

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

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# Outline

- Technology appraisal at NICE
- NICE's preferred methodology
- Issues with NICE

# The new NICE

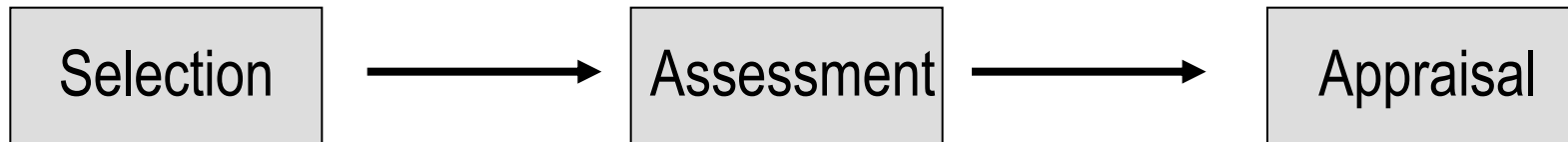
- Technology appraisal
- Guidelines
- Public health

## 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



# 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

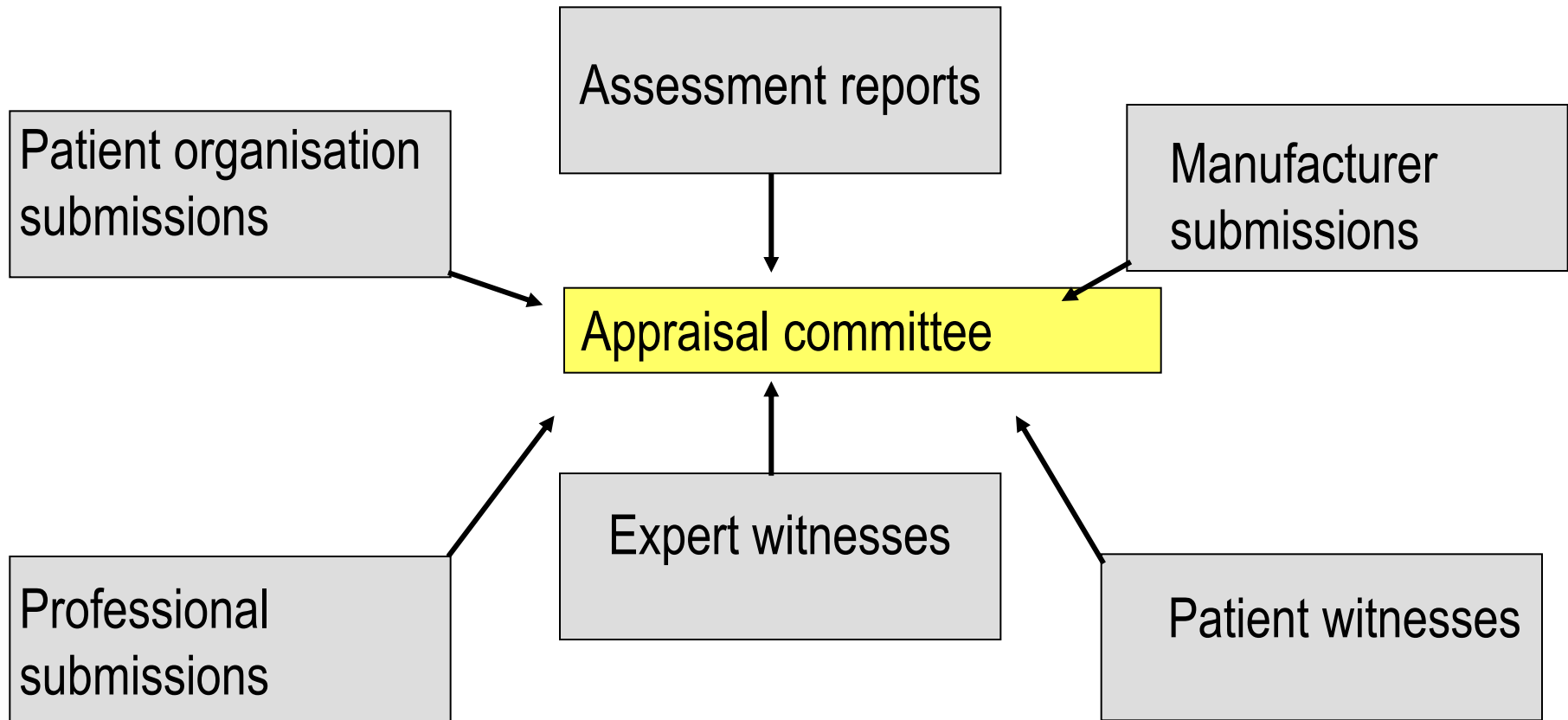
## Assessment – consultee submissions

- 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  - provision of unpublished data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](http://www.nice.org.uk))

