

The National Institute for Clinical Excellence in the UK – Experience and Impact

Mark Sculpher

Professor of Health Economics

Centre for Health Economics

University of York, UK

Background

- Brief overview of NICE
- Issues with NICE's approach
- The impact of NICE guidance

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 (particularly drugs)
- Desire to use best available methods to address difficult questions
- Range of activities (see www.nice.org.uk) – focus here on technology appraisal

The NICE process

Overview



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
- Process of scoping:
 - Patient population
 - Comparators

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

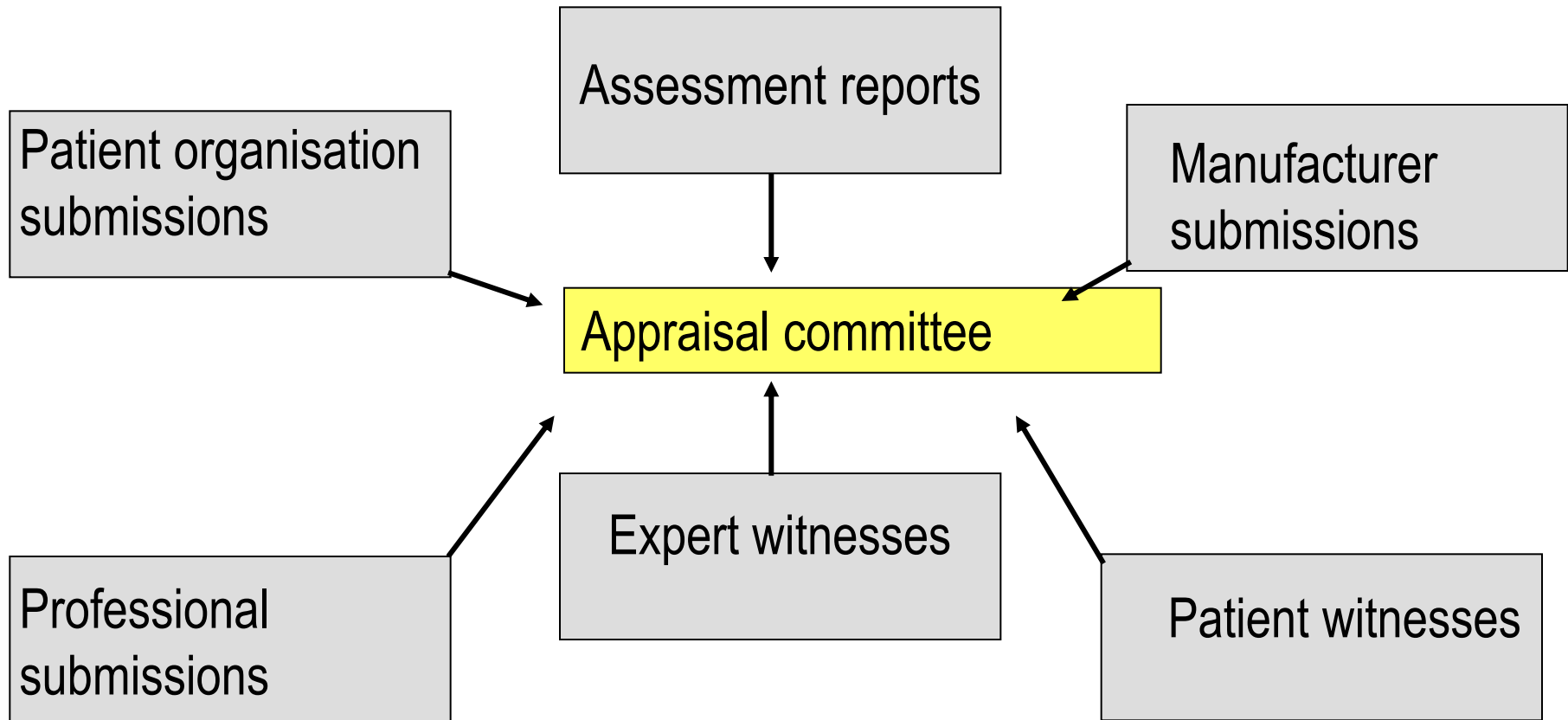
- Most important ones from manufacturers
- Key contribution to appraisal process:
 - provision of unpublished data
 - development of own model to synthesise evidence
- Attention paid to explaining discrepancies between company and TAR analyses
- Debate about the decision often centres around model
- Prescriptive methods guidance issued in 2004 (to be updated 2007)

