

# A NICE way of Appraising Health Technology

Presented by:

John Brazier

Professor of Health Economics

School of Health and Related Research

University of Sheffield, UK



## Overview of talk

- Explain the NICE Appraisal process
- Describe some of the problems in assessing and appraising new technologies
- Criticisms of NICE



University of Sheffield

# National Institute of Clinical Excellence for England and Wales

Established in 1999 to provide guidance on 'best practice'

Three parts to its activities:

- Appraisal aimed at reviewing specific technologies - Guidance
- Guidelines on patient management (based around conditions)
- Audit (ensuring NICE Appraisal and Guidelines are being followed)

## Secretary of state's directions

- broad clinical priorities for the NHS
- degree of clinical need of patients with the condition
- broad balance of benefits and costs
- guidance on resources likely to be available
- effective use of available resources
- encouraging innovation

# Aims of appraisal

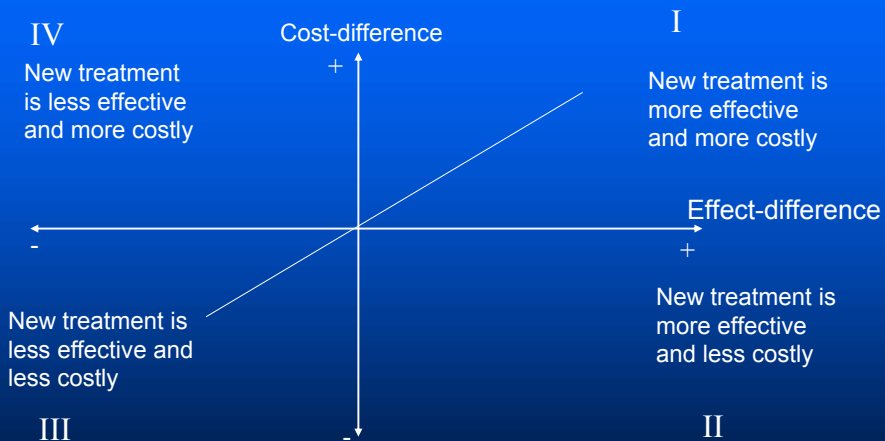
Appraisal is undertaken in terms of:

- Clinical effectiveness – does the technology work in practice (i.e. more than simply efficacy)
- Cost effectiveness
  - bearing in mind the secretary of states directions
  - NICE Appraisal guidance is mandatory



University of Sheffield

## Costs and effects of a new intervention



## Cost Effectiveness analysis

Clinical effectiveness is assessed using a range of clinical outcomes – that increasingly includes quality of life

Cost-effectiveness is now assessed primarily in terms of *cost per quality adjusted life years (QALYs)*

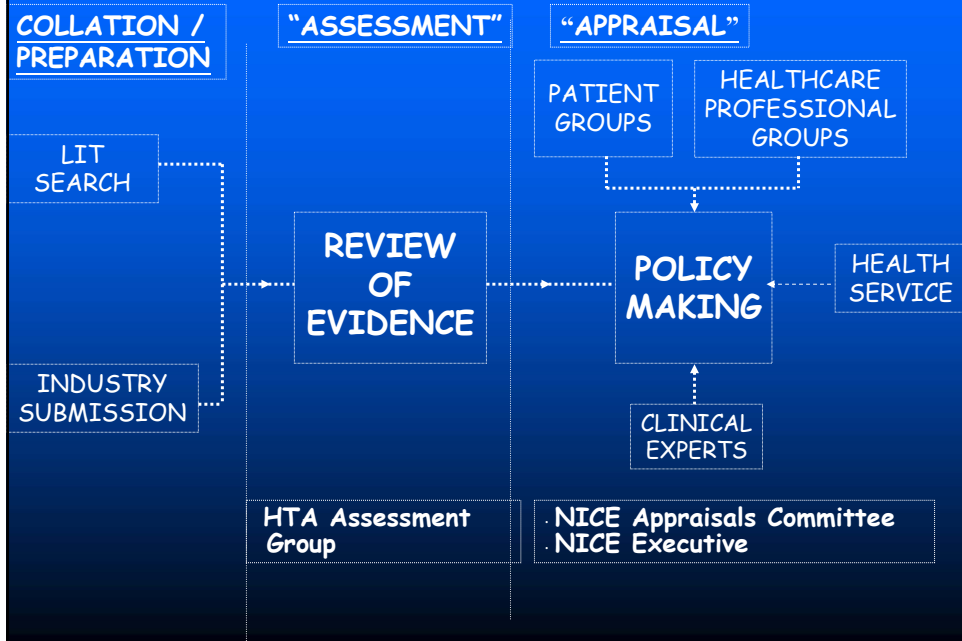
- The QALY is a generic measure that combines quality of life and length of life into the single measure of benefit of a quality adjusted survival
- Achieved by assigning to each health state a value from zero to one, where zero is for state equivalent to death and one for full health)

## Overview of the NICE Appraisal Process

- Identification of topics – DoH
- Scoping – NICE/DoH
- Assessment – HTA Assessment Groups
- Appraisal - Committee
- Consultation – at each stage
- Dissemination (Guidance)
- Review – in each FAD

See recent review at [http://www.nice.org.uk/pdf/TAP\\_Methods.pdf](http://www.nice.org.uk/pdf/TAP_Methods.pdf)

## Outline of NICE process



## Technical issues: Technology Assessment

# Technology Assessment Reports

- The Technology Assessment Report (TAR) is a key input into the Appraisal Committee Committee
- The Technology Assessment Reports are produced by 6 independent University based Groups