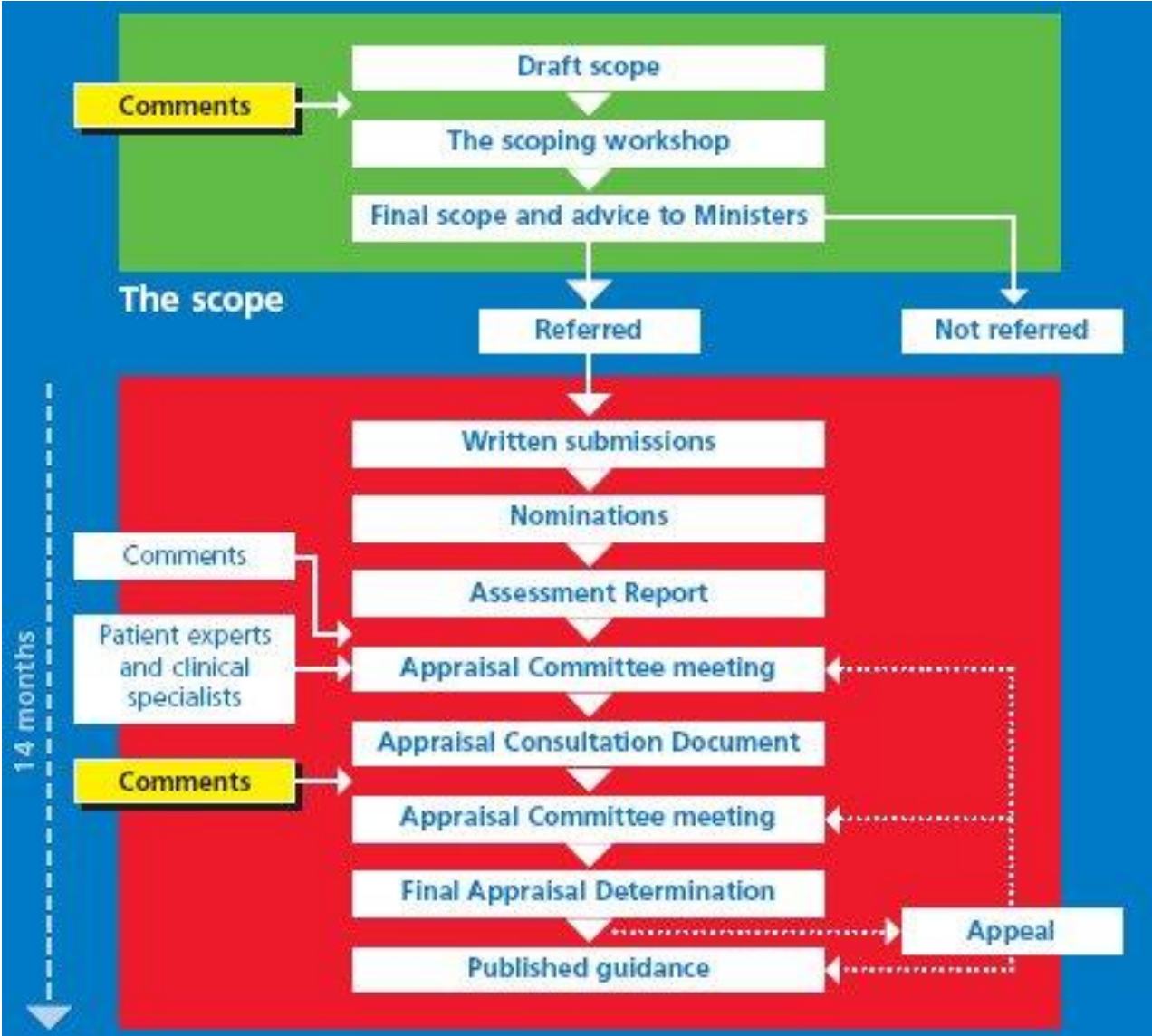


# The NICE process

## Appraisal



# The NICE process



# 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

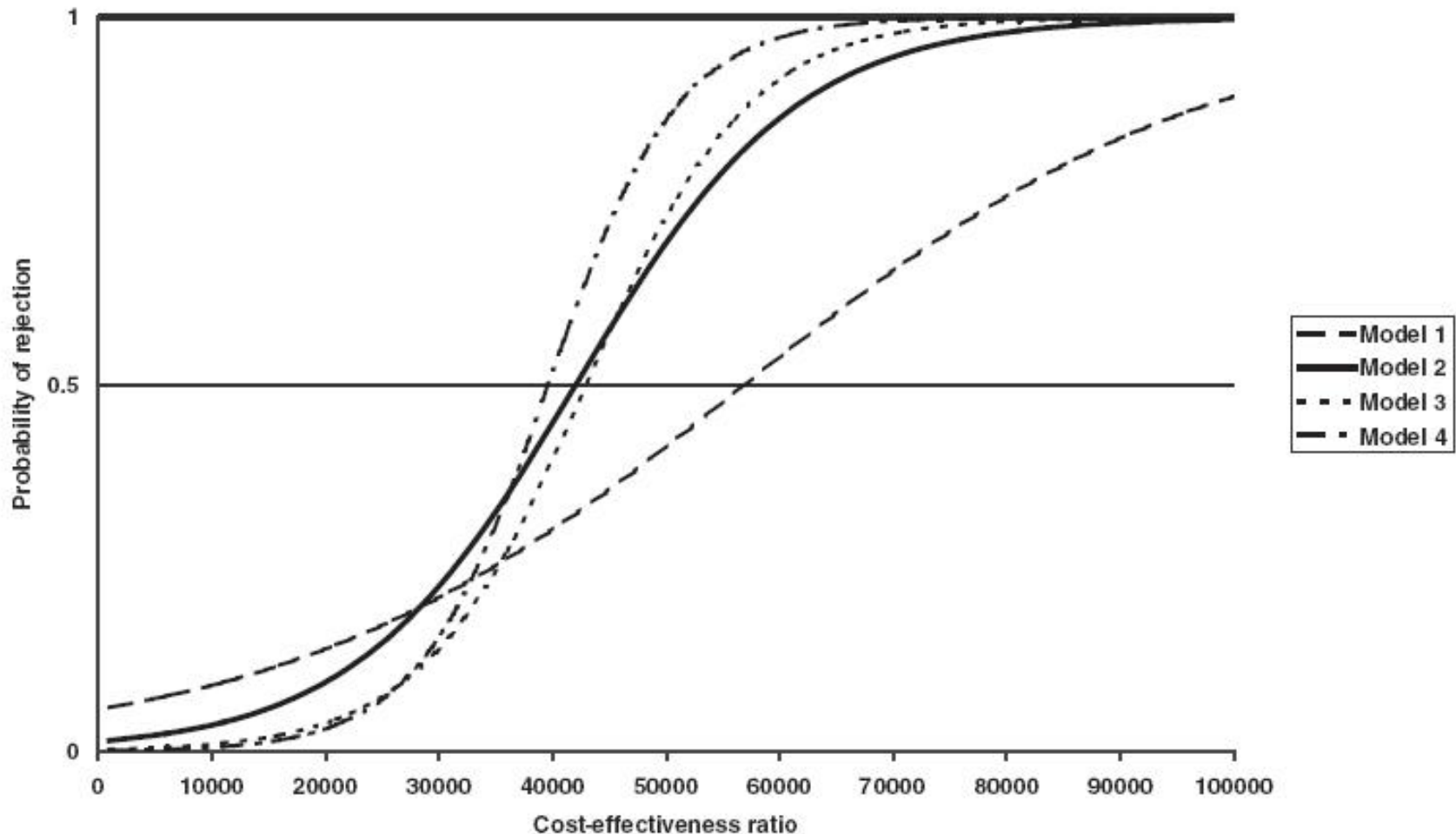


Figure 5. Probabilistic cost-effectiveness thresholds for NICE decisions

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

# 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

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



# Recently completed NICE appraisals

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

Source: nice.org.uk; 10<sup>th</sup> 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

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.



# 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