

**The NICE Technology Appraisals
Programme:
Personal reflections from the front line**

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Chair Appraisals Committee NICE**

Why was NICE created?

- **To provide clear standards (guidance) based on clinical and cost effectiveness**
- **To resolve uncertainty**
- **To minimise inappropriate variation in clinical practice**

Personal Reflections

- Getting the question right – Topic Selection
- The nature of NICE guidance
- Balancing Clinical and Cost Effectiveness
- Committee decision making
- NICE in the ‘real’ world

Topic Selection - the issues

- Clarity
 - A complex question leads to a complex answer or is unanswerable
- Simplicity
 - What does the NHS really want to know
- The most appropriate programme/process
 - Clinical practice guideline
 - Technology Appraisal
 - Multiple Technology Appraisal (MTA)
 - Single Technology Appraisal (STA)

Topic Selection - Clarity and Simplicity

- Complex questions should be avoided
- A 'simple' question will provide the most useful answer to what the NHS really wants to know

e.g.

1. Appraisal of newer antipsychotic drugs
2. Appraisal of statins for the prevention of cardiovascular events

Complex or simple questions?

- **Appraise the clinical and cost effectiveness of the newer antipsychotic drugs for the treatment of schizophrenia**
 - 7 'atypicals' (amisulpride, olanzapine, quetiapine, risperidone, sertindole, zotepine, clozapine)
 - 2 'typicals' (haloperidol, chlorpromazine)
 - At least 3 different clinical scenarios (e.g. acute and chronic use)
 - 172 randomised controlled trials (RCTs) including evidence from 29 head-to-head trials of atypical agents. In addition, 53 other studies which were either case-control, had more than 2 years of follow up, or included more than 2000 participants.
 - Plus 31 published economic evaluations of antipsychotic medication

Complex or simple questions?

~~Appraisal of statins for the prevention of~~
But scope of guidance restricted only to the 'initiation' of statin therapy in adults with clinical evidence of cardiovascular disease (CVD) and in adults considered to be at risk of CVD.

Implementation use cheapest generic statin (?simvastatin) first line could save the NHS millions

- Starting versus target cholesterol levels

The Correct Programme/Process

- **TA guidance or clinical practice guideline**
 - TA
 - Clinical and cost effectiveness of individual health technologies
 - Funding mandate
 - Guideline
 - Complete guidance on a pathway of care
 - No funding mandate
- **Multiple Technology Appraisal (MTA)**
 - Multiple technologies and manufacturers
 - Independent evidence assessment
 - Full consultation
- **Single Technology Appraisal (STA)**
 - Single technology, single indication and single manufacturer
 - Independent evidence critique
 - Limited consultation
 - Guidance issued close to licensing

NICE appraisals topic selection - the final word

Things should be made as simple as possible, but not simpler.

Albert Einstein (1879 – 1955)

If you don't know what you are going to do with the answer don't ask the question.

David Barnett (1944 -)

Features of NICE TA guidance

- **Robust**
 - underpinned by a sound evidence base
- **Inclusive**
 - all stakeholders have their say (multiple perspectives)
- **Transparent**
 - evidence and conclusions in the public domain
- **Independent**
 - developed by external experts
- **Fully consultative**
 - public and professional
- **Timely and relevant**
 - Rapid process (STA)
 - Regular review

The Appraisal Committee is concerned with effectiveness

- **Clinical effectiveness**
 - How well does something work in comparison with what we already use?.
- **Cost effectiveness**
 - How much more life and/or quality of life do we get for the extra money we have to pay?

Clinical effectiveness

“Guiding Principle”

