

The HTA challenge of medical device assessment: The perspective of assessor

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Disclosures

- First Director of Technology Appraisals at NICE (1999-2001) & member of NICE Technology Appraisal & Interventional Procedures Advisory Committees (2003-present)
- Co-director of a UK University health technology assessment group
- Consultant for healthcare industry

Background

- In addition to pharmaceuticals, many health care systems also assessing clinical effectiveness & cost-effectiveness of medical devices to inform reimbursement/coverage decisions.
- However, argued that there are important differences between devices & medicines that make the HTA methods used for pharmaceuticals inappropriate for devices.

Assessing the Clinical and Cost-Effectiveness of Medical Devices and Drugs: Are They That Different?

Drugs	Devices
Unchanging compound	Constantly evolving
Complications increase with use	Complications decrease with use
Results unrelated to physician skill	Results vary with operator
Placebo usually available	No placebo
Crossover rare	Crossover common

Taylor & Iglesias. Value in Health 2009;12:404-6.

Outline of presentation

- NICE medical device HTA process
- Are medical devices different? A case study
 - Spinal cord stimulation for pain syndromes
- Conclusions

NICE & Medical Devices

- 20% of all current published NICE appraisals are 'device' appraisals
 - MTA process
- Most have recommended the use of the technology either generally or in specific circumstances
- Many involve the combination of evaluation of a device and a surgical procedure

NICE & Medical Devices

- Hip replacement
- Coronary artery stents
- Hearing disability - hearing aids, cochlear implants
- Inhaler devices
- Ultrasound locating devices
- Tension-free vaginal tape
- Insulin pumps, inhaled insulin
- Endometrial ablation techniques
- Pacemakers, ICDs, resynchronisation therapy
- Continuous positive airway pressure devices
- Spinal cord stimulation



