NICE’s approach to the development of guidance for medical devices and diagnostics

Sheryl Warttig, Technical Adviser

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About NICE
The National Institute for Health and Care Excellence

• Established in 1999 to reduce variation in the availability and quality of NHS treatments and care
• Enacted in legislation in 2012
• Run by an independent board appointed by public advertisement
• Decisions and outputs independent of government
• Offices in London (~200 staff) and Manchester (~400 staff)
NICE
Improving outcomes for people

Evidence-based guidance and advice for health, public health and social care

Information services for commissioners, practitioners and managers

Quality standards and performance metrics for those providing and commissioning health, public health and social care
NICE medical technology evaluation programme

Background, methods & process
Background to MTEP

• Medical Technologies Evaluation Programme (MTEP) established in 2009
• Selects and evaluates new or innovative medical technologies (including devices and diagnostics).
• Aim to help the NHS adopt efficient and cost effective medical devices and diagnostics more rapidly and consistently.
• Use of appropriate methodology
## MTEP methodology

### Notification and selection

<table>
<thead>
<tr>
<th>Method</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Innovators notify directly to NICE</td>
<td>The medtech industry is large and diverse with a high output of innovative products</td>
</tr>
<tr>
<td>Products which are novel but not new can be notified if:</td>
<td>Innovative products may be slowly and/or unevenly adopted</td>
</tr>
<tr>
<td>• they have plausible claimed benefits</td>
<td></td>
</tr>
<tr>
<td>• they are not being routinely adopted</td>
<td></td>
</tr>
<tr>
<td>The case for adoption drives the initial assessment</td>
<td>Medical technologies often have benefits when used in place of or addition to standard care</td>
</tr>
<tr>
<td>Short timelines:</td>
<td>Medical technologies evolve at a rapid pace</td>
</tr>
<tr>
<td>• 10 weeks from notification to selection</td>
<td></td>
</tr>
<tr>
<td>• 38 weeks from selection to guidance development</td>
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</tbody>
</table>
Process overview
Notification and selection

**Notification**
- Company notifies technology

**Criteria met**
- Notification reviewed against eligibility criteria

**Selection & routing**
- Independent advisory committee selects technologies for guidance
- Routes technology to appropriate programme at NICE

10 week process
### Eligibility and selection criteria

<table>
<thead>
<tr>
<th>Eligibility</th>
<th>Selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Timing</td>
<td>Patient benefit</td>
</tr>
<tr>
<td>New or novel</td>
<td>Systemic benefit</td>
</tr>
<tr>
<td>Suitable for evaluation</td>
<td>Disease impact</td>
</tr>
<tr>
<td></td>
<td>Cost considerations</td>
</tr>
<tr>
<td></td>
<td>Sustainability</td>
</tr>
</tbody>
</table>

Ineligible or not-selected topics are returned to the sponsor with a summary of the Committee’s considerations.
## MTEP methodology

### Guidance development

<table>
<thead>
<tr>
<th>Method</th>
<th>Rationale</th>
</tr>
</thead>
<tbody>
<tr>
<td>All forms of evidence are considered</td>
<td>Medtech has a relatively sparse evidence base compared to pharma</td>
</tr>
<tr>
<td>• Can generate evidence</td>
<td></td>
</tr>
<tr>
<td>Consideration given to:</td>
<td>Medical technologies are often claimed to be resource-releasing and more convenient.</td>
</tr>
<tr>
<td>• System benefits</td>
<td></td>
</tr>
<tr>
<td>• Patient benefits</td>
<td></td>
</tr>
<tr>
<td>• Sustainability</td>
<td></td>
</tr>
<tr>
<td>Access to world-leading technical expertise</td>
<td>Technical considerations can significant influence clinical utility</td>
</tr>
<tr>
<td>Specific focus on products that are resource releasing</td>
<td>Improving the efficiency of health services is a top policy priority</td>
</tr>
<tr>
<td>• primary economic methodology is cost-consequences analysis</td>
<td></td>
</tr>
</tbody>
</table>
## MTEP methodology
### Value proposition

<table>
<thead>
<tr>
<th>Performance</th>
<th>Better</th>
<th>Non inferior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cost</td>
<td>Higher</td>
<td>Less overall</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evaluation method</th>
<th>Cost effectiveness (QALY)</th>
<th>Cost consequences</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Technologies</th>
<th>Devices</th>
<th>Diagnostics</th>
<th>Devices or Diagnostics</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>NICE programme</th>
<th>Technology Appraisals (TA)</th>
<th>Diagnostics Assessment Programme (DAP)</th>
<th>Medical Technologies Evaluation Programme (MTEP)</th>
</tr>
</thead>
</table>
MTEP methodology
Cost consequence analysis

• 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
MTEP methodology
Cost consequence analysis

Cost model - examples

- Acquisition costs
- Running costs eg disposables or concomitant treatment
- Staffing costs
- System savings (eg change in setting)
- Reduced costs of improved health outcomes
- Improved ease of use or patient acceptability
Process overview

• Company notifies technology

• Notification reviewed against eligibility criteria

• Independent advisory committee selects technologies for guidance
  • Routes technology to appropriate programme at NICE

