – ICER & decision rule
  – Types of technologies (e.g. medical devices as a whole vs. sub-categories of MDs)
  – Stakeholders’ involvement (e.g. industry, patients)
• Harmonisation vs. duplication:
  – E.g. only in EU countries, 33 reports on TAVI have been issued in the last 6 years

NICE’s approach to evaluating the value of medical technologies

Mark Campbell,
Associate Director, Medical Technologies Evaluation Programme,
National Institute for Health and Care Excellence
Considerations in design of programmes

- Traditional strengths of medtech products in improving the efficiency of services
- Existing NICE technology appraisal guidance programme based on cost-effectiveness
- Limitations of sparse evidence base
- Need to accommodate complex diagnostic interventions
- Strategic importance to health care systems of quality and efficiency

Common medtech product claims (compared with standard care)

- Replace ongoing therapy costs with one-off intervention or device
- Deliver treatment decision or care nearer to home
- Reduce unnecessary surgical interventions
- Enable self-care
- Reduce length of stay
- Enable treatment by a lower grade or less scarce type of staff
- Improve patient dignity and treatment compliance
- Reduce future hospitalisation
- Speed up recovery
- Etc
Quality and efficiency - UK policy

“....The challenge both for the NHS and for its industry partners is to pursue innovations that genuinely add value but not cost – the NHS for its productivity and quality goals and industry for its international competitiveness. Indeed, adding value and reducing cost is the basis of the NHS QIPP challenge. This puts a premium on game-changing innovations that change patient pathways and traditional delivery systems, and that are implemented in a way that strips out the processes that no longer add value....”

Medtech evaluation encompasses NICE’s core principles

- Based on the best evidence available
- Expert input
- Patient and carer involvement
- Independent advisory committees
- Genuine consultation
- Regular review
- Open and transparent process
Medical Technologies Evaluation Programme – single point of entry to evaluation options

<table>
<thead>
<tr>
<th>Technology Appraisals Guidance</th>
<th>Interventional Procedures Guidance</th>
<th>Medical Technologies Guidance</th>
<th>Diagnostics Guidance</th>
</tr>
</thead>
<tbody>
<tr>
<td>• new treatments with potential significant impact on NHS, or policy priorities (cancer, heart disease, stroke)</td>
<td>• safety and efficacy of novel procedures</td>
<td>• Single product</td>
<td>• More cost/more benefit</td>
</tr>
<tr>
<td>• clinical and cost-effectiveness</td>
<td>• New device in a novel procedure where safety and efficacy are still unknown</td>
<td>• Innovative devices and diagnostics (early stage evidence)</td>
<td>• Complex care pathways</td>
</tr>
<tr>
<td>• 3-month funding direction</td>
<td></td>
<td>• More benefit/same cost</td>
<td>• Multiple or single products</td>
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</table>

Pre-2009  2009 onwards

### Clinical performance
- Better
- At least equivalent

### Cost
- Higher
- Less overall

### Guidance programme
- Diagnostics or Technology Appraisal
- Medical Technologies

### Patient benefits (inc preference)
- Evidenced and used to adjust value
- Evidenced and anecdotal – but not used to adjust value

### Appropriate evaluation method
- Cost effectiveness
- Cost consequences

### Example
- Drug-eluting stents (TA152)
- Depth of anaesthesia monitors (DG6)
- Oesophageal doppler system for intra-operative fluid monitoring (MTG3)
- Low intensity ultrasound for healing of non-union fractures (MTG12)
Medical technologies guidance: cost consequences methodology

• Expectation technology is therapeutically near equivalent to comparator
• Costs and resource consequences of the technology as well as relevant clinical benefits
• Not required: valuation of patient health status or treatment preferences

Cost modelling – cost consequences analysis

<table>
<thead>
<tr>
<th>Cost model - examples</th>
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<tbody>
<tr>
<td>Acquisition costs</td>
</tr>
<tr>
<td>Running costs eg disposables or concomitant treatment</td>
</tr>
<tr>
<td>Staffing costs</td>
</tr>
<tr>
<td>System savings (eg change in setting)</td>
</tr>
<tr>
<td>Reduced costs of improved health outcomes</td>
</tr>
<tr>
<td>Improved ease of use or patient acceptability</td>
</tr>
</tbody>
</table>
### NICE Medical Technologies Guidance (MTG)