*National Institute for
Health and Clinical Excellence*

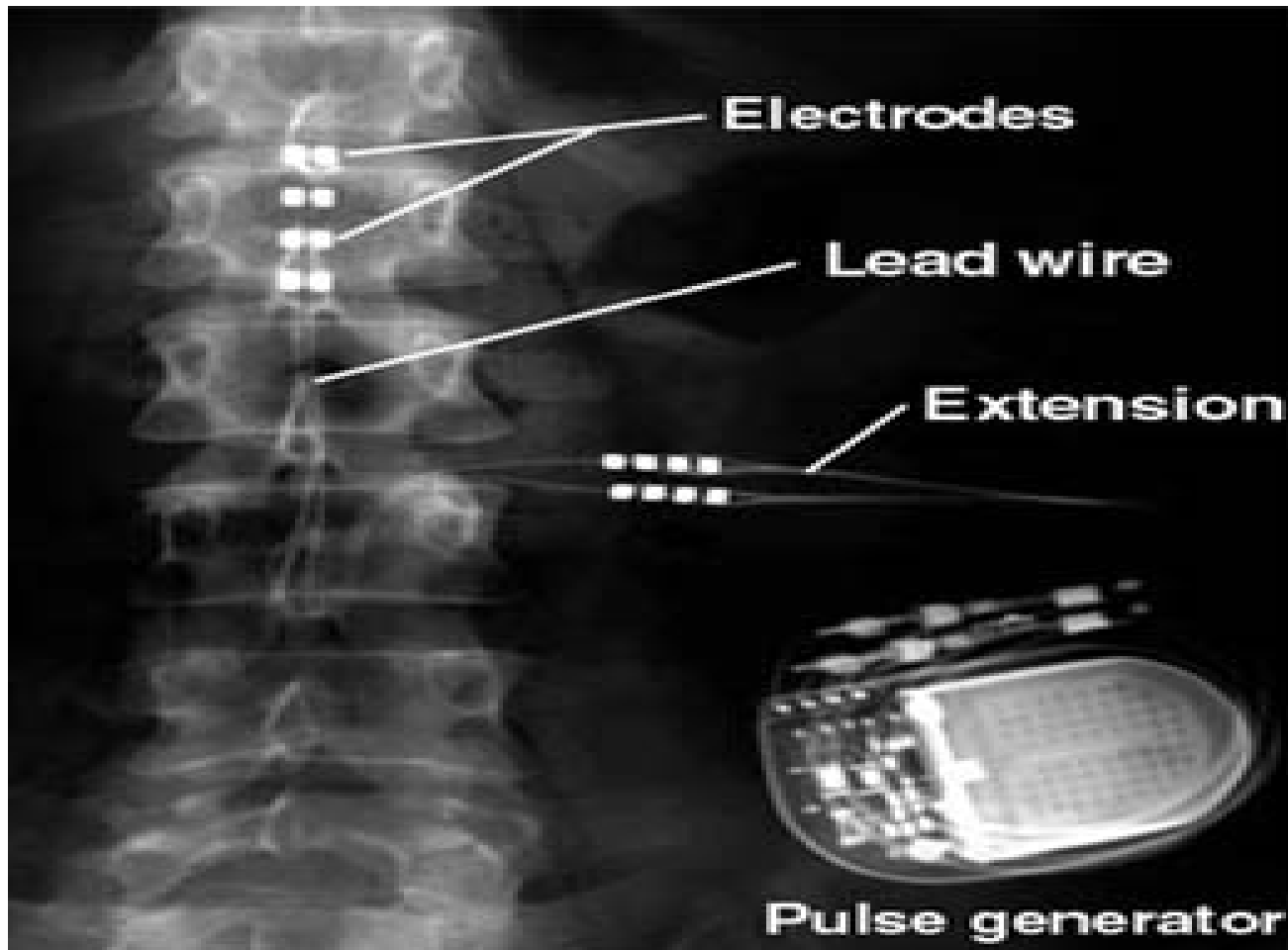
Issue date: June 2008

**Guide to the methods
of technology appraisal**

The NICE Reference Case...

Comparator	Alternatives routinely used in the NHS
Perspective on costs	NHS & PSS
Perspective on outcomes	All health effects on individuals
Type of economic evaluation	Cost-effectiveness analysis
Synthesis of evidence on outcomes	Based on systematic review
Measure of health benefits	QALYs
Description of health states	Standardised-validated generic instrument
Preference elicitation	Choice-based , preferably EQ-5D
Source of preference data	Representative sample of the public
Discount rate	3.5% pa on costs and health effects
Equity position	A QALY is a QALY is a QALY...

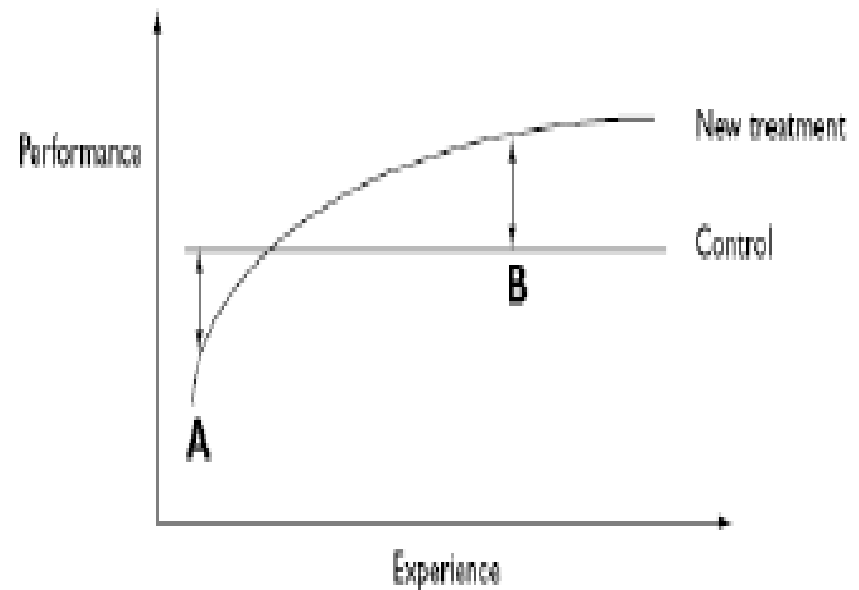
Spinal Cord Stimulation



HTA Challenge I - Learning Curve

Unlike in pharmaceuticals, the effect of a medical device that is applied through surgical or other interventional means depends considerably on the **skills and the experience of the user**.

This has an impact on the **appropriate timing for a clinical trial and on the external validity of study results**.