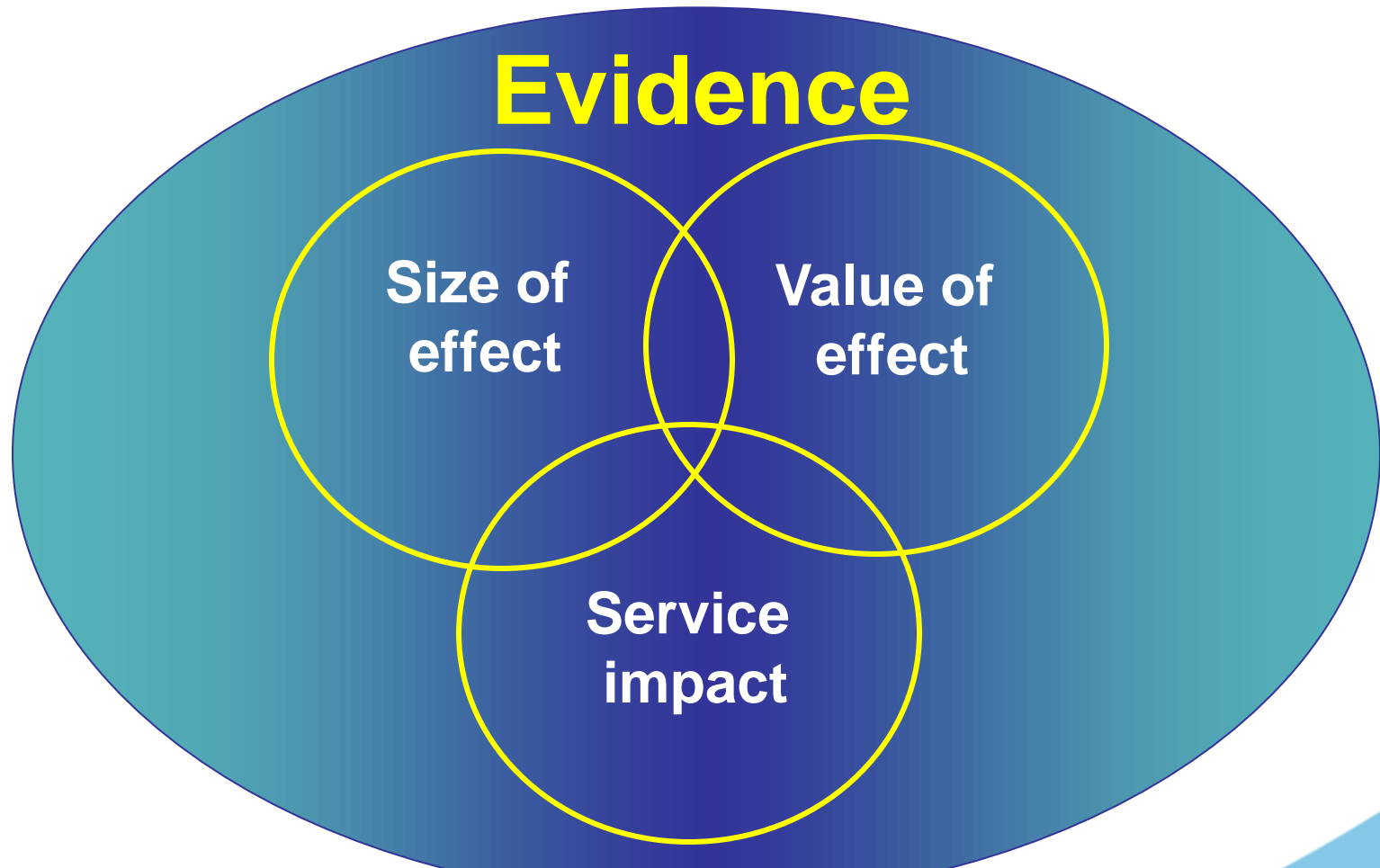
- In general, technologies can be considered ***clinically effective*** if, in **normal clinical practice**,
 - they confer a **health benefit** (**net of harms**)
 - when **compared to relevant alternative technologies**.
- The concern is with effectiveness rather than efficacy

Evaluating the evidence – clinical effectiveness



Judgements to be made

Evaluating the evidence – cost effectiveness



Judgements to be made

Balancing Clinical and Cost Effectiveness

- At the heart of decision-making for NICE
- The most controversial area of appraisals

The Fundamental Economic Problem

- Limited resources
- Unlimited wants
- The need to make choices
 - If you can't have both A and B you need to make a choice
 - When making the choice you must decide to do without one thing for the sake of having something else
 - Deciding how best to do this and maximise the use of available resources is the fundamental economic problem

Balancing Clinical and Cost-Effectiveness – a game of two halves

How cheap does this technology need to be to make it cost effective?