• Routed to medical technologies guidance
  • Cost consequence analysis

• Medical technologies guidance published
  • Recommends whether the technology should be adopted or not
Process overview

- **Notification**
  - Company notifies technology

- **Criteria met**
  - Notification reviewed against eligibility criteria

- **Selection & routing**
  - Independent advisory committee selects technologies for guidance
  - Routes technology to appropriate programme at NICE

- **Other NICE programme**
  - Routed to other programme at NICE (Diagnostics, Technology Appraisals, Interventional procedures, Guidelines)
  - Cost effectiveness analysis
  - Duration of guideline development varies by programme

10 weeks
NICE medical technology evaluation programme

Evidence
What evidence does NICE use?
Evidence considerations

• MTEP methodology requires manufacturers to submit evidence, including an economic model

• The evidence should demonstrate:
  – Equivalent or superior clinical performance compared to current standard clinical care – the comparator
  – NHS cost savings (which may occur anywhere in the care pathway)

• The evidence may be based on:
  – Systematic review of the clinical and economic evidence with appropriate meta-analyses
  – De novo cost analysis (where needed)
  – Clinical and technical expert advice

• The submitted evidence is reviewed by an independent external assessment centre
Evidence considerations

• All relevant evidence; No design/quality thresholds
  – Published and in-press trials (academic/commercial in confidence)
  – Unpublished data
  – Regulatory data
  – Post-market register data, audits and ‘real-life’ experience
  – Forthcoming trial results
  – Planned trials in a reasonable timeframe

• Evidence is submitted by the company – Cost model

• Expert advice – clinical/patient
MTG recommendations

• Case for adoption supported (fully, partly or not)
  – Recommendation for use
  – Recommendation for use in specific circumstances +/- further research
  – Recommendation for use in research
  – Case for adoption not supported

NICE medical technology guidance addresses specific technologies notified to NICE by manufacturers. The ‘case for adoption’ is based on the claimed advantages of introducing the specific technology compared with current management of the condition. This ‘case’ is reviewed against the evidence submitted and expert advice. If the case for adopting the technology is supported, then the technology has been found to offer advantages to patients and the NHS. The specific recommendations on individual technologies are not intended to limit use of other relevant technologies which may offer similar advantages.
Development of further evidence

• MTEP has a research workstream as an integral part of programme
• Designed to facilitate research to address gaps in evidence which led to research recommendations in MTG or DG
• Work with academic partners, industry, clinical researchers to design and manage further studies
• Flexible approach to research products but must be able to be completed within ~ two years
• Subject to findings and evaluation – updated guidance
• 6 active topics + 2 completed topics

Fig 1. Indirect research facilitation. Yellow stages are facilitated by NICE.
Research facilitation examples

- Medical Technologies Guidance 5: MIST (wound healing therapy)
  - Case for adoption not supported
  - Insufficient evidence to recommend MIST, but does have potential to enhance the healing of chronic, 'hard-to-heal', complex wounds, compared with standard methods of wound management.
  - Recommendation for further research
  - Pragmatic randomised controlled trial of MIST ultrasound therapy compared to UK standard care for the treatment of non-healing venous leg ulcers.
  - Trial results do not support the technology
Research facilitation examples

- Diagnostics Guidance 5: SonoVue (contrast enhanced ultrasound) for liver imaging
  - SonoVue recommended for use in adults in whom an unenhanced ultrasound scan is inconclusive
  - Submitted evidence estimated that 43% of ultrasound scans are inconclusive, but committee lacked confidence in the evidence due to issues with the methods, technology and population used in the evidence
  - Further research also recommended, as committee were uncertain about the percentage of unenhanced inconclusive scans
  - Retrospective audit of Radiology Information System
  - Results show that unenhanced ultrasound are frequently inconclusive
  - Supports use of SonoVue
Example of outputs

March 2015

<table>
<thead>
<tr>
<th>Output</th>
<th>Activity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical technologies guidance</td>
<td></td>
</tr>
<tr>
<td>• Published</td>
<td>24</td>
</tr>
<tr>
<td>• In development</td>
<td>5</td>
</tr>
<tr>
<td>Diagnostics guidance</td>
<td></td>
</tr>
<tr>
<td>• Published</td>
<td>16</td>
</tr>
<tr>
<td>• In development</td>
<td>9</td>
</tr>
</tbody>
</table>
## Common problems and potential solutions

<table>
<thead>
<tr>
<th>Common problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>Evidence doesn’t match the claim</td>
<td>Be clear about best possible application of product before commissioning study</td>
</tr>
<tr>
<td>Lack of clarity about the product’s position in care pathway</td>
<td>Talk to UK-based clinicians about how they might use the product and how it would change treatment</td>
</tr>
<tr>
<td>Unrealistic view of potential savings</td>
<td>Understand current treatment and availability – don’t assume a more expensive comparator is widely used</td>
</tr>
<tr>
<td>Not enough evidence to support the case for adoption</td>
<td>Share all possible sources of data with NICE – post-market, audit, unpublished</td>
</tr>
</tbody>
</table>
Find out more, get in touch

www.nice.org.uk/mt
medtech@nice.org.uk