Technology Appraisal at the National Institute for Health and Clinical Excellent (NICE)

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Outline

• Technology appraisal at NICE
• NICE’s preferred methodology
• Issues with NICE
The new NICE

• Technology appraisal
• Guidelines
• Public health
NICE’s origins

• 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
The NICE process
Overview

Selection → Assessment → Appraisal
The NICE process

Selection

• Focus on pharmaceuticals but not exclusively
• Not all new technologies selected
• Separate committee identifies priorities against criteria:
  – High clinical need
  – Potential for significant health gain
  – Potential for significant cost impact
  – Potential to free up resources
• Some freedom to suggest priorities
• Room for dialogue between NICE and manufacturer
• New collaborative arrangements around ‘scoping’
The NICE process

Assessment – independent report

• Undertaken by academic groups (mainly 6 contracted to NICE), typically over a period of 6 months

• 3 key elements of the review:
  – systematic review of clinical and economic evidence
  – cost-effectiveness analysis
  – critical review of sponsor (manufacturer) submission(s)

• TAR team invited to participate in appraisal committee meeting, but not decision making

• All documents (and economic model) made available to consultees
The NICE process

Assessment – consultee submissions

- Most important ones from manufacturers
- Key contribution to appraisal process:
  - provision of unpublished data
  - development of own model to synthesise evidence
- Attention paid to explaining discrepancies between company and TAR analyses
- Some collaboration between academic team and company in developing models
- Debate about the decision often centres around model
- Guidance on methods currently being updated (see www.nice.org.uk)
The NICE process

Appraisal

- Assessment reports
  - Appraisal committee
    - Expert witnesses
      - Professional submissions
      - Patient organisation submissions
      - Manufacturer submissions
      - Patient witnesses
The NICE process

1. Draft scope
2. The scoping workshop
3. Final scope and advice to Ministers
4. Referral
   - Referred
   - Not referred

   - Written submissions
   - Nominations
   - Assessment Report
   - Appraisal Committee meeting
   - Appraisal Consultation Document
   - Appraisal Committee meeting
   - Final Appraisal Determination
   - Published guidance
   - Appeal

Comments

Patient experts and clinical specialists

14 months
The NICE process

Decisions

• Unconditional reimbursement
• Reimbursement conditional on future research
• Reimbursement conditional on particular patient characteristics
• Unconditional refusal to reimburse
• Opportunity for appeal
• Decisions are reviewed in future
The impact of cost-effectiveness on NICE decisions

How NICE says it makes decisions...

6.2.6.10 Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate. Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including:

► the degree of uncertainty surrounding the calculation of ICERs
► the innovative nature of the technology
► the particular features of the condition and population receiving the technology
► where appropriate, the wider societal costs and benefits.

6.2.6.11 Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong. The reasoning for the Committee’s decision will be explained, with

## Recently completed NICE appraisals

<table>
<thead>
<tr>
<th>Number</th>
<th>Title</th>
<th>Wave</th>
<th>Completed</th>
<th>Review</th>
</tr>
</thead>
<tbody>
<tr>
<td>75</td>
<td>Hepatitis C - pegylated interferons, ribavarin and alfa interferon (No. 75)</td>
<td>7</td>
<td>Jan 2004</td>
<td>Nov 2006</td>
</tr>
<tr>
<td>74</td>
<td>Trauma - fluid replacement therapy (No. 74)</td>
<td>7</td>
<td>Jan 2004</td>
<td>Jan 2007</td>
</tr>
<tr>
<td>76</td>
<td>Epilepsy (adults) - newer drugs (No. 76)</td>
<td>6</td>
<td>Mar 2004</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>79</td>
<td>Epilepsy (children) - newer drugs (No. 79)</td>
<td>6</td>
<td>Apr 2004</td>
<td>Dec 2006</td>
</tr>
<tr>
<td>77</td>
<td>Insomnia - newer hypnotic drugs (No. 77)</td>
<td>7</td>
<td>Apr 2004</td>
<td>Apr 2007</td>
</tr>
<tr>
<td>78</td>
<td>Menstrual bleeding - fluid-filled thermal balloon and microwave endometrial ablation (No. 78)</td>
<td>6</td>
<td>Apr 2004</td>
<td>Apr 2007</td>
</tr>
<tr>
<td>80</td>
<td>Acute coronary syndromes - clopidogrel (No. 80)</td>
<td>7</td>
<td>Jul 2004</td>
<td>Jul 2007</td>
</tr>
<tr>
<td>82</td>
<td>Atopic dermatitis (eczema) - pimecrolimus and tacrolimus (No. 82)</td>
<td>8</td>
<td>Aug 2004</td>
<td>Aug 2007</td>
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<tr>
<td>81</td>
<td>Atopic dermatitis (eczema) - topical steroids (No. 81)</td>
<td>8</td>
<td>Aug 2004</td>
<td>Jul 2007</td>
</tr>
<tr>
<td>83</td>
<td>Hernia - laparoscopic surgery (review) (No. 83)</td>
<td>R</td>
<td>Sep 2004</td>
<td>Sep 2007</td>
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<tr>
<td>85</td>
<td>Renal transplantation - immuno-suppressive regimens (adults) (No. 85)</td>
<td>6</td>
<td>Sep 2004</td>
<td>Sep 2007</td>
</tr>
<tr>
<td>84</td>
<td>Sepsis (severe) - drotrecogin (No. 84)</td>
<td>8</td>
<td>Sep 2004</td>
<td>Sep 2007</td>
</tr>
<tr>
<td>86</td>
<td>Gastro-intestinal stromal tumours (GIST) - imatinib (No. 86)</td>
<td>8</td>
<td>Oct 2004</td>
<td>Oct 2007</td>
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<tr>
<td>87</td>
<td>Osteoporosis - secondary prevention (No. 87)</td>
<td>6</td>
<td>Jan 2005</td>
<td>Oct 2007</td>
</tr>
<tr>
<td>88</td>
<td>Dual-chamber pacemakers for the treatment of symptomatic bradycardia (No. 88)</td>
<td>8</td>
<td>Feb 2005</td>
<td>Jan 2007</td>
</tr>
</tbody>
</table>