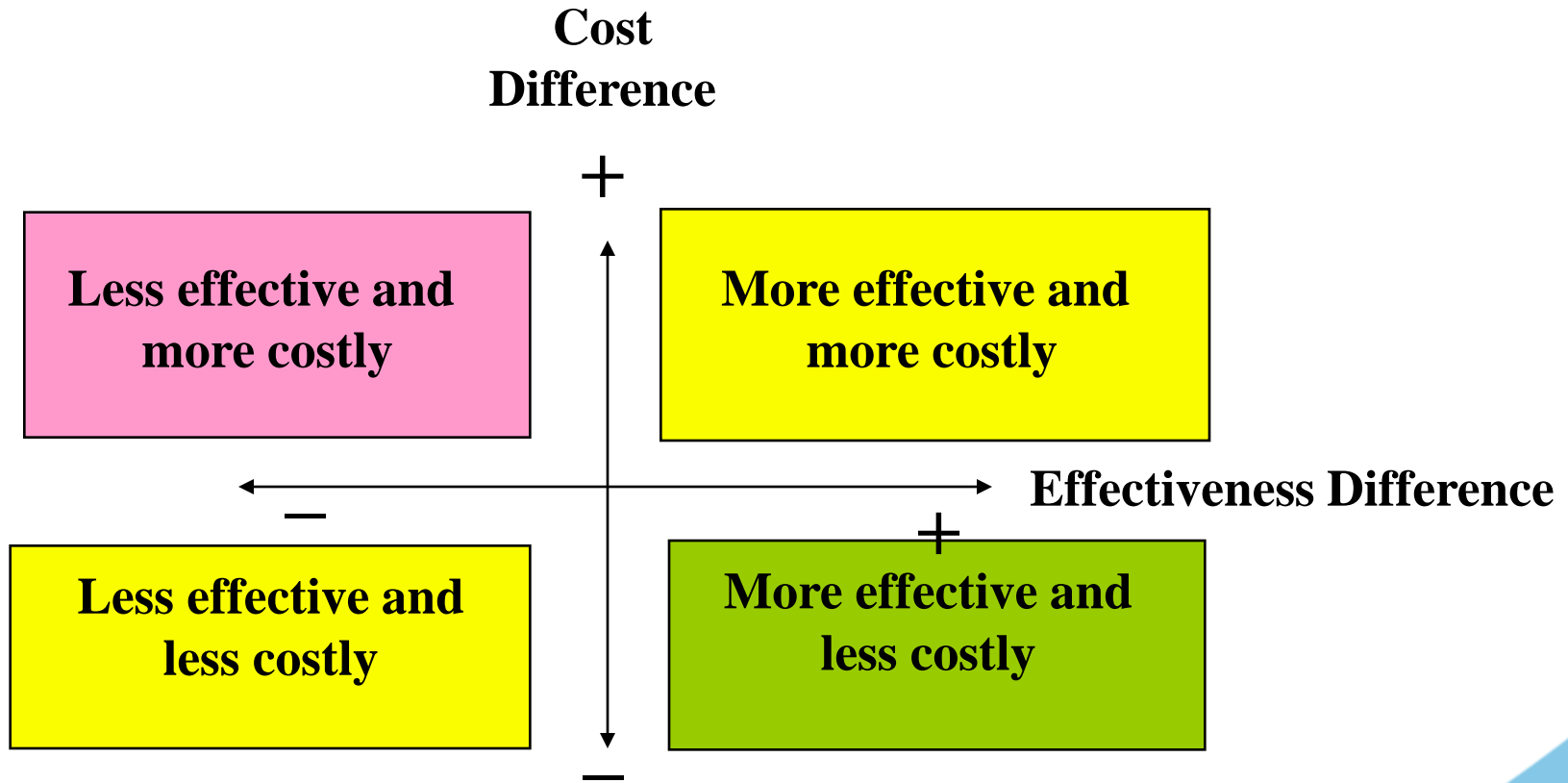
CLINICIAN

How clinically effective does this technology have to be to make it worth paying that much for?



ECONOMIST

Comparison of two alternative treatments



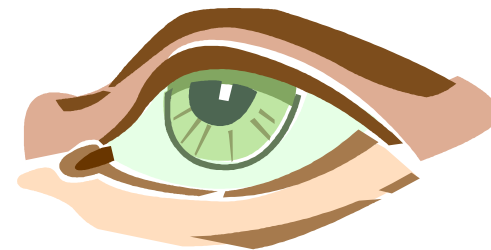
How can we compare the costs and benefits to derive relative cost effectiveness ?

- Different classes of treatments for the same disease
- Similar classes of treatments for different diseases
- Different treatments for different diseases

We need a level playing field



ICDs for sudden cardiac death



Photodynamic therapy for age related macular degeneration

Types of economic evaluation

- **Cost minimisation analysis**
 - Use the cheapest if there is equivalence in clinical effectiveness
- **Cost effectiveness analysis**
 - Based on clinical end point measure e.g. blood pressure reduction, improved glycaemic control
- **Cost Utility Analysis**
 - Based on assessment of health gains for the individual e.g. life expectancy and quality of life