The Reports include:

- A rapid systematic review of the clinical evidence (mainly though not only RCT based) based on a systematic search, quality reviewing and synthesis
- Cost effectiveness modelling – now a key component

Submissions from manufacturers, patients groups, health professional groups and individuals experts



University of Sheffield

## The reference case

Due to variation in methods, particularly around the assessment of cost effectiveness, NICE has adopted the notion of a reference case

The reference case is a set of methods that must be used in any submission purporting to assess cost effectiveness - though others can be used and justified



University of Sheffield

# Summary of reference case

Defining the decision problem	The scope developed by the Institute
Comparator	Alternative therapies routinely used in the NHS
Perspective on costs	NHS and PSS
Perspectives on outcome	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	Quality adjusted life years
Description of health state for calculation of QALYs	Using a standardised and validated generic instrument
Method of preference elicitation for health state valuation	Choice-based method, for example time trade-off, standard gamble (not rating scale)
Source of preference data	Representative sample of the general population
Discount rate	An annual rate of 3.5% on both costs and health benefits
Equity position	A QALY has the same value regardless of who receives it

# Potential problems with RCT evidence

- Choice of comparison therapy
- Length of follow-up
- Atypical care – leading to protocol driven costs and outcomes
- Atypical patient populations
- Limited generalisability
- Inadequate sample size
- Logistical difficulties

## The role of modelling

- Modelling enables evidence from a range of sources to be combined in order to address the decision problem
- Addresses problems with comparator, limited follow-up, atypical patient group etc.
- Use of probabilistic sensitivity analysis addresses the uncertainty around all relevant parameters
- Modelling has become a fact of life

## The Process of Technology Appraisal

# Appraisal

- Currently three appraisal committees (A,B and C)
- Each committee has a Chair and 20 (ish) members including patient representatives, clinicians, nurses, managers, statisticians, Health economists
- The Committee has Experts witnesses, the Technology Assessment Report and a summary from the NICE Technical lead
- Recommendation to Secretary to state



University of Sheffield

# Consultation and Openness

- There is consultation with interested parties at identification, scoping, assessment and appraisal phases
- Assessment reports and evidence that is not commercial in confidence are published on the NICE website
- The preliminary conclusions of the Appraisal Committee are published on the website and comments received and considered before a final appraisal is published
- There is a right of appeal - appeals are held in public

## Content of Final Appraisal Determination

Appraisal guidelines usually will indicate:

- whether a technology is supported at all
- the patient groups in which it is supported
- when treatment should be started (e.g. only after others have failed, first line etc)
- when treatment should stop (eg when there is no prospect of further benefit)

## NICE Appraisal in practice

## Basis for NICE decisions

- Clinical benefit cited in all cases
- Cost per QALY figures quoted in support of decision in half of the appraisals in the first year and this proportion is increasing
- Cost per QALY cited as reason for initial rejection of some technologies
- Restrictions on recommended use kept Cost per QALY below £30,000 in first year (except for riluzole for MND)

## That threshold

- Raftery (BMJ, 2001) and others have identified a £30,000 threshold,
- NICE argue they consider a broad range of factors in making their decisions (in line with the Secretary of State's Directions), but clinical and cost effectiveness are clearly important
- Recent review states that: 1) 20K per QALY or less then the decision is based on Cost effectiveness 2) 20-30K decision will take account of other considerations 3) other considerations would have to be strong to overturn CE

# NICE Decisions

First 30 decisions:

- 3 no
- 16 yes/but
- 11 accepted fully

# Criticisms of NICE Appraisal

# Criticisms of NICE Appraisal

- Uncertainty in costs and effectiveness
- Lack of relevant data on costs and effectiveness due to differences in patient population, treatments and cost
- use of cost effectiveness thresholds alternatives
- ethics and fairness
- The role of patients and clinicians

# Uncertainty and Quality of evidence in NICE Appraisals

- A decision will be made (possibly only in force for a short period) on the evidence presented, whatever the quality
- The luxury of not making a decision is not available
- The NHS must decide 1) whether or not the fund the service and 2) whether or not to conduct more research
- Decision uncertainty now be quantified using Probabilistic Sensitivity Analysis
- The value of reducing uncertainty is important for setting priorities (through value for information analysis)

## Criticisms of thresholds

- A 'golden goose' for new pharmaceuticals?
- Ignores budget impact - net cost in first year of NICE guidance was £200m or less than 0.5% of annual spend (but 25% of growth in 2000/2001)
- Birch and Gafni '*...the puzzle is how the recommendations can be made for maximizing health gain from a given NHS Expenditure where such recommendations require additional requirements (and unknown opportunity cost)*'
- Ignores local variation and priorities

## Fairness

- A QALY is a QALY is a QALY regardless of who received it
- This ignores the fact that the value of a QALY may be effected by the characteristics of the recipient e.g health status, past health profile, degree of choice

Re. Social QALY project

## The growing use of economics in decision-making around the world

- Health technology Board for Scotland, Belgium, Netherlands, Sweden, Germany and Italy
- Australia, Canada

## Conclusions

- Decisions must be made and NICE centralises these decisions
- NICE has brought economic arguments to the fore - cost per QALY has become a key criterion for assessing technologies, but there is evidence of other factors (e.g. uncertainty, impact and the existence of alternatives)
- NICE has survived its first four years and attracted considerable international interest
- Process is becoming more open and public, but further reform likely (e.g. role of patients)
- Scope for transferability of some activities