Source : Ramsay et al (2001)

Cook et al (2004)

Buxton's Law

“It always too early (for rigorous evaluation) until, unfortunately, it's suddenly too late”



EUROPEAN
SOCIETY OF
CARDIOLOGY®

European Heart Journal
doi:10.1093/eurheartj/ehi827

An open label, single-centre, randomized trial of spinal cord stimulation vs. percutaneous myocardial laser revascularization in patients with refractory angina pectoris: the SPiRiT trial

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SCS for RA

Cost per QALY @ 2-yr

	SCS (n=34)	Percutaneous myocardial laser revascularisation (n=34)	Difference
Costs	£17,736	£12,215	+£5,520
QALYs	1.19	1.07	+0.12
ICER			£46,000 per QALY

Dyer (2008) *Trials* 2008;9:40-51

- *“Exploring the cost-effectiveness of SCS versus PMR in the first and second half of the study suggested there was an improvement over time, which could be indicative of a learning curve effect.*
- *For patients recruited during 2000/01, the ICER was estimated at £230,000 per QALY (95% CI: -£2,670,000 to £590,000) whereas for 2002/03, the ICER was estimated at £18,000 per QALY (95% CI: -£21,000 to 51,000).*
- *This improvement can largely be explained by better outcomes, in terms of survival and QoL, experienced by SCS patients in the second half of the study. “*



PAIN

Pain 2007;132:179-88

www.elsevier.com/locate/pain

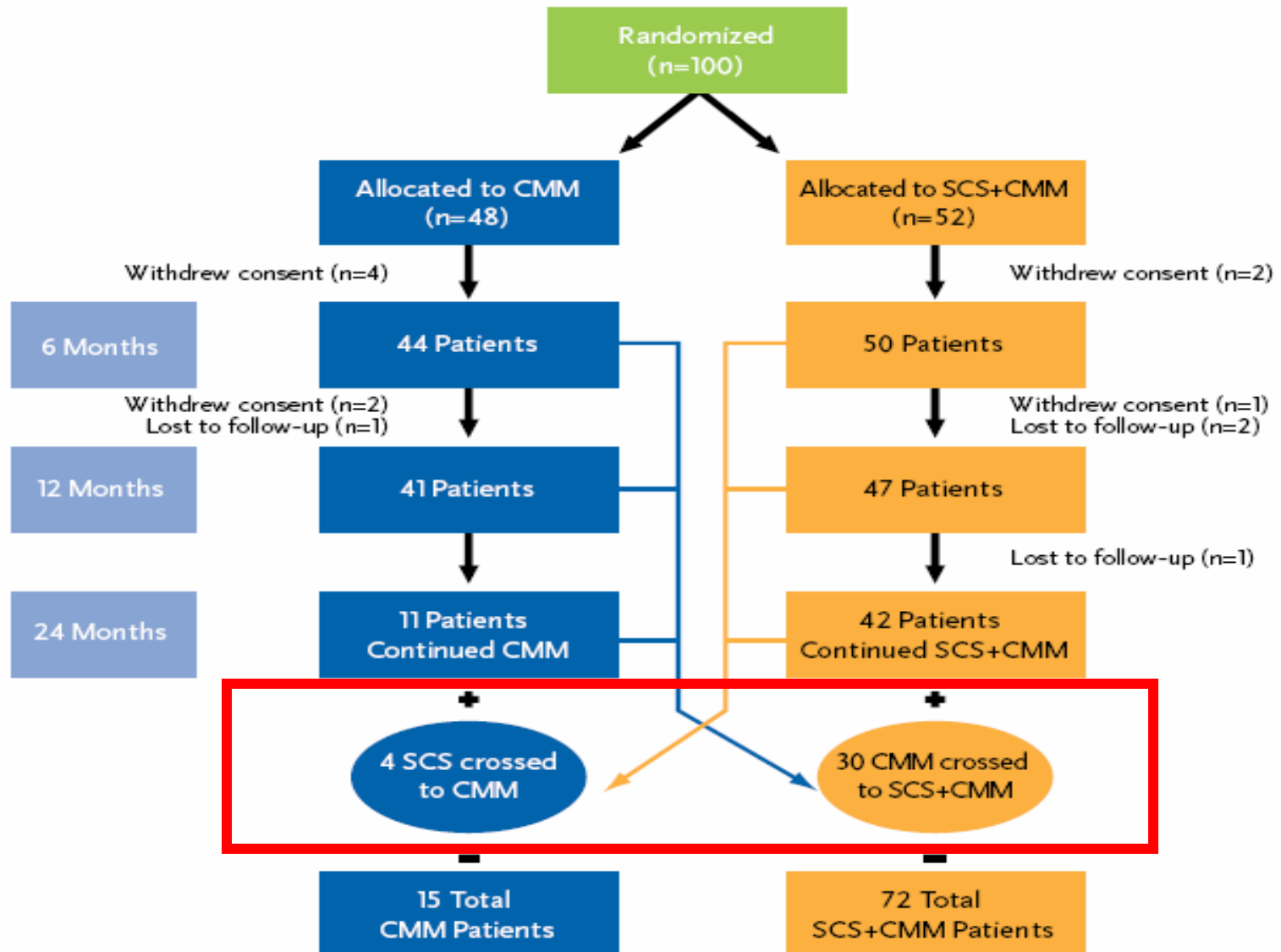
Spinal cord stimulation versus conventional medical management
for neuropathic pain: A multicentre randomised controlled trial
in patients with failed back surgery syndrome