**NICE is primarily interested in
cost utility analysis i.e. cost/QALY**

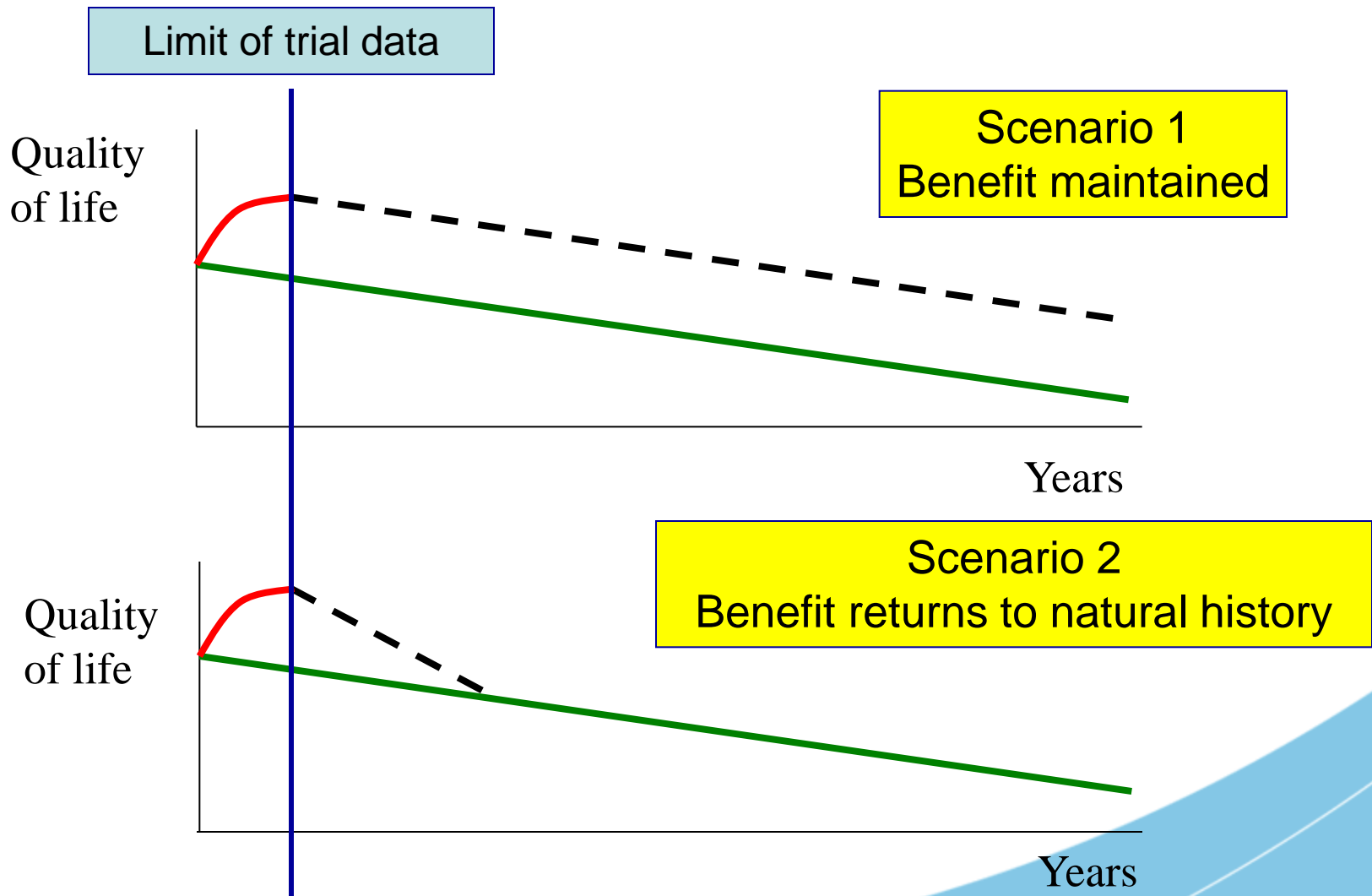
QALYs – the basis of cost utility analysis

- Quality adjusted life years are a means for combining the impact of health care (or illness) on life expectancy and health related quality of life
- Internationally recognised standard
- Not perfect but probably the best we currently have
 - Health states considered to be worse than death assume a negative value.