<table>
<thead>
<tr>
<th>Topic</th>
<th>Patient benefits</th>
<th>System benefits</th>
<th>Cost saving (per patient)</th>
</tr>
</thead>
<tbody>
<tr>
<td>MTG 1 Sequent Please balloon catheter for restenosis.</td>
<td>Lower rate of restenosis and reduced need for re-treatment and major cardiac adverse events.</td>
<td>Fewer repeat procedures.</td>
<td>450</td>
</tr>
<tr>
<td>MTG 2 moorLDI imager for medium-severe burns.</td>
<td>Better treatment planning</td>
<td>Fewer skin grafts.</td>
<td>1248</td>
</tr>
<tr>
<td>MTG 3 Cardio Q ODM for intraoperative fluid management.</td>
<td>Fewer post-op complications Earlier mobilisation (No increase in repeat surgery or re-admission).</td>
<td>Reduced length of stay.</td>
<td>1100</td>
</tr>
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### NICE Diagnostics Guidance (DG)

<table>
<thead>
<tr>
<th>Number (date)</th>
<th>Title</th>
<th>Summary of recommendation(s)</th>
</tr>
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<tbody>
<tr>
<td>DG4 (August 2012)</td>
<td>Adjunctive colposcopy technologies for examination of the uterine cervix - DySIS and the Niris Imaging System</td>
<td>DySIS is a clinically and cost-effective option, compared with standard colposcopy, for examining the uterine cervix in women referred for colposcopy, and should be considered in procurement plans for colposcopy equipment. (ICER £10-12k per QALY gained)</td>
</tr>
<tr>
<td>DG5 (August 2012)</td>
<td>SonoVue (sulphur hexafluoride microbubbles) - contrast agent for contrast-enhanced ultrasound imaging of the liver</td>
<td>Contrast-enhanced ultrasound with SonoVue is recommended for characterising incidentally detected focal liver lesions in adults in whom an unenhanced ultrasound scan is inconclusive. (ICER £12-20k per QALY gained)</td>
</tr>
<tr>
<td>DG6 (November 2012)</td>
<td>Depth of anaesthesia monitors (E-Entropy, BIS and Narcotrend)</td>
<td>The use of electroencephalography (EEG)-based depth of anaesthesia monitors is recommended as an option during any type of general anaesthesia in patients considered at higher risk of adverse outcomes. The Bispectral Index (BIS) depth of anaesthesia monitor is therefore recommended as an option in these patients. (ICER £5-21k per QALY gained, IV anaesthesia, high-risk)</td>
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European initiatives to define a methodological framework for the evaluation of medical devices

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ISPOR Dublin, November 4h-XX 2013
Medtechta: overview

1. Project name: Methods for Health Technology Assessment of Medical Devices: A European Perspective
2. Acronym: MedtechHTA
3. Leader: CERGAS – Bocconi University
4. Partners: Hamburg Center for Health Economics; Centre for Health Economics, University of York; University of Exeter Medical School; University for Health Sciences, Medical Informatics and Technology; Institute for Economic Research, Slovenia; European Society of Cardiology
5. EC contribution: 2,055,134.00€
6. Duration: 36 months
7. Starting date: 01/01/2013

Medtechta: aims

1. To improve the existing methodological framework within the paradigm of Health Technology Assessment (HTA) for the assessment of medical devices
2. To investigate:
   • comparative effectiveness of medical devices and allowing for a 'learning curve' and user characteristics;
   • incremental innovation vs. radical innovations
   • value of information and the characterization of uncertainty surrounding the development of new devices;
   • organizational impacts of introducing new devices, including the need for changes in existing clinical practices, the organization of patient care and service delivery;
   • current differences in methods used for HTA of medical devices in EU countries and differences in terms of within- and between country variations in access to innovative medical devices that have important implications on equity.
3. To provide recommendations for methods in conducting HTA on medical devices
HTA: the way forward

- Evidence from MedtecHTA would bring new insights and guidelines to improve harmonisation across jurisdictions in EU
- Although socio-economic contexts and institutional arrangements of healthcare systems in EU will always influence final recommendations, harmonisation in methods is likely to increase efficiency in the HTA process
- However, equity of access across EU patients still remains unclear and opens further area of research

Thank You

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