Technology Assessment of Medical Devices at NICE – Methods, Practice and Impact

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Outline

• Policy context of NICE
• NICE’s concept of value
• Are devices different?
• The role of randomised trials
• Impact of NICE guidance
• Issues with NICE
The National Institute for Health and Clinical Excellence (NICE)

- Following election of Labour government 1997
- Prolonged controversy about ‘post code prescribing’ in the UK National Health Service
- Wish to ‘de-politicize’ decisions about which technologies to cover in NHS
- Desire to use best available methods to address difficult questions
- Focus on drugs but devices also included
The NICE process

Selection

• Specific technologies
• Lacking in transparency
• Subject to some criteria

Assessment

• Independent group
• Review plus model
• Good methods supported
• Assess company submissions
• 6 months or more
• Companies can also provide unpublished data

Appraisal

• Multi-disciplinary committees
• Take information from range of sources
• Range of decisions possible
## NICE decisions overall

<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Number</th>
<th>%</th>
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<tbody>
<tr>
<td>‘Yes’</td>
<td>27</td>
<td>23%</td>
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<tr>
<td>‘Yes, with major restrictions’</td>
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<td>32%</td>
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<tr>
<td>‘Yes, with minor restrictions’</td>
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<td>26%</td>
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<td>‘No,</td>
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<td>19%</td>
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<td>Total</td>
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<td>100%</td>
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### NICE and medical devices (1)

<table>
<thead>
<tr>
<th>NICE ID</th>
<th>DISEASE/CONDITION</th>
<th>Health Technology</th>
<th>‘Yes, should be used’</th>
<th>‘Yes, can be used’</th>
<th>Yes, Major Rstrcts</th>
<th>Yes, Minor Rstrcts</th>
<th>No, due to Cost Eff.</th>
<th>No, due to insuff. evidence</th>
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<tbody>
<tr>
<td>2</td>
<td>Primary total hip replacement</td>
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<td>4</td>
<td>Ischaemic heart disease</td>
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<td>8</td>
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<td>Hearing aid technology</td>
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<td>11</td>
<td>Arrhythmias</td>
<td>Implantable cardioverter defibrillators</td>
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<td>Colorectal cancer</td>
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<tr>
<td>18</td>
<td>Inguinal hernia, recurrent and bilateral</td>
<td>Laparoscopic surgery</td>
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<td>18</td>
<td>Inguinal hernia, primary</td>
<td>Laparoscopic surgery</td>
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<tr>
<td>38</td>
<td>Asthma, older children</td>
<td>Inhaler devices</td>
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<tr>
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<td>Central venous catheters</td>
<td>Audio-guided Doppler ultrasound guidance device</td>
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<td>ultrasound guidance device</td>
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## NICE and medical devices (2)

<table>
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<tr>
<th>NICE ID</th>
<th>DISEASE/CONDITION</th>
<th>Health Technology</th>
<th>‘Yes, should be used’</th>
<th>‘Yes, can be used’</th>
<th>Yes, Major rstrcts</th>
<th>Yes, Minor rstrcts</th>
<th>No, due to Cost Eff.</th>
<th>No, due to insuff. evidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>56</td>
<td>Stress incontinence</td>
<td>Tension-free vaginal tape (Gynecare TVT)</td>
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<td>59</td>
<td>Severe depressive illness, catatonia, prolonged or severe manic episode</td>
<td>Electroconvulsive therapy (ECT)</td>
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<tr>
<td>59</td>
<td>Schizophrenia: schizophrenia</td>
<td>Electroconvulsive therapy (ECT)</td>
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<tr>
<td>71</td>
<td>Coronary heart disease (angina or MI)</td>
<td>Bare-metal stent</td>
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</tr>
<tr>
<td>71</td>
<td>Coronary heart disease (angina or MI)</td>
<td>Drug eluting stent</td>
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<td>73</td>
<td>Coronary artery disease</td>
<td>MPS with SPECT,</td>
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<tr>
<td>78</td>
<td>Heavy menstrual bleeding</td>
<td>Fluid filled balloon, microwave ablation</td>
<td>X</td>
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<tr>
<td>83</td>
<td>Inguinal hernia repair</td>
<td>Laparoscopic surgery</td>
<td>X</td>
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</tbody>
</table>

NICE's conception of value

Cost-effectiveness Threshold
£20,000 per QALY

Price > P* £60,000
Price = P* £40,000
Price < P* £20,000

Cost

QALYs gained

Net Health Benefit
1 QALY

Net Health Benefit
-1 QALY
What is the appropriate framework for economic evaluation?