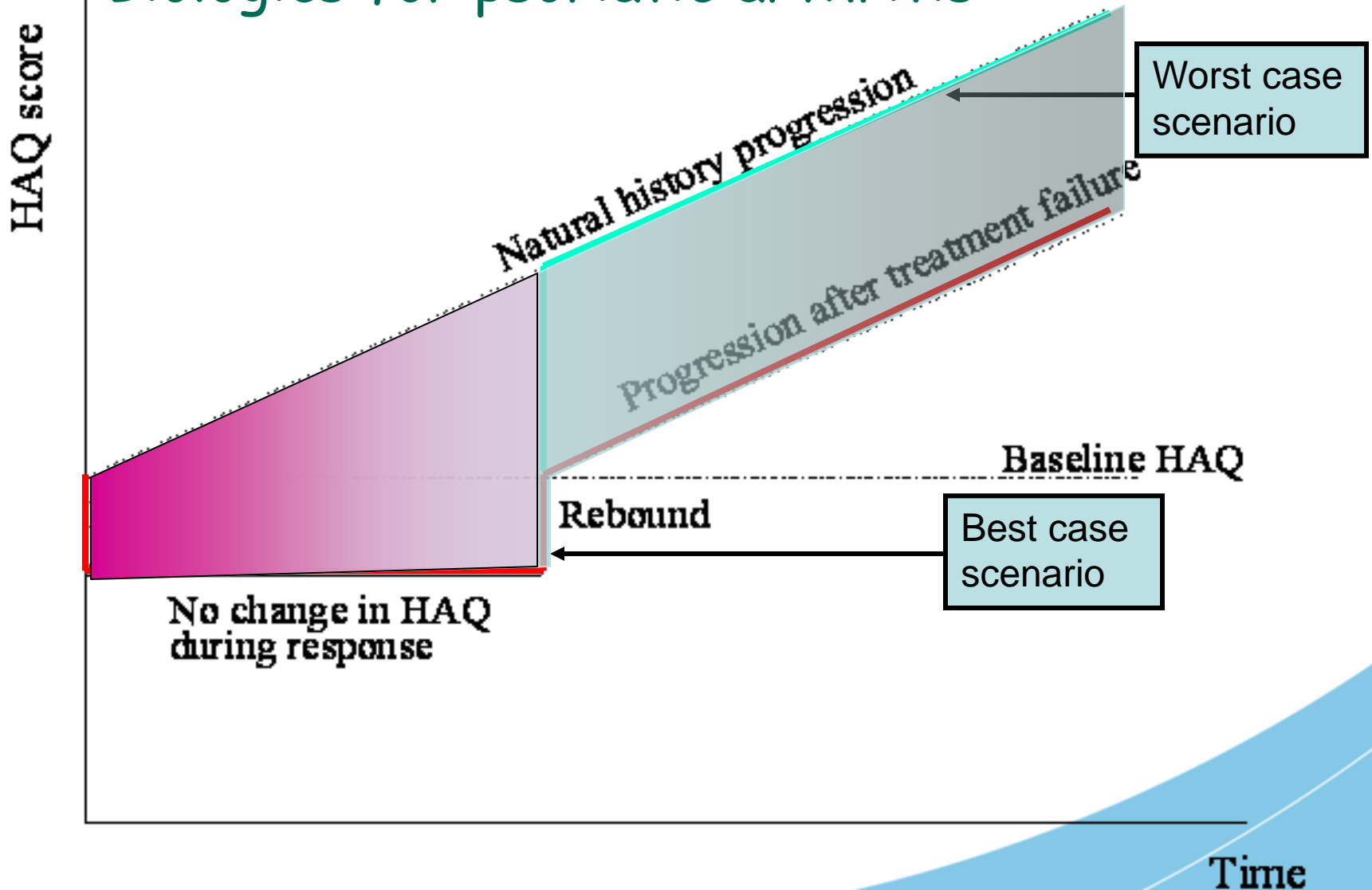
Economic modelling

- Brings together all available data on the effectiveness, resource use, costs, and the
- **If you don't have all the evidence you would like and cannot make up your mind try modelling!**
- Enables extrapolation to the long term if necessary
- Enables evaluation of all sources of uncertainty in the evidence

Extrapolating beyond the data

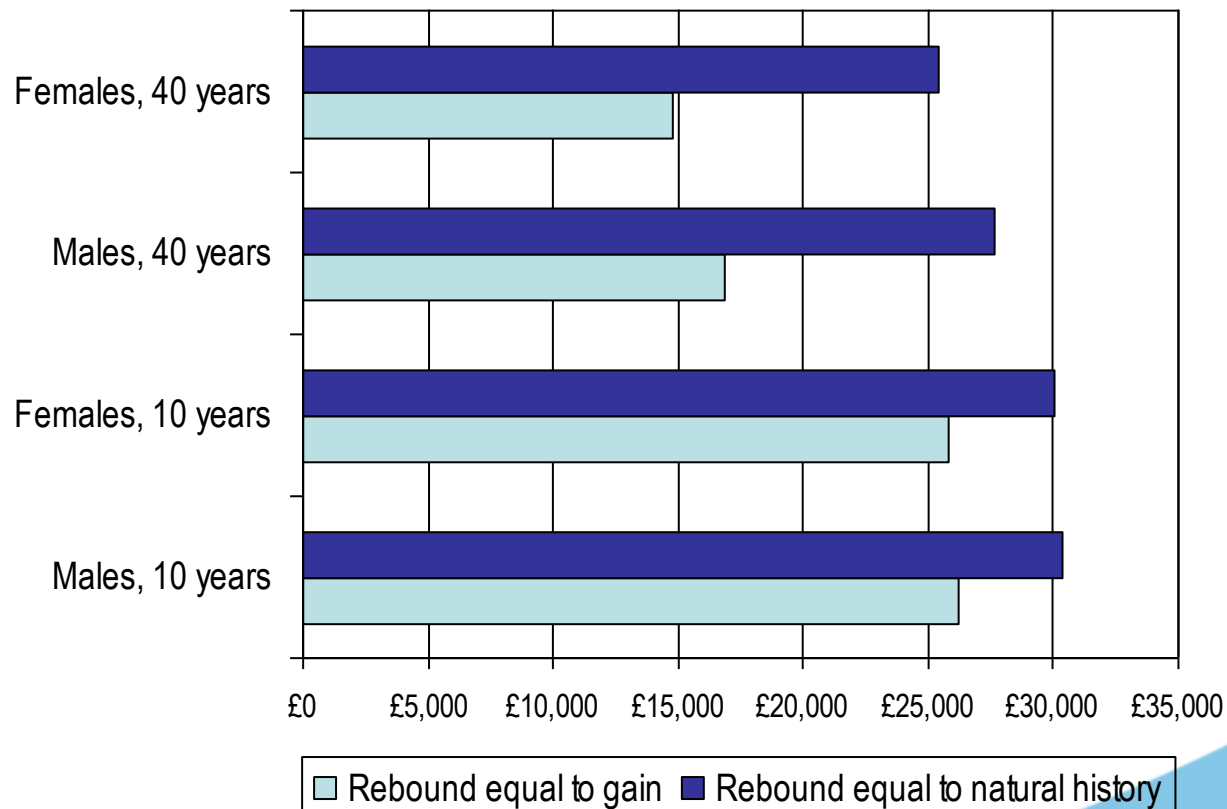


Cost Effectiveness Modelling Biologics for psoriatic arthritis



Cost Effectiveness Modelling Biologics for psoriatic arthritis

ICER for Etanercept for males and females over 10 and 40 year time horizons and different assumptions about rebound in treatment effect when therapy loses efficacy



