Innovation; pain or value …

Or … NICE’s (increasing) role in technology assessment and appraisal in England and Wales

Meindert Boysen
Programme Director Technology Appraisals
Centre for Health Technology Evaluation
You searched for: treatment pain

Results are currently sorted by relevance (Sort results by date)

Treatments for spasticity and pain in multiple sclerosis: a systematic review

...spasticity and 15 interventions for treatment of pain. The quality and outcomes of... 786 Review of the treatment of pain in MS: methods...BM J Review of the treatment of pain in MS: results... read summary

NHR Health Technology Assessment programme, 01 December 2003 - Publication type: HTA Technology Assessment Report

Drug treatments for neuropathic pain This... other (non-drug) treatments for neuropathic pain. Contents

Your care...are already having treatment for neuropathic pain and this is helping you...

National Institute for Health and Clinical Excellence, 19 March 2010 | save result

United Kingdom back pain exercise and manipulation (UKBEAM) randomised trial: cost effectiveness of physical treatments for back pain in primary care

...effectiveness of physical treatments for back pain in primary care UK BEAM...technology Different physical treatments for back pain were compared. The treatments...effectiveness of physical treatments for back pain in primary care. BMJ 2004... read summary

NHS Economic Evaluation Database, 31 December 2005 - Publisher: Centre for Reviews and Dissemination - Publication type: Economic evaluation | save result

A randomized-control study of active and passive treatments for chronic low back pain following L5 laminectomy

...active and passive treatments for chronic low back pain following L5 laminectomy...tech exercise for the treatment of chronic low back pain (CLBP) following...the only effective treatments for chronic low back pain. Measure of benefits... read summary

NHS Economic Evaluation Database, 31 January 2000 - Publisher: Centre for Reviews and Dissemination - Publication type: Economic evaluation | save result

Economic evaluation of oral treatments for neuropathic pain

...Economic evaluation of oral treatments for neuropathic pain Soledad Cepeda M...Health technology Four treatments for neuropathic pain were evaluated: anticholinergic...different therapies for the treatment of neuropathic pain of enteric-coated or...
Search results for pain

Refrine your search using the links below

Illness or health topic
- Cancer (20)
- Cardiovascular (49)
- Central nervous system (7)
- Diagnostic procedures (12)
- Digestive system (26)
- Endocrine, nutritional and metabolic (9)
- Gynecology, pregnancy and birth (20)
- Injuries, accidents and wounds (3)
- Mouth and dental (10)
- Musculoskeletal (104)
- Public health (5)

Search results

1. Neuropathic pain - pharmacological management
   Description: The summary of the published clinical guideline on Neuropathic pain - pharmacological management

2. Neuropathic pain - pharmacological management : Full Guidance
   Description: No description available

   Description: The quick reference guide on Neuropathic pain - pharmacological management presents

4. Neuropathic pain - pharmacological management : NICE guidance written for patients and carers
   Description: The summary of the key recommendations of the clinical guideline on Neuropathic pain

5. Chest pain of recent onset
Pain at NICE

- Neuropathic pain – pharmacological management SCG
- Low back pain – CG
- Spinal cord stimulation – chronic neuropathic or ischaemic pain TA
- Pain and bleeding in early pregnancy – CG
- Percutaneous intradiscal radiofrequency thermocoagulation for lower back pain – IPG
- Deep brain stimulation for refractory chronic pain syndromes – IPG in development
- Percutaneous intradiscal electrothermal therapy for low back pain – IPG
- Percutaneous disc decompression using coblation for lower back pain – IPG
- Laparoscopic uterine nerve ablation (LUNA) for chronic pelvic pain – IPG
- Non-rigid stabilisation techniques for the treatment of low back pain - IPG
- Distal Iliotibial band lengthening for refractory greater trochanteric pain (trochanteric bursitis) – IPG in development
A short history of NICE

- **1999** -> established as Special Health Authority
  - Technology appraisals / Interventional Procedures
- **2000/1** -> creation of the National Collaborating Centres
  - Clinical Guidelines
- **2003** -> funding ‘directions’ to PCTs and NHS trusts
- **2004** -> focus implementation
- **2005** -> take over Health Development Agency functions
  - Public Health Interventions & Programmes
- **2006** -> speeding up appraisals & administration of topic selection
  - Single Technology Appraisals
- **2007** -> pilot patient safety guidance
  - Joined Patient Safety Guidance
- **2008** -> external ‘consultancy’
  - International Policy & Scientific Advice
- **2009** -> …
A short history of NICE
NICE Guidance Programmes