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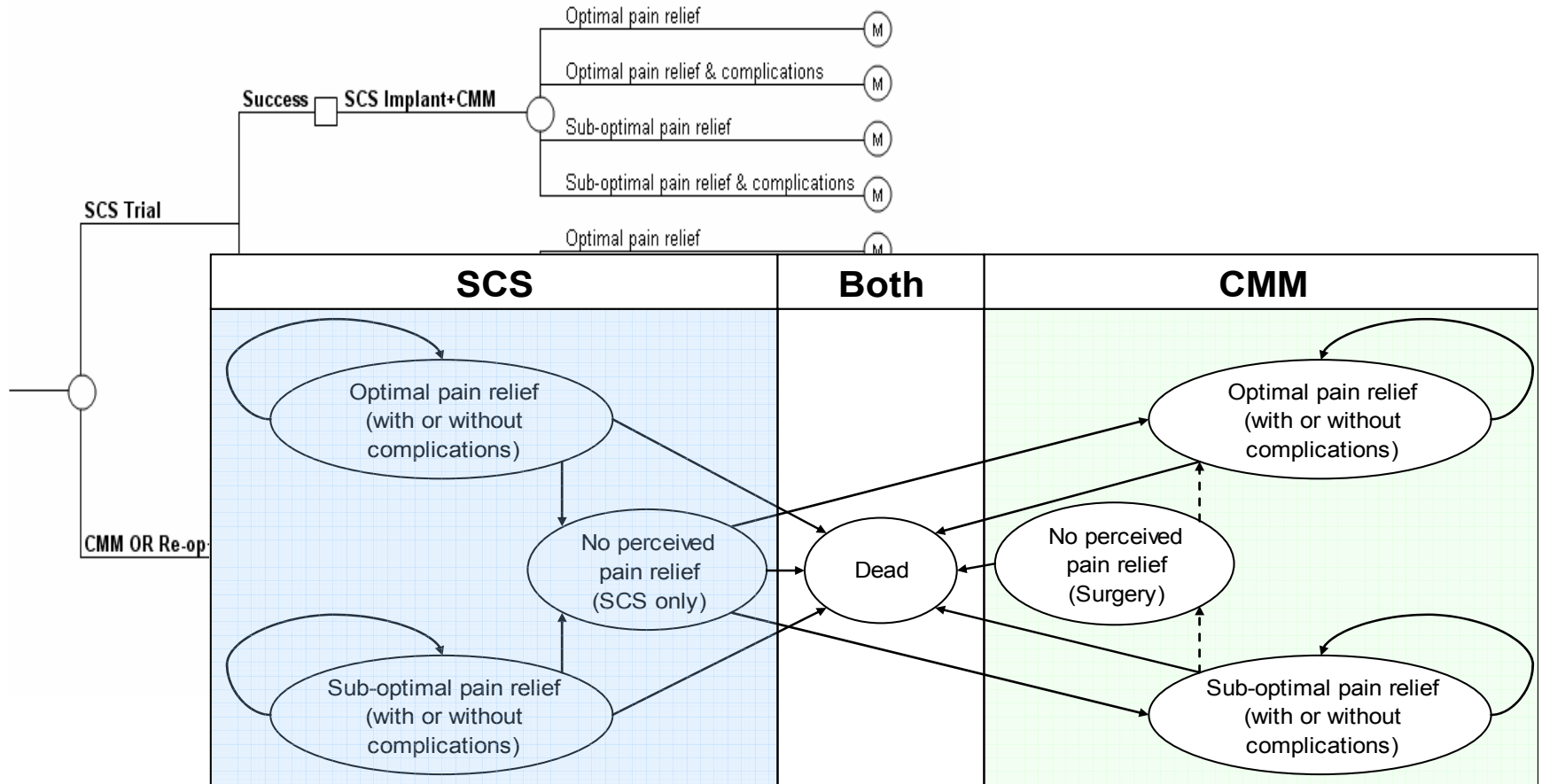
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HTA Challenge II – Unplanned cross-over