Committee Decision Making

- The cost effectiveness 'threshold'
- Social value judgements

The problem

A fixed 'budget' and lost 'opportunity costs'



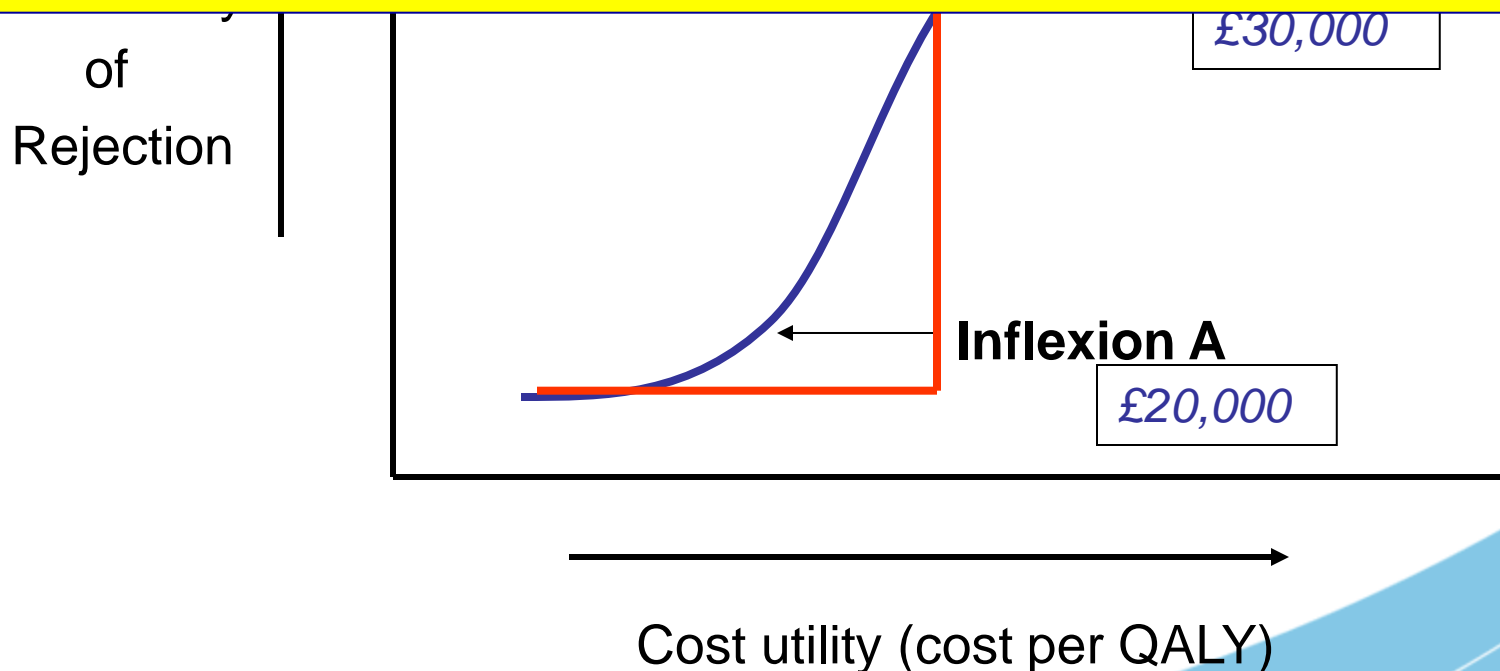
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Below a most plausible ICER of £20,000/QALY decision is primarily based on the cost-effectiveness estimate.

Above a most plausible ICER of £20,000/QALY requires more explicit consideration of other factors including:

- The degree of uncertainty surrounding the calculation of ICERs
- The innovative nature of the technology
- The particular feature of the condition and population receiving the technology
- Where appropriate, the wider societal costs and benefits.

Above an ICER of £30,000/QALY, the case for supporting the technology on these factors has to be increasingly strong.



Social Value Judgements

Services

NICE could deny drugs to smokers

Too old for treatment

CAMILLA CAVENDISH

There's an ill
healthcare

... joke

... resent footing the

HEADLINE: WE SPEND MORE ON VIAGRA THAN ON DRUGS FOR DEMENTIA. WHAT KIND OF NATION HAVE WE BECOME?

... MUCH AND NHS MAY DENY YOU CARE

... and the overweight could be denied NHS treatment because of their
life ... yesterday.

Controversial guidance from the Health Service drugs rationing watchdog raises the prospect of them being refused help if their condition makes treatment ineffective.

