

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



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

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- Companies can also provide unpublished data

- Multi-disciplinary committees
- Take information from range of sources
- Range of decisions possible

NICE decisions overall

Recommendation	Number	%
'Yes'	27	23%
'Yes, with major restrictions'	38	32%
'Yes, with minor restrictions'	30	26%
'No,	22	19%
Total	117	100%

Source: Raftery, *BMJ* 2006.

NICE and medical devices (1)

NICE ID	DISEASE/CONDITION	Health Technology	'Yes, should be used'	'Yes, can be used'	Yes, Major rstrcts	Yes, Minor Rstrcts	No, due to Cost Eff.	No, due to insuff. evidence
2	Primary total hip replacement	Hip prostheses				X		
4	Ischaemic heart disease	Coronary artery stents				X		
8	Hearing	Hearing aid technology			X			
10	Asthma, under 5s	Inhaler systems			X			
11	Arrhythmias	Implantable cardioverter defibrillators				X		
17	Colorectal cancer	Laparoscopic surgery						X
18	Inguinal hernia, recurrent and bilateral	Laparoscopic surgery				X		
18	Inguinal hernia, primary	Laparoscopic surgery					X	
38	Asthma, older children	Inhaler devices				X		
44	Hip resurfacing	Metal on metal				X		
49	Central venous catheters	2-D imaging ultrasound guidance device				X		
49	Central venous catheters	Audio-guided Doppler ultrasound guidance device						X

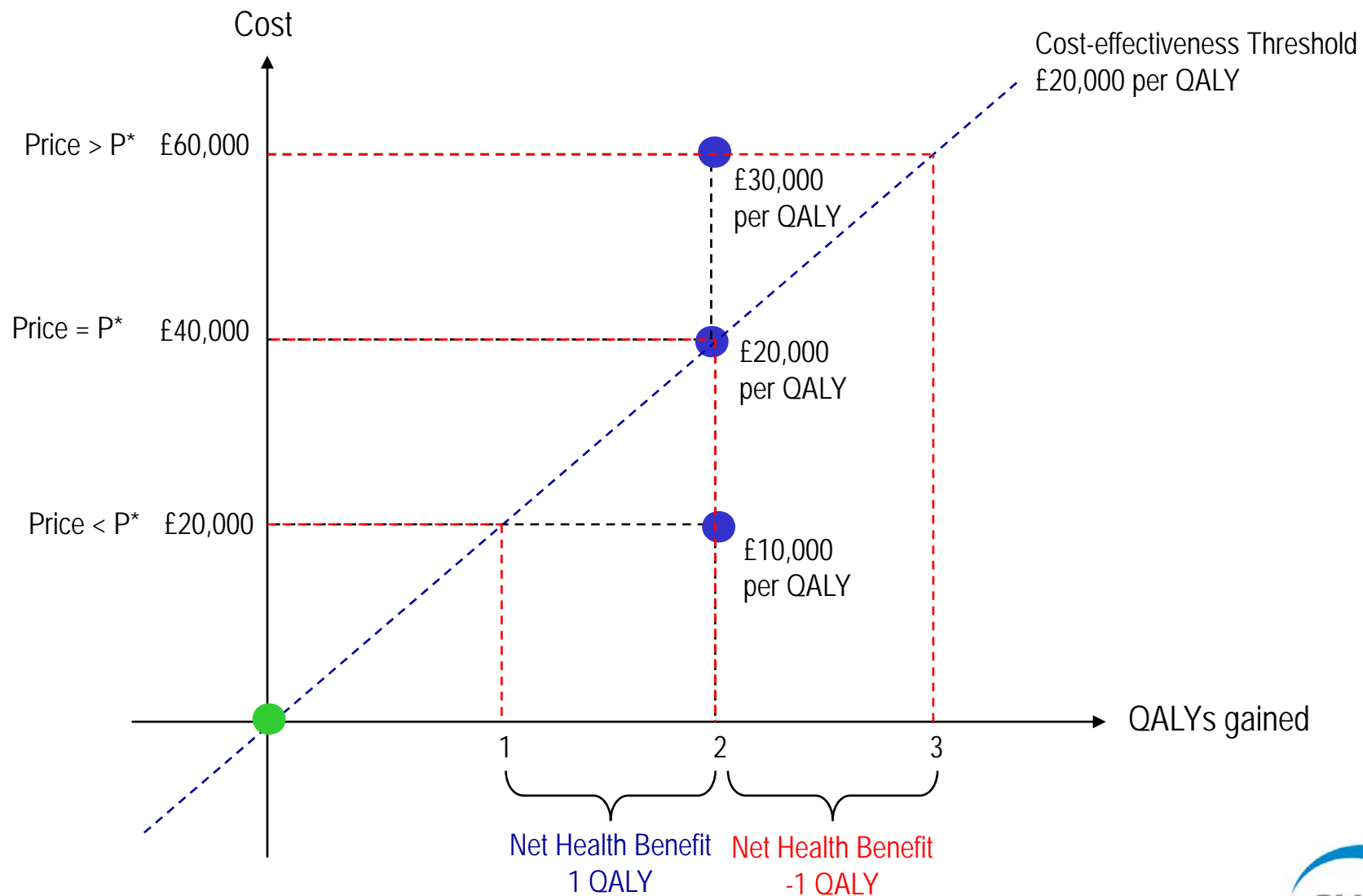
Source: Raftery, *BMJ* 2006.