- Technology Appraisals
- Interventional Procedures
- Medical technologies
- Diagnostic technologies
- Service Delivery Guidelines
- Clinical Practice Guidelines
- Public Health Interventions
- Public Health Programmes
## NICE products

<table>
<thead>
<tr>
<th>Products</th>
<th>Clin &amp; cost effectiveness</th>
<th>Ministerial referral needed</th>
<th>Mandatory for the NHS; appeal</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Technology Appraisals</strong></td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>• Drugs, medical devices, diagnostics</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Interventional Procedures</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Regulating new surgical techniques</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Clinical Guidelines</strong></td>
<td>✓</td>
<td>✓</td>
<td>no</td>
</tr>
<tr>
<td>• Care pathways for diseases and conditions</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Public health programmes</strong></td>
<td>✓</td>
<td>✓</td>
<td>no</td>
</tr>
<tr>
<td>• Disease prevention</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Implementation support</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• Costing tools and commissioning guides</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
New Prioritisation Criteria (TAs only)

1. **Population 1-5** The larger the population, the more important a technology is for evaluation.

2. **Disease severity 1-5** Severity of condition impacts on importance of evaluation; takes into account: life expectancy; how far the individual is away from perfect health and health states that incur social stigma.

3. **Resource impact 1-5** Potential resource impact of guidance including cost of implementing guidance, including any additional service, facilities or staff requirements.

4. **Claimed Therapeutic benefit 1-5** Extent to which a new technology claims measurable therapeutic benefit over currently available NHS treatments.
## NICE guidance in the UK

<table>
<thead>
<tr>
<th></th>
<th>England</th>
<th>Wales</th>
<th>Scotland</th>
<th>Northern Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technology Appraisals</td>
<td>✓</td>
<td>✓</td>
<td>NICE Multiple Technology Appraisal guidance is generally disseminated after local review</td>
<td>NICE guidance is generally disseminated after local review</td>
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<tr>
<td>Interventional Procedures</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Clinical Guidelines</td>
<td>✓</td>
<td>✓</td>
<td>-</td>
<td>NICE guidance is generally disseminated after local review</td>
</tr>
<tr>
<td>Public Health</td>
<td>✓</td>
<td></td>
<td>NICE guidance is generally disseminated after local review</td>
<td>NICE guidance is generally disseminated after local review</td>
</tr>
</tbody>
</table>
A short future of NICE
Evidence in Health and Social Care

Search

This is a new site, please give us your feedback
The “virtual” Institute

NICE

- Appraisal Committees
- Interventional Procedures
- Specialist advisors
- Technology Assessment Groups
- Public health interventions
- Collaborating Centres (clinical guidelines)
- Collaborating Centres (public health)
- GDGs
- PDGs (Public health)
NICE decision cycle

- Evidence review
- Appraisal
- Consultation
- Guidance
- Update decision
Assessment and appraisal

**ASSESSMENT**

- Published Evidence
- Unpublished Evidence?
- Review of Evidence

**APPRAISAL**

- Patient Groups
- Healthcare Professional Groups
- Policy Making
- Clinical Experts
- Health Service
Methods and processes

Evidence assessment

Scientific and social value judgements

Expert advice
Technology Appraisal Programme

10 years of process adaptation

2000
First review of methods
Appeal rights to all consultees

2003
Second review of methods and process
WHO review positions NICE as ‘world leader’

2006
Third review of methods and process
Faster appraisals: single technology appraisal process

2009
3 judicial reviews
Fourth review of process PPRS

Health and Clinical Excellence
2009 Process updates

**Transparent**
- Meetings in public
- Non-submissions & terminated appraisals

**Methodological robustness**
- Factual error checks
- Evidence submitters at meeting
- HTA groups at scoping

**Clarification and consultation**
- Economic model release

**Independent decision making**
- Nominating & selecting experts
- PCTs

**Inclusive**
- Patient access schemes & flexible pricing
Test of time – judicial policy
… ‘industrial’ policy
The NICE value proposition

- Improved health outcomes
- Well constructed evidence base
- Competitive Price

Value
A win-win value formula

Value-added fairly priced technology

Informed discriminating customers

A healthy long-term partnership

NICE
## Encouraging results

<table>
<thead>
<tr>
<th>Decision</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unrestricted</td>
<td>99</td>
<td>29%</td>
</tr>
<tr>
<td>Optimised</td>
<td>193</td>
<td>55%</td>
</tr>
<tr>
<td>Only in Research</td>
<td>22</td>
<td>6%</td>
</tr>
<tr>
<td>Not recommended</td>
<td>32</td>
<td>9%</td>
</tr>
<tr>
<td>Non-submission</td>
<td>4</td>
<td>1%</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>342</strong></td>
<td><strong>100%</strong></td>
</tr>
</tbody>
</table>

55% of our advice optimises the use of new treatments.