SCS Economic Model

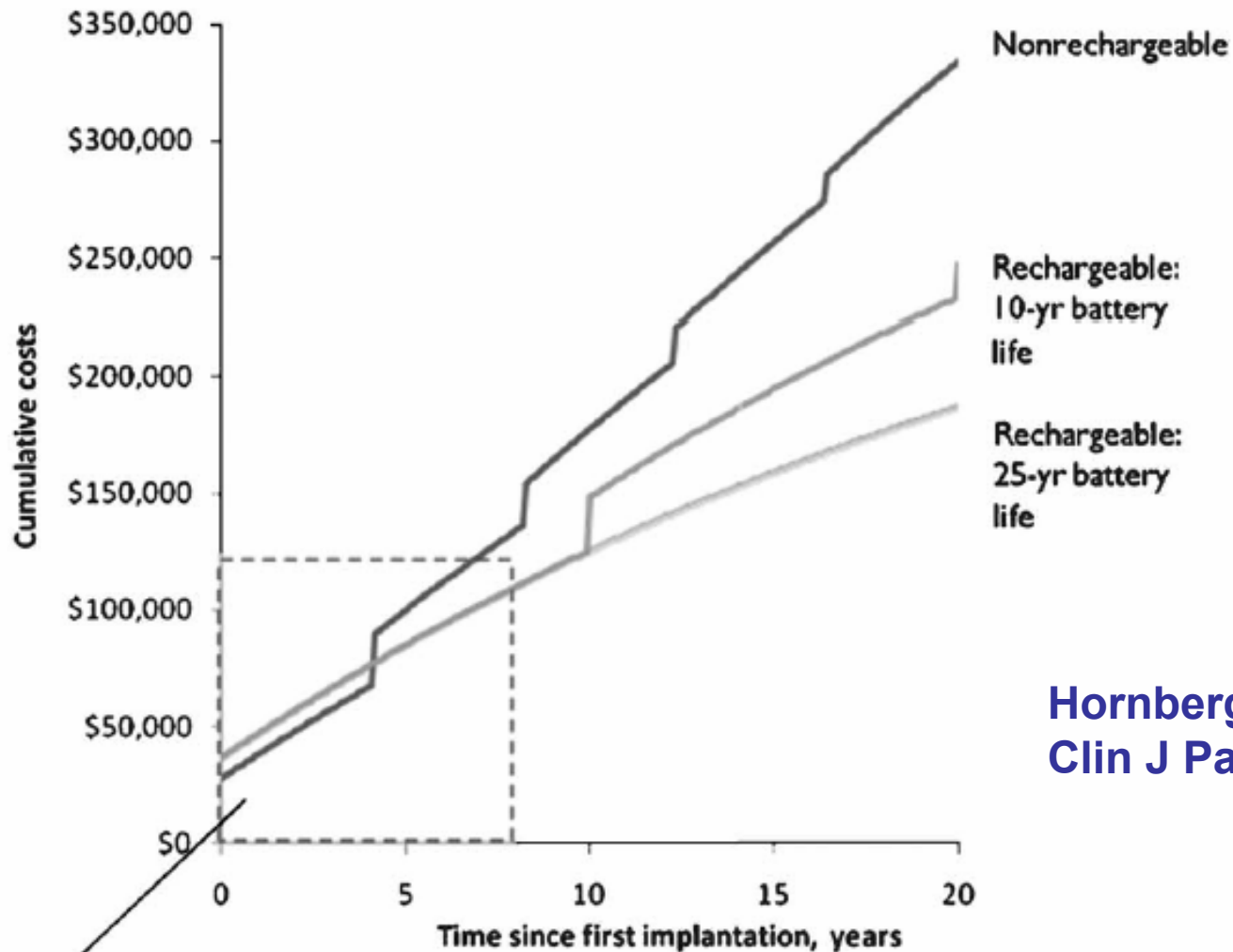


HTA Challenge III

Technological Innovations

- **Electrodes**
 - Degree of coverage
 - Efficiency/longevity
- **Battery**
 - Miniaturisation
 - Longevity
 - Rechargeability

Rechargeable Devices?