Social Value Judgements

- Based on discussions in the NICE Citizens' Council
- Defined by agreement internally with the NICE Board
- Methods of implementation into Committee decision making currently being debated

Social Value Judgements

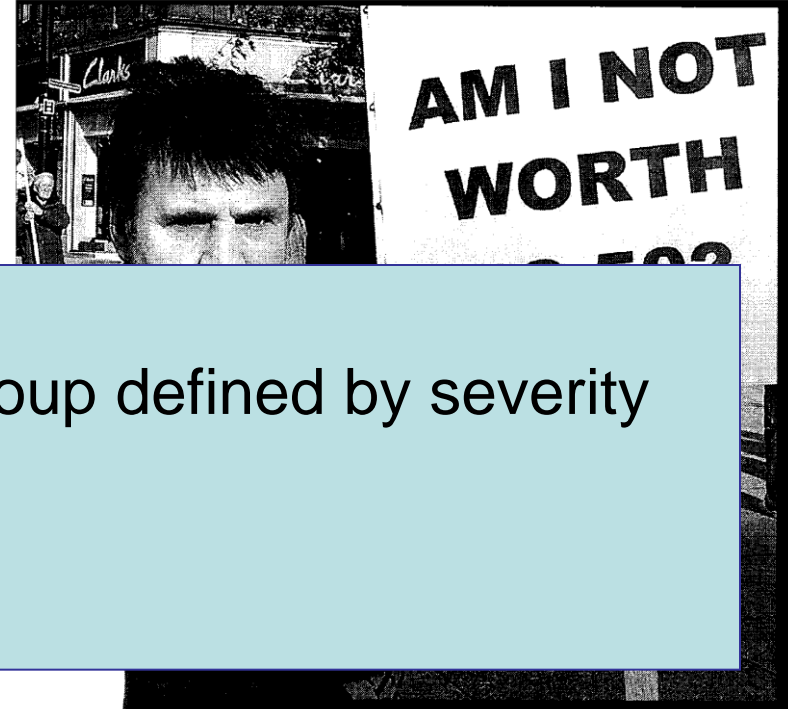
- Cost/QALY thresholds defined, but cost/QALY is not the only thing that matters
- Main issues to be considered
 - Age only if relevant to differences in clinical effectiveness
 - Gender or sexual orientation only if relevant to benefits/risks
 - Ethnic groups considered only if relevant to clinical effectiveness
 - Self inflicted illness considered only if relevant to clinical effectiveness
 - Social class or societal roles not given priority
 - Individual choice does not 'trump' clinical and cost effectiveness

NICE in the 'real' world

- Perspectives
 - NHS and PSS (?others e.g. societal)
 - Patients and carers
- NICE 'versus' Scottish Medicines Consortium (SMC)
- The NICE experience
- As others see us

Patients and Carers

Dementia: What's the score?



The Issues

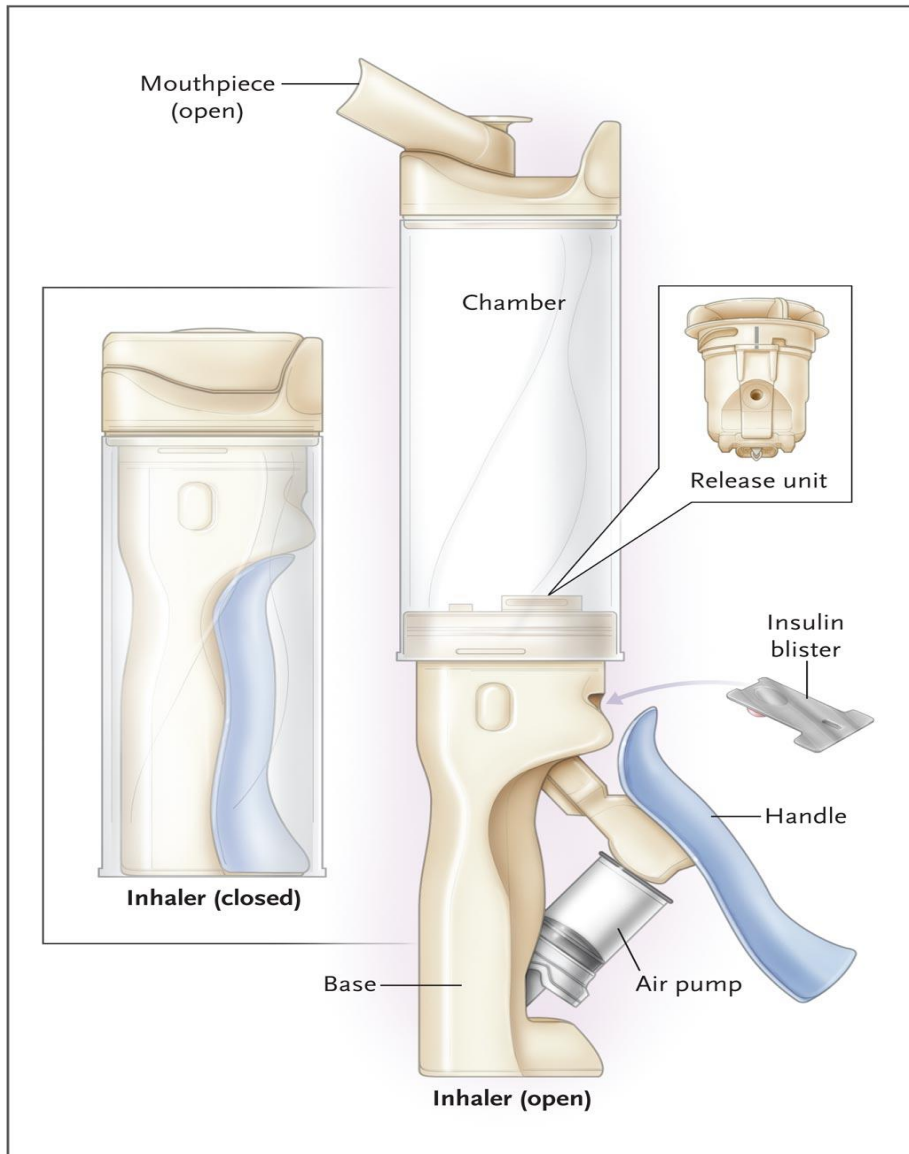
- Cost effectiveness in a sub group defined by severity
- Carer costs
- Drug costs
- Budget impact

