

Quality of Health Care and the Design of the Basic Benefit Package

Lessons from Overseas

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Outline of Presentation

- Efficiency and the use of economic evaluation
- Challenges in designing an efficient health insurance package
- Lessons from overseas
- Conclusions

Definition of Quality in Health Care

Quality in health care requires consideration of:

- Effectiveness
- Safety
- Patient-centredness
- Timeliness
- Efficiency

Netherlands Quality Institute of Health Care (NZi)

Obtaining Effectiveness and Efficiency in Health Care