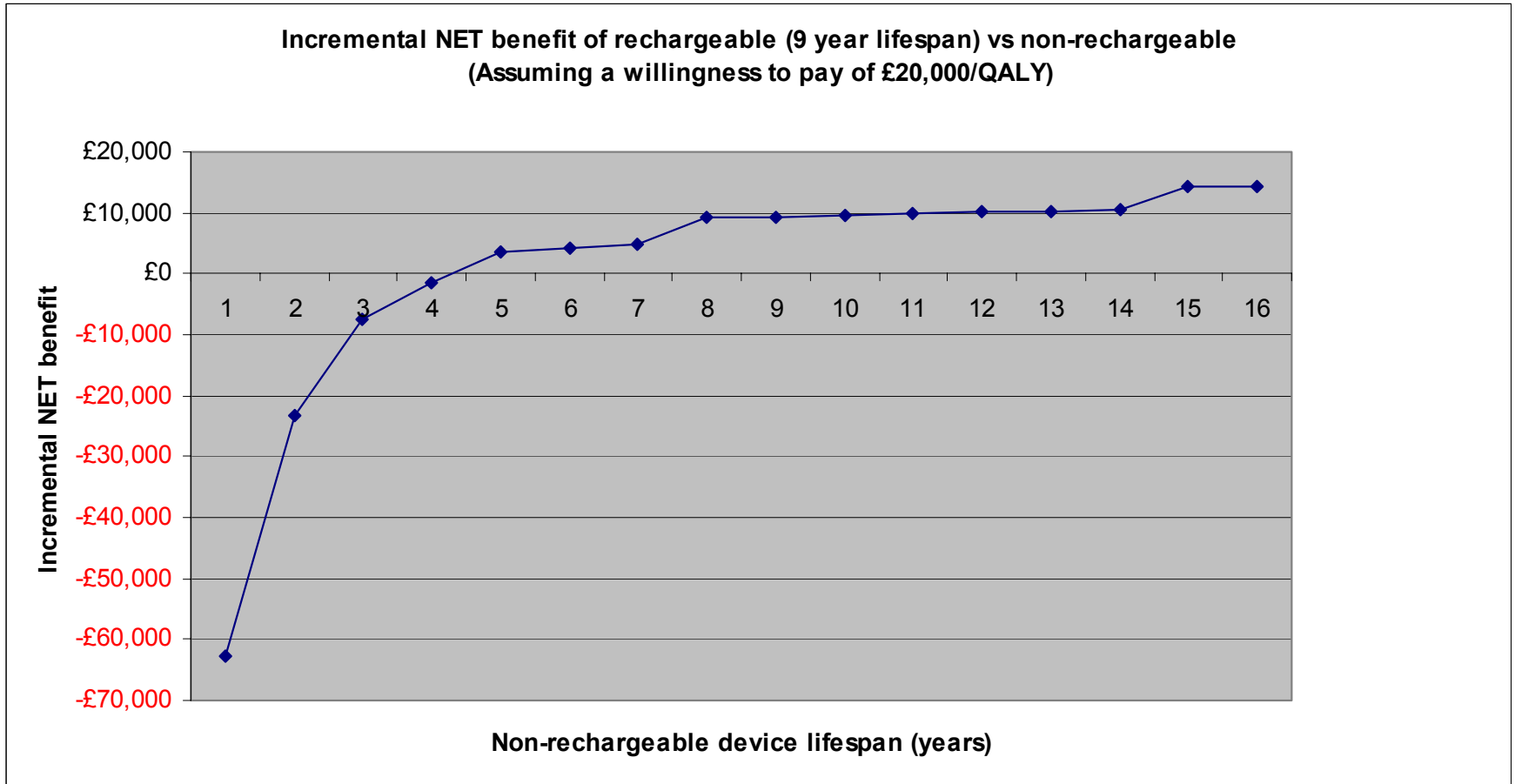


Hornberger
Clin J Pain 2008

SCS for FBSS

Rechargeable vs. Non-rechargeable Device

Synergy - £7,761 vs. Restore Ultra - £15,076



Taylor et al (2009) *Pain* In press

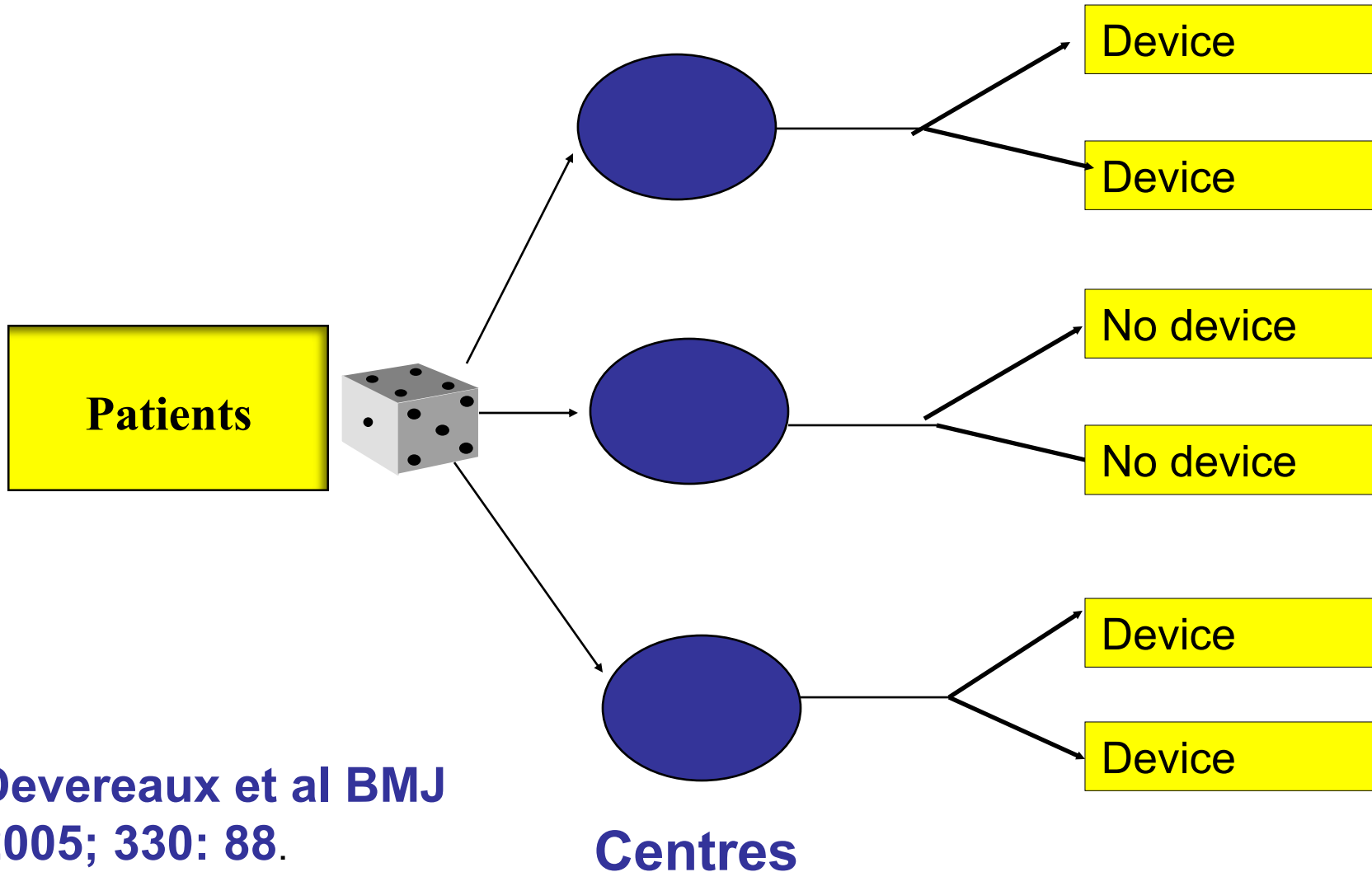
Conclusions I

- Increasing desire of healthcare systems to....
 1. apply HTA methods to medical devices in order to inform their coverage/reimbursement decisions.
 2. apply same HTA methods regardless of health technologies (i.e. drugs, medical devices or diagnostics)

Conclusions II

- However, there are issues related to medical devices that need to be considered by HTA assessors
 - Lack of RCT evidence
 - Learning curve – external validity
 - Incremental technological innovation vs. cost
- Evidence generation/assessment
 - Head-to-head trials of incremental innovations
 - Cluster (expertise) RCTs
 - Medical devices = “complex intervention”

Cluster (Expertise) RCT design



Devereaux et al BMJ
2005; 330: 88.

Extending the CONSORT Statement to Randomized Trials of Nonpharmacologic Treatment: Explanation and Elaboration

Isabelle Boutron, MD, PhD; David Moher, PhD; Douglas G. Altman, DSc; Kenneth F. Schulz, PhD, MBA; and Philippe Ravaud, MD, PhD, for the CONSORT Group*