**Evidence synthesis**
- Systematic review
- Meta-analysis
- Mixed treatment comparisons
- Differing endpoints and follow-up
- Patient-level and summary data

**Decision analysis**
- Structure reflecting disease
- Incorporation of evidence on range of parameters
- Facilitates extrapolation and separation of baseline and treatment effects
- Probabilistic methods
Are devices different?

Decision problem

- Need to include all relevant alternatives to the technology of interest
  - May include pharmaceuticals
  - May include sequences and other strategies (e.g. diagnostic)

- Need to define relevant populations and sub-populations

- May differ between jurisdictions

No clear differences between devices and pharmaceuticals
Are devices different?

Evidence base

• Less likely to need trials for regulatory purposes
• Does not mean should not be used for reimbursement
• Typical ‘regulatory’ trials have limitations for economic evaluation
• The evolution of devices over time
  – Not unique to devices
  – Has implications for evidence gathering
  – Need larger longitudinal studies, sub-groups on device types
  – Comparators may also be changing over time
## Limitations of trials as a vehicle for decision making

<table>
<thead>
<tr>
<th>Trial limitations</th>
<th>NICE Examples</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inappropriate or partial comparisons</td>
<td>Temozolomide (recurrent malignant glioma)</td>
</tr>
<tr>
<td>More than one trial</td>
<td>Drugs for Alzheimer’s</td>
</tr>
<tr>
<td>Partial measurement</td>
<td>Riluzole (resource use)</td>
</tr>
<tr>
<td>Unrepresentative practice</td>
<td>Glycoproteins</td>
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<tr>
<td>Intermediate outcomes</td>
<td>Beta interferon (MS)</td>
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<tr>
<td>Limited follow-up</td>
<td>Implantable cardioverter defibrillators</td>
</tr>
<tr>
<td>No trials</td>
<td>Liquid-based cytology</td>
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</tbody>
</table>
Making trials more ‘naturalistic’

The design continuum

Comparators
- Placebo controlled
- All relevant comparators

Measurement
- Few efficacy and safety endpoints
- Resource use, QoL

Follow-up
- Shortest acceptable for registration
- Long-term follow-up

Patients
- Tightly defined
- Reflective of full range of likely patients

Practice
- Highly protocolised
- Reflective of routine practice
Evidence on impact of NICE decision on the NHS

What’s the evidence that NICE guidance has been implemented? Results from a national evaluation using time series analysis, audit of patients’ notes, and interviews

Trevor A Sheldon, Nicky Cullum, Diane Dawson, Annette Lankshear, Karin Lowson, Ian Watt, Peter West, Dianne Wright, John Wright

BMJ VOLUME 329 30 OCTOBER 2004

Conclusions Implementation of NICE guidance has been variable. Guidance seems more likely to be adopted when there
Evidence on Orlistat for obesity

We found a significant increase in the average monthly prescribing of orlistat after the guidance had been published 22 per month (0.43, 95% confidence interval 15.9 to 27.8, P < 0.001; fig

Evidence on ICDs for arrhythmias

implanted has risen, we found no evidence of a significant change after NICE guidance had been published (fig 3). Given

What influences uptake?

Box 2: Features of trusts consistent with high compliance

- Commitment to managing process of implementing guidance
- Identification of lead clinician at point of NICE announcement of topic for review
- Proactive assessment of local costs and implications of implementation
- Responsibility for funding and implementation vested in locality-wide group
- Strong clinical governance function appropriately resourced
- Culture of consensus
- Recognition of legitimacy of NICE
- Involvement of clinicians in guideline process
- Financial stability
- Expectation that compliance is mandatory, subject to identification of funding
- Targeted audit of areas of non-compliance

Issues with NICE

- They can’t look at everything
- They impose costs on local health systems
- How does NICE (on behalf of the NHS) value innovation?