2005 changes: Single Technology Assessments

- Concern about delay in giving guidance
- From 2006, a new process for 'some' drug technologies
- All evidence and analysis comes from a single manufacturer
- Assessment team provides a critical review of submission – no independent analysis
- Decision making similar although burden of proof now more firmly with manufacturer

The NICE process

Appraisal



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

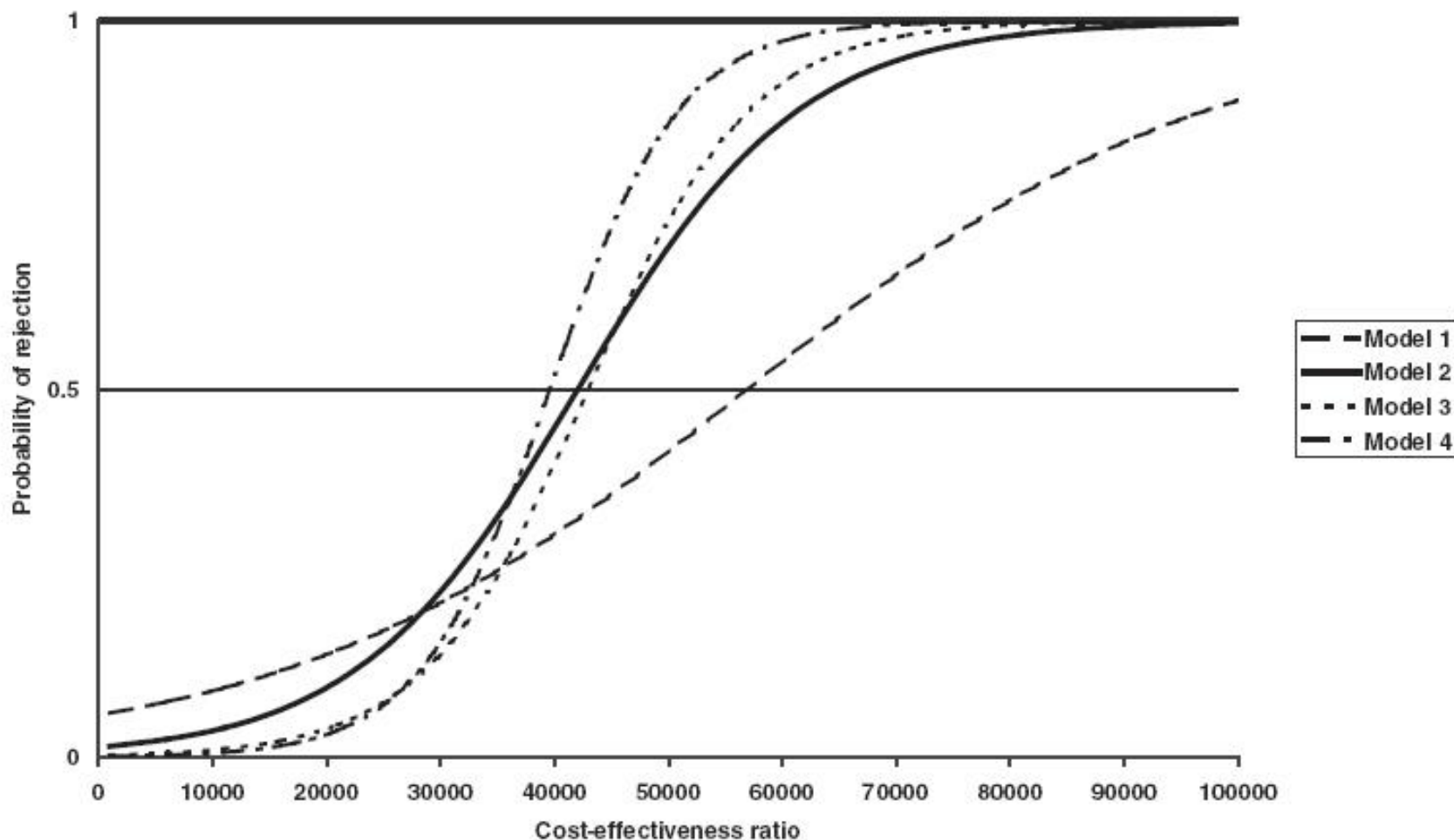


Figure 5. Probabilistic cost-effectiveness thresholds for NICE decisions

Source: Devlin N, Parkin D. *Health Economics* 2004;13:437-52.