Adequate reporting of randomized, controlled trials (RCTs) is necessary to allow accurate critical appraisal of the validity and applicability of the results. The CONSORT (Consolidated Standards of Reporting Trials) Statement, a 22-item checklist and flow diagram, is intended to address this problem by improving the reporting of RCTs. However, some specific issues that apply to trials of nonpharmacologic treatments (for example, surgery, technical interventions, devices, rehabilitation, psychotherapy, and behavioral intervention) are not specifically addressed in the CONSORT Statement. Furthermore, considerable evidence suggests that the reporting of nonpharmacologic trials still needs improvement. Therefore, the CONSORT group developed an extension of the CONSORT Statement for trials assessing nonpharmacologic treatments. A consensus meeting of 22 experts was organized in Paris, France, in February

trials of nonpharmacologic treatments. The participants extended 11 items from the CONSORT Statement, added 1 item, and developed a modified flow diagram.

To allow adequate understanding and implementation of the CONSORT extension, the CONSORT group developed this elaboration and explanation document from a review of the literature to provide examples of adequate reporting. This extension, in conjunction with the main CONSORT Statement and other CONSORT extensions, should help to improve the reporting of RCTs performed in this field.



Who we are

What we do

How we work

NICE website development

Jobs

Tenders

Scientific advice

Quality and Outcomes Framework

Quality standards

Medical technologies

NICE International

Evaluation Pathway Programme for Medical Technologies

NICE is launching a new programme focusing specifically on the evaluation of innovative medical technologies (including devices and diagnostics). This new programme will both compliment and operate in conjunction with NICE's existing technology appraisal capacity, which will continue to evaluate new pharmaceutical and biotechnology products. The new programme is designed to help the NHS adopt effective and cost effective medical devices and diagnostics more rapidly and consistently.

The types of products which might be included are medical devices that deliver treatment such as those implanted during surgical procedures, technologies that give greater independence to patients, and diagnostic devices or tests used to detect or monitor medical conditions.

The establishment of this programme follows the acknowledgement in the 2008 report 'High quality care for all' of the need to simplify the pathway by which medical technologies pass from development into wider use.

Medical Technologies Advisory Committee

The Evaluation Pathway Programme will support the newly created Medical Technologies Advisory Committee. Its functions will include identifying and selecting innovative medical technologies and routing these products to the appropriate NICE guidance production programme. The Committee will also develop its own recommendations to be issued as Medical Technologies Guidance