Source: nice.org.uk; 10\textsuperscript{th} May 2005
The NICE process

Impact

• NICE offers guidance, but ‘mandatory’ for payers
• But little evidence on how guidance influences practice
• Rejection hard to override if expensive technology
• Acceptance will typically mean product used if clinician accepts guidance
• Little formal monitoring of restricted use
• Widespread acceptance of ‘NICE blight’
• Realisation that NICE guidance important in medical negligence cases
• NICE can affect research
NICE’s preferred methodology – the Reference Case

<table>
<thead>
<tr>
<th>Element of health technology assessment</th>
<th>Reference case</th>
<th>Section providing details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defining the decision problem</td>
<td>The scope developed by the Institute</td>
<td>5.3.2</td>
</tr>
<tr>
<td>Comparator</td>
<td>Alternative therapies routinely used in the NHS</td>
<td>5.3.2</td>
</tr>
<tr>
<td>Perspective on costs</td>
<td>NHS and PSS</td>
<td>5.3.3</td>
</tr>
<tr>
<td>Perspective on outcomes</td>
<td>All health effects on individuals</td>
<td>5.3.3</td>
</tr>
<tr>
<td>Type of economic evaluation</td>
<td>Cost-effectiveness analysis</td>
<td>5.3.4</td>
</tr>
<tr>
<td>Synthesis of evidence on outcomes</td>
<td>Based on a systematic review</td>
<td>5.4.1</td>
</tr>
<tr>
<td>Measure of health benefits</td>
<td>Quality-adjusted life years (QALYs)</td>
<td>5.5</td>
</tr>
<tr>
<td>Description of health states for calculation of QALYs</td>
<td>Health states described using a standardised and validated generic instrument</td>
<td>5.5</td>
</tr>
<tr>
<td>Method of preference elicitation for health state valuation</td>
<td>Choice-based method, for example, time trade-off, standard gamble (not rating scale)</td>
<td>5.5</td>
</tr>
<tr>
<td>Source of preference data</td>
<td>Representative sample of the public</td>
<td>5.5</td>
</tr>
<tr>
<td>Discount rate</td>
<td>An annual rate of 3.5% on both costs and health effects</td>
<td>5.7.2</td>
</tr>
<tr>
<td>Equity position</td>
<td>An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit</td>
<td>5.9.7</td>
</tr>
</tbody>
</table>

Issues with NICE

Economic evaluation for other NICE activities

• Clinical guidelines
  – Much more complicated decision problems
  – Less resource for economics
  – Clinically led

• Public health interventions
  – Perspective
  – Outcomes

• Other areas
  – Early stage interventions
Issues with NICE

Issues with manufacturers’ submissions

• Main value:
  – unpublished evidence
  – economic model

• Variable quality

• Evidence of increasing standards
  – cost-effectiveness in sub-groups

• Thorny issue of commercial in confidence data
  – Arguments for and against

• The changing perception of NICE by industry
Issues with NICE

Methodology

• Role of QALYs
  – Need for generic measure of health
  – Clear statement about preferred methods

• Role of modelling
  – Need for synthesis
  – Appropriate outcomes
  – Appropriate time horizon
  – Appropriate comparators

• Focus on explicitness

• Quantifying uncertainty
Issues with NICE

The politics of decisions

• The NICE appraisal committee is genuinely independent of government
• Comes at a political ‘cost’
  – Beta-interferon
  – Alzheimer’s drugs
• Political ‘fixes’ in some situations