Anger at 'betrayal' of Alzheimer's patients

By **Victoria Fletcher**
Health Editor

Over
dementia
drug rules
published

Patients and Carers



The Issues

- Innovation
- Portability
- Needle phobia
- Choice

NICE versus the SMC

NICE

- All health

SMC

- Only drugs (all new to

• This is not a competition
 • The two processes are complimentary
 • and rarely disagree

- Independent review of (MTA)
- Independent evidence (S)
- Mandated funding

- No external independent academic evidence review
- No mandated funding

Cancer drug

England won't get lung drug

The NICE Experience

- Acceptance that assessment of cost-effectiveness as well as clinical effectiveness is valid and important
- Importance of rigorous and consistent methodology in the assessment of clinical and cost-effectiveness
- Need for transparency and clarity in decision-making

The NICE Experience

“You cannot please all of the people all the time”



NICE bans drugs

the use COX II inhibitors only
s including those aged 65

mmatory drugs denied to

NICE recommends long a

- “Pill ‘jab’ could spark s
- “Charter for promiscuit

Daily Mail 2005



NICE encourages ‘sex’

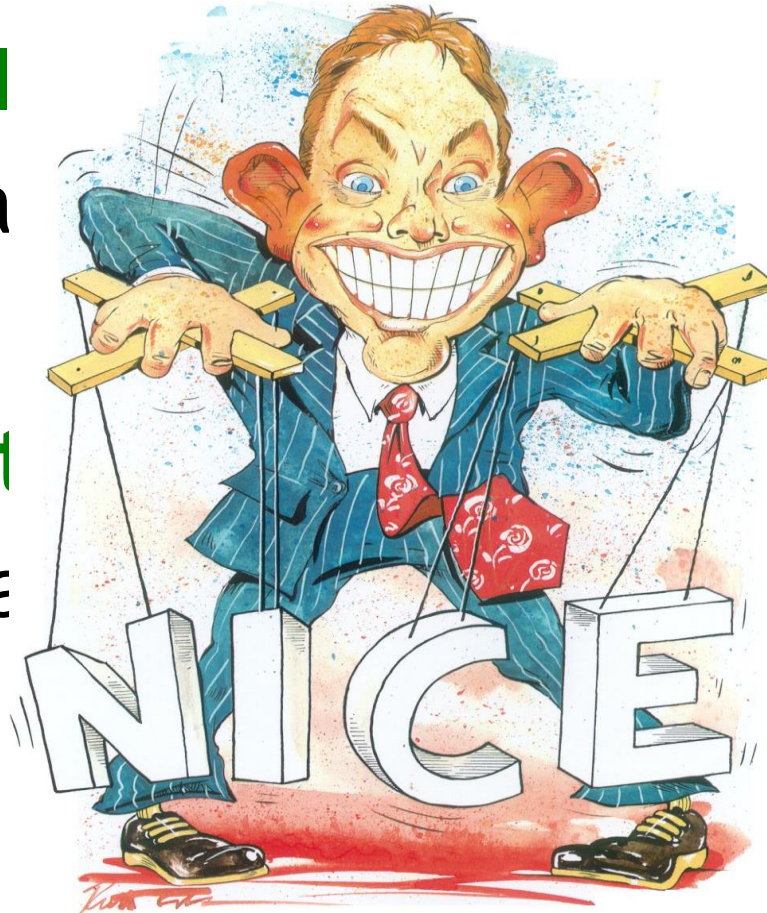
How do others see us?

National

– Broad

International

– Extra



NICE the bottom line -

Making policy decisions is not easy!!...



Implementing change (winning hearts and minds) is even more challenging!