NICE and medical devices (2)

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

Source: Raftery, *BMJ* 2006.

NICE's conception of value



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

Trial limitations

NICE Examples

Inappropriate or partial comparisons

Temozolomide (recurrent malignant glioma)

More than one trial

Drugs for Alzheimer's

Partial measurement

Riluzole (resource use)

Unrepresentative practice

Glycoproteins

Intermediate outcomes

Beta interferon (MS)

Limited follow-up

Implantable cardioverter defibrillators

No trials

Liquid-based cytology

Making trials more 'naturalistic'

The design continuum



Evidence on impact of NICE decision on the NHS

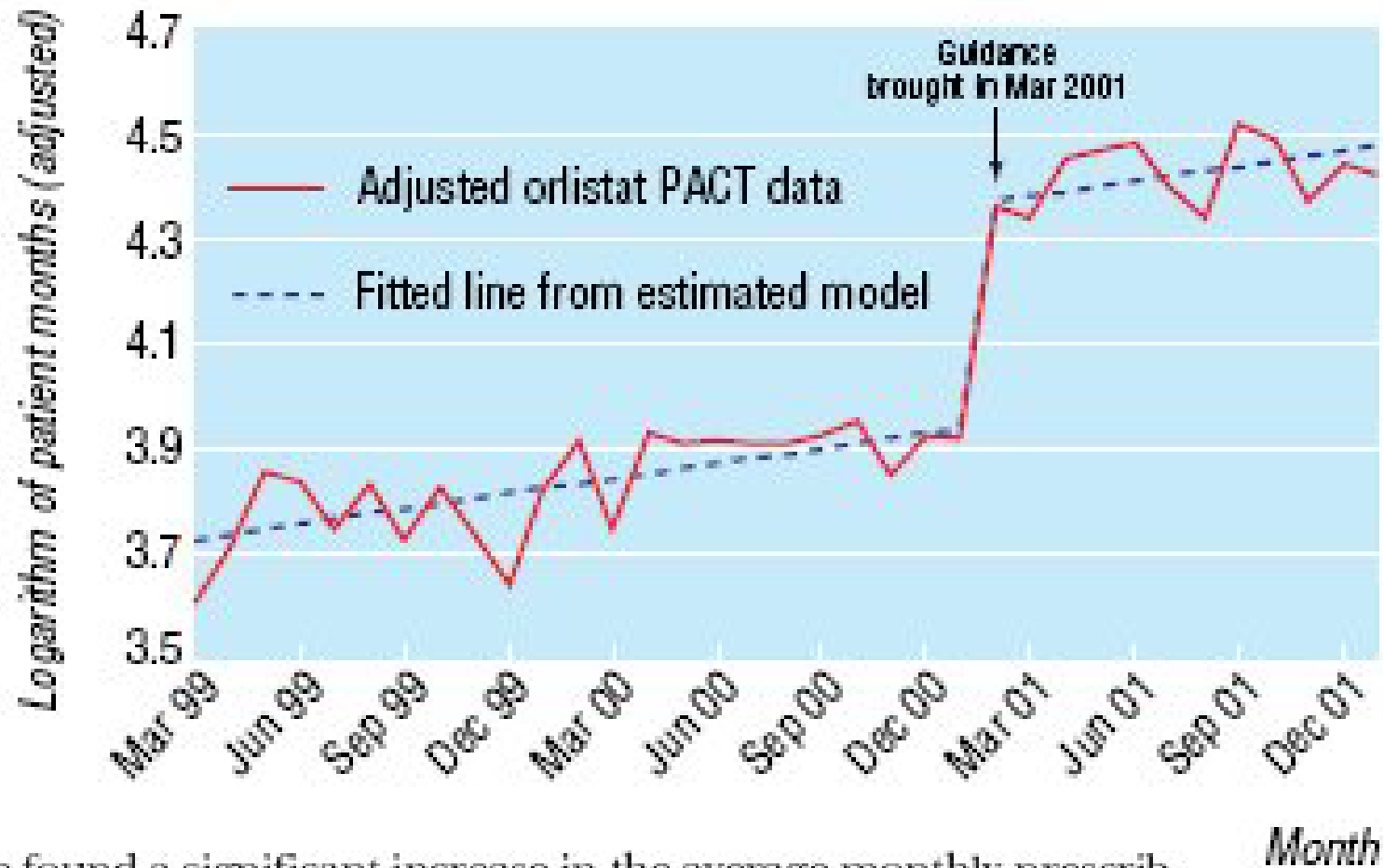
What's the evidence that NICE guidance has been implemented?
Results from a national evaluation using time series analysis, audit of patients' notes, and interviews