NICE's preferred methodology – the Reference Case

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

Source: National Institute for Clinical Excellence (NICE). *Guide to the Methods of Technology Appraisal*. London: NICE, 2004.

Selected issues with NICE

- Selection of topics
 - Often unclear
- Move to STA process
 - Quicker 'no' decisions?
- How are decisions made?
 - Role of cost-effectiveness threshold
- How is equity included
 - Explicit vs implicit

Evidence on impact

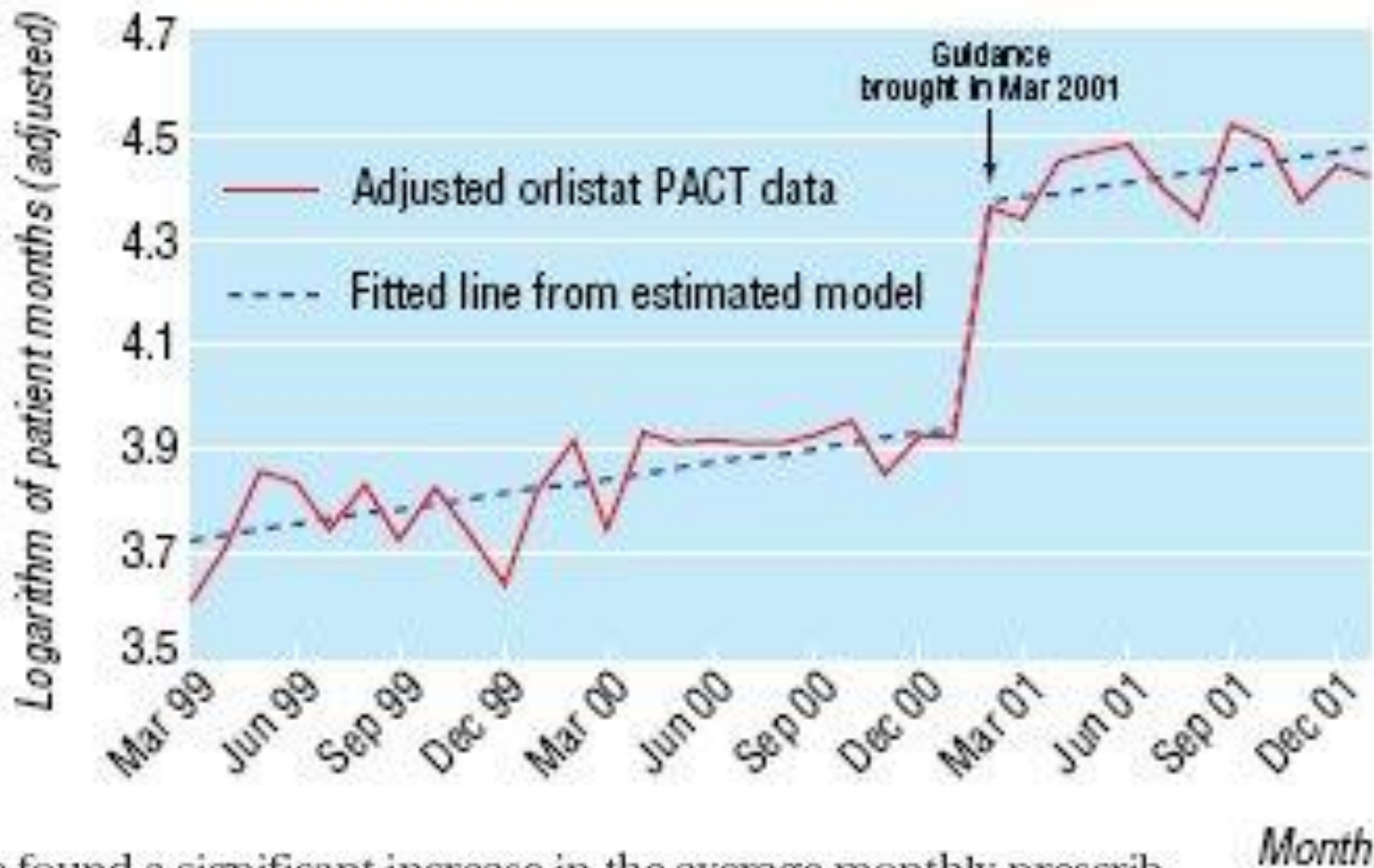
What's the evidence that NICE guidance has been implemented?
Results from a national evaluation using time series analysis, audit of patients' notes, and interviews