350 decisions in 170 technology appraisals: 2000 – 2009 (May)

<table>
<thead>
<tr>
<th>Rationale</th>
<th>Number</th>
<th>Percent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient group</td>
<td>153</td>
<td>79%</td>
</tr>
<tr>
<td>Price</td>
<td>53</td>
<td>27%</td>
</tr>
<tr>
<td>Continuation rule</td>
<td>31</td>
<td>16%</td>
</tr>
<tr>
<td>Regimen</td>
<td>5</td>
<td>3%</td>
</tr>
<tr>
<td>Setting</td>
<td>4</td>
<td>2%</td>
</tr>
</tbody>
</table>

Most optimised decisions are based on the patients' capacity to benefit...
# Methods - 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>5.2.5 &amp; 5.2.6</td>
</tr>
<tr>
<td>Comparator</td>
<td>Therapies routinely used in the NHS, including technologies regarded as current best practice</td>
<td>5.2.5 &amp; 5.2.6</td>
</tr>
<tr>
<td>Perspective on costs</td>
<td>NHS and PSS</td>
<td>5.2.7 to 5.2.10</td>
</tr>
<tr>
<td>Perspective on outcomes</td>
<td>All health effects on individuals</td>
<td>5.2.7 to 5.2.10</td>
</tr>
<tr>
<td>Type of economic evaluation</td>
<td>Cost-effectiveness analysis</td>
<td>5.2.11 &amp; 5.2.12</td>
</tr>
<tr>
<td>Synthesis of evidence on outcomes</td>
<td>Based on a systematic review</td>
<td>5.3</td>
</tr>
<tr>
<td>Measure of health effects</td>
<td>QALYs</td>
<td>5.4</td>
</tr>
<tr>
<td>Source of data for measurement of HRQL</td>
<td>Reported directly by patients and/or carers</td>
<td>5.4</td>
</tr>
<tr>
<td>Source of preference data for valuation of changes in HRQL</td>
<td>Representative sample of the public</td>
<td>5.4</td>
</tr>
<tr>
<td>Discount rate</td>
<td>An annual rate of 3.5% on both costs and health effects</td>
<td>5.6</td>
</tr>
<tr>
<td>Equity weighting</td>
<td>An additional QALY has the same weight regardless of the other characteristics of the individuals receiving the health benefit</td>
<td>5.12</td>
</tr>
</tbody>
</table>

HRQL, health-related quality of life; NHS, National Health Service; PSS, personal social services; QALYs, quality-adjusted life years.
Comparison of Alternative Treatments

- Less effective and more costly
- More effective and more costly
- Less effective and less costly
- More effective and less costly

Cost Difference

Effectiveness (QALY) difference
The Quality Adjusted Life Year

- Health-related quality of life
- Length of life (years)
- Initial QALY loss due to side effects
- Current treatment
- New treatment
- QALYs gained

QALYs gained

Current treatment

Initial QALY loss due to side effects

New treatment

0

1

Health-related quality of life

Length of life (years)
## Definition of health states:

**e.g. The EuroQoL**

<table>
<thead>
<tr>
<th>Mobility</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems in walking about</td>
<td>✓</td>
</tr>
<tr>
<td>I have some problems in walking about</td>
<td></td>
</tr>
<tr>
<td>I am confined to bed</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Self-care</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems with self care</td>
<td>✓</td>
</tr>
<tr>
<td>I have some problems washing or dressing myself</td>
<td></td>
</tr>
<tr>
<td>I am unable to wash or dress myself</td>
<td></td>
</tr>
</tbody>
</table>

**Usual activities (e.g. work, study, housework, family or leisure activities)**

<table>
<thead>
<tr>
<th>Usual activities</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no problems with performing my usual activities</td>
<td>✓</td>
</tr>
<tr>
<td>I have some problems with performing my usual activities</td>
<td></td>
</tr>
<tr>
<td>I am unable to perform my usual activities</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pain/discomfort</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I have no pain or discomfort</td>
<td>✓</td>
</tr>
<tr>
<td>I have moderate pain or discomfort</td>
<td></td>
</tr>
<tr>
<td>I have extreme pain or discomfort</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Anxiety/depression</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>I am not anxious or depressed</td>
<td>✓</td>
</tr>
<tr>
<td>I am moderately anxious or depressed</td>
<td></td>
</tr>
<tr>
<td>I am extremely anxious or depressed</td>
<td></td>
</tr>
</tbody>
</table>
The Cost-Effectiveness Threshold?