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

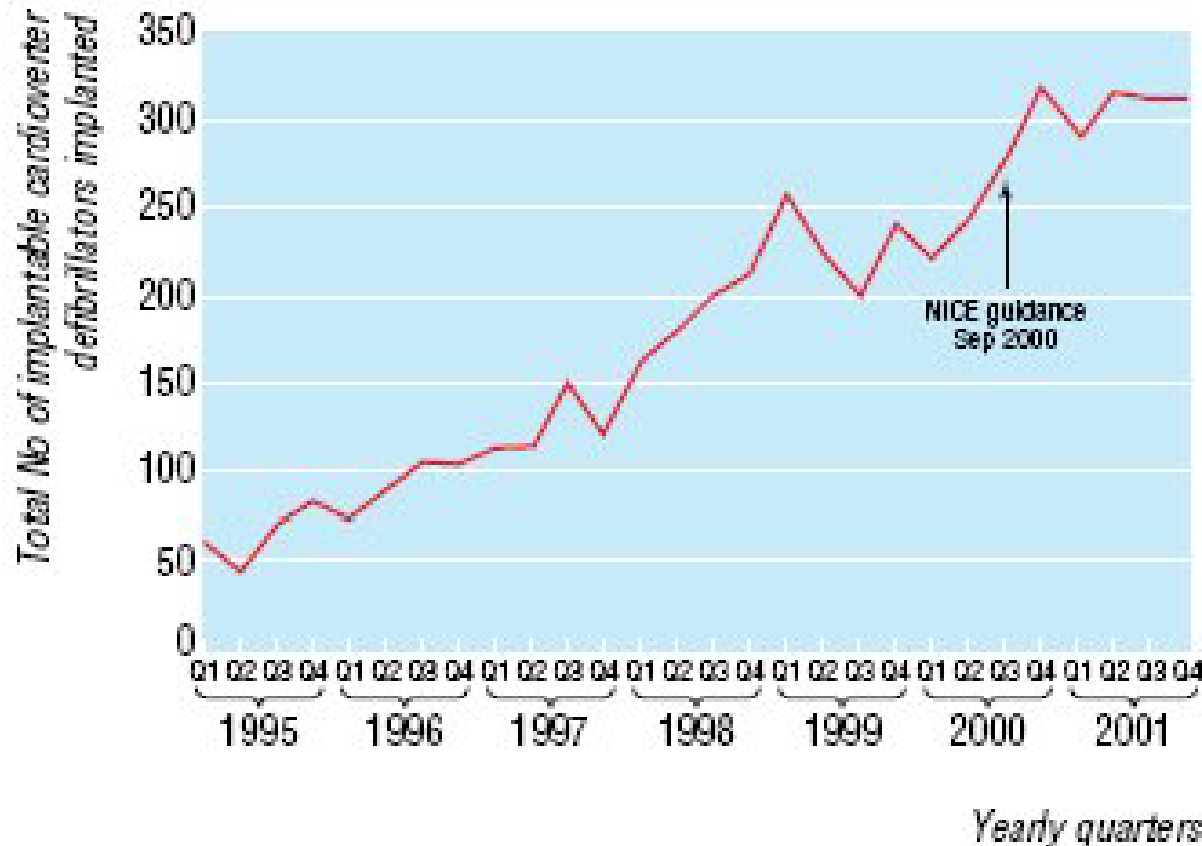
Conclusions Implementation of NICE guidance has been variable. Guidance seems more likely to be adopted when there

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?