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

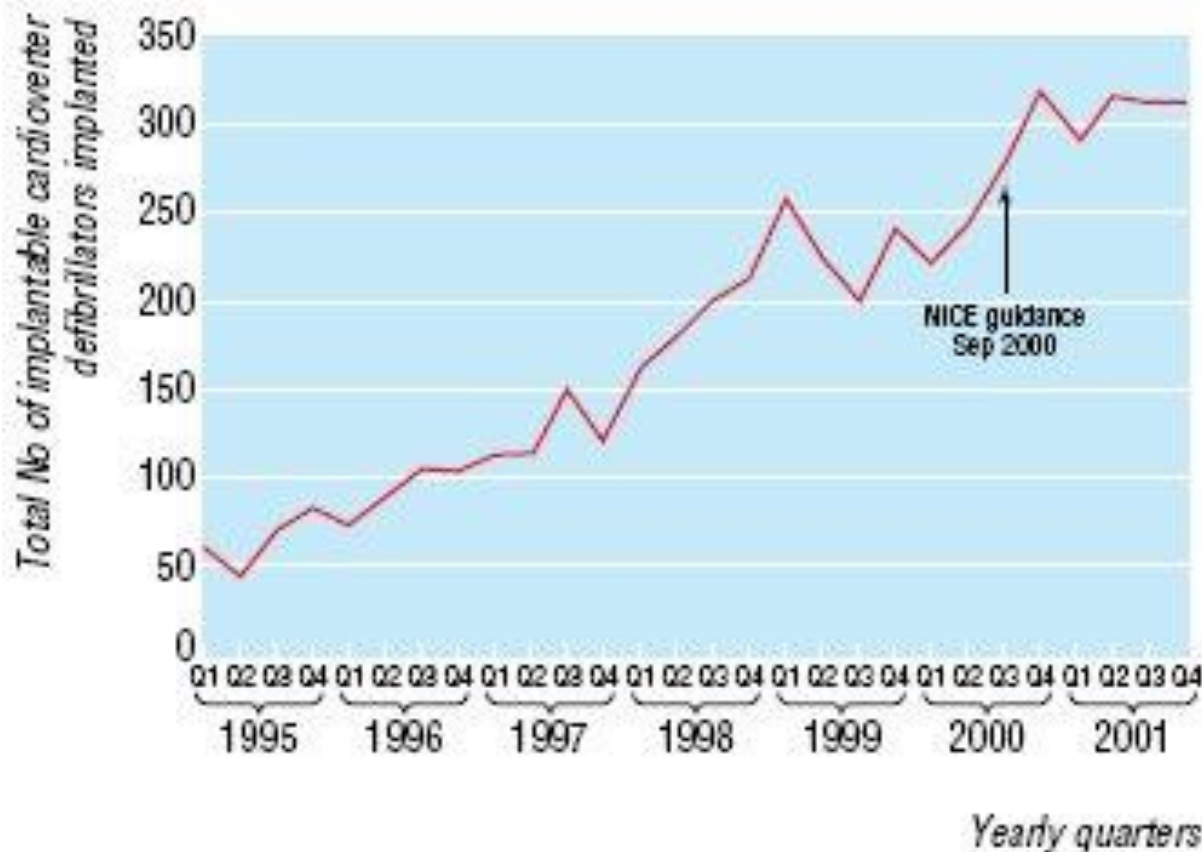
Conclusions Implementation of NICE guidance has been variable. Guidance seems more likely to be adopted when there

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

Conclusions

- NICE part of an international trend towards greater use of economics in decision making
- NICE has some specific features which have met with mixed success
- NICE is prescriptive about methods
- Impact of NICE guidance has been variable