- No fixed floor or ceiling
- Comparisons with other programmes that are currently funded in the NHS
- Cost effectiveness versus affordability
- Consideration of opportunity costs
The problem

A fixed ‘budget’ and lost ‘opportunity costs’

• No fixed floor or ceiling
• Comparisons with other programmes that are currently funded in the NHS
• Cost effectiveness versus affordability
• Consideration of opportunity costs

One in, one out?
Appraising Cost-Effectiveness

- Below £20,000/QALY - CE
- Above £20,000/QALY - CE and other factors
  - The degree of certainty surrounding the calculation of ICERs
  - Change in HRQoL inadequately captured
  - The innovative nature of the technology
- Above £30,000/QALY as above but much stronger (!)
- Always give reasons
- ADDENDUM 2009: ‘Appraising life-extending, end of life treatments’
Why NICE doesn’t have a fixed cost effectiveness threshold?

- Cost-effectiveness
- Extent of uncertainty
- Innovation
- Equality & Diversity legislation
- Social Value Judgements

NICE DECISIONS
Kennedy and Innovation

• Where innovation is considered to be a specific and identifiable benefit of the technology
  – scoping process to explore the characteristics and the data sources

• When identified, the Appraisal Committee investigates
  – potential to make a significant and substantial impact on health-related benefits
  – how it might improve the way that a current need is met
  – whether it can be regarded as a ‘step-change’

• Where satisfied that the product is a ‘step change’
  – demonstrate either that the product’s identified innovative characteristics have been taken into account in the QALY calculation or
  – how it has separately evaluated them and what their impact is on its judgement of the most plausible ICER
Neuropathic pain
The pharmacological management of neuropathic pain in adults in non-specialist settings
Neuropathic Pain – CG96 (2010)

- ‘Blanket condition’ / PHN & PDN
- Specific technologies / all technologies / class
- Limited number of health states / more levels of pain states / lack of utilities for AEs
- Dosing in practice / dosing per SPC / titration
- Expert opinion for resource use and adverse events
- Real practice / inclusion limited to RCTs
- No inclusion of combination therapy
- Cross-over effects in trials
- No accounting for comorbidities
- Extrapolation to different disease severities
- Indirect comparison technologies – hierarchy of pharmaceuticals in net benefit
- Threshold 30k/QALY in BC and 20k/QALY in SA
- Sequential and VIO as separate analyses by GDG
- Compliance 100% in BC and 50% in SA
Research recommendations CG96

• For all of these research recommendations, trials on the efficacy of drugs in relieving neuropathic pain should have a sufficiently long follow-up to assess the long-term effects of the drugs.

• Minor and major adverse events should be reported separately for all trial arms, and data on failure to respond to other analgesics should be collected.

• Definitions of primary and secondary outcomes and data collection methods must be consistent for all neuropathic pain research.

• Data on pain reduction should be reported not only as a dichotomous outcome of pain reduction at a threshold of 30% or 50%, but also as a more clinically representative measure that better captures the degree of pain reduction with a greater number of categories.
Research recommendations CG96

• There is evidence suggesting that people with neuropathic pain experience poorer physical and mental health than people with other forms of pain, even when adjusted for pain intensity. The **discrepancy between pain intensity and quality of life** implies that other, unrecognised factors are important for people with neuropathic pain and that these factors may influence their daily activities and participation. An observational or qualitative study should be carried out to identify the key factors that may influence the daily activities and participation of people with neuropathic pain. The study population should be adults (aged 18 or over) with neuropathic pain. The primary outcome of interest is the improvement in overall quality of life.
Pain, innovation and NICE?

• NICE is entering its second decade with a broad range of products that will help guide the NHS in its activities to provide access to innovation.
• Using an adaptable process that focuses on stakeholder involvement and transparency.
• Approaching its task using an accepted methodology.
• And focussing on independent decision making that allows for scientific and social value judgements to play a part.
• Pain features in a variety of ways in NICE’s work, albeit that few products have been appraised.