The role of NICE in the Assessment of Innovative Medical Technologies

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NICE
Guidance Generation is based on NICE’s core principles

- **Independent advisory committees**
- Best evidence available
- Expert input
- Patient and carer involvement
- Open and transparent process
- Genuine consultation
- Regular review
INTERVENTIONAL PROCEDURES  MEDICAL TECHNOLOGIES

EFFICACY

SAFETY

COST UTILITY
The Aims of the Interventional Procedures Advisory Committee (IPAC)

- To protect patients and help clinicians, healthcare organizations and the NHS introduce procedures appropriately
- To provide guidance on the safety and efficacy of procedures
- To provide advice on training, data collection and analysis and other conditions of use for interventional procedures in the NHS
IPAC Guidance Recommendations

• Use with normal arrangements for clinical governance, consent and audit
• Use with special arrangements for clinical governance, consent and audit
• Use only in research
• Do not use
Medical Technologies Evaluation Programme

- Simplify access to medical technology evaluation
- Speed up the process
- Increase the evaluative capacity for devices within NICE
- Increase the uptake of beneficial new technologies
  - Support commissioners and providers
  - Assist clinicians
  - Inform patients
- To encourage collaborative research in industry and the NHS to generate evidence on the clinical utility and/or healthcare system benefits of selected technologies
Challenges for Generating Medtech Guidance

• Limited published evidence
  • Resource constraints of industry
  • Device-specific challenges to trial design
  • Confounding factors eg. operator skills, learning curve
  • Blinding bias; recruitment; drop-out

• Short product lifecycle
NICE Medtech evaluation
- levels of evidence -

• ‘Permissive’ approach
• No design or quality threshold
• Published research studies
• Unpublished information
  • Technical studies
  • Conference abstracts
  • Expert advice
  • Patient and carer organization views
What do decision makers need to know about new technologies?

- Incremental benefit for patients
- Impact on health system resources
- Fit with health system priorities

Product value
## NICE medtech value proposition options

<table>
<thead>
<tr>
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<th>Better</th>
<th>Non-inferior</th>
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<tbody>
<tr>
<td><strong>Clinical performance</strong></td>
<td></td>
<td></td>
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<tr>
<td><strong>Cost</strong></td>
<td>Higher</td>
<td>Less overall</td>
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<tr>
<td><strong>Evaluation method</strong></td>
<td>Cost effectiveness (QALY)</td>
<td>Cost consequences</td>
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<tr>
<td><strong>NICE guidance programme</strong></td>
<td>Technology Appraisals Programme (TAP)</td>
<td>Diagnostics Assessment Programme (DAP)</td>
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<tr>
<td><strong>Technologies</strong></td>
<td>✔ Devices ✔ Diagnostics</td>
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NICE Medtech Assessment of Innovative Technologies
Dec ‘09 – Nov ‘14

186 Technologies notified

147 considered by
Medical Technologies Advisory Committee

39 ineligible

67 Selected

35 Not selected

29 Diagnostics (DAP)

2 Technology Appraisal

1 Clinical Guidelines

Campbell et al 2016 In Press
NICE Medtech Evaluation

• Scoping
• Manufacturer submission
  • Clinical evidence
  • Cost modelling
• External Assessment Centre
  • Independent expert academic group
  • Assessment report
• MTAC draft guidance
• Public consultation
MTEP AND COST ANALYSIS

• Cost and resource consequences
• Comparative analysis vs standard NHS care
• Cost of the technology (acquisition, use and maintenance)
• Cost of healthcare use and outcomes
• Appropriate time horizon
• Uncertainty analysis
NICE Medical Technology Guidance

• Can the case for adoption be supported?
  • Quality and quantity of evidence
  • Plausible promise

• What are the advantages to patients?
  • Defined benefits
  • Defined indications

• What are the advantages to the system?
  • Cost consequences

• Is further research recommended?
Research Recommendations

**MTEP**

- Case for adoption not fully supported but potential to provide substantial benefits to patients and/or system
- Uncertainty about whether potential benefits are realizable in normal clinical settings
- Evidence gaps and research questions explicitly stated
- Must not preclude innovation but support wider adoption
- After guidance publication, NICE works with academic partners, industry, clinical researchers to design and manage further studies
- Timely to support guidance review
Conclusions

• NICE supports the adoption of safe and effective medical procedures (IPAC) and innovative medical technologies (MTAC)

• Patient safety is paramount and is a fundamental consideration in NICE evaluations

• Please consider notification of innovative technologies to MTEP that have the potential for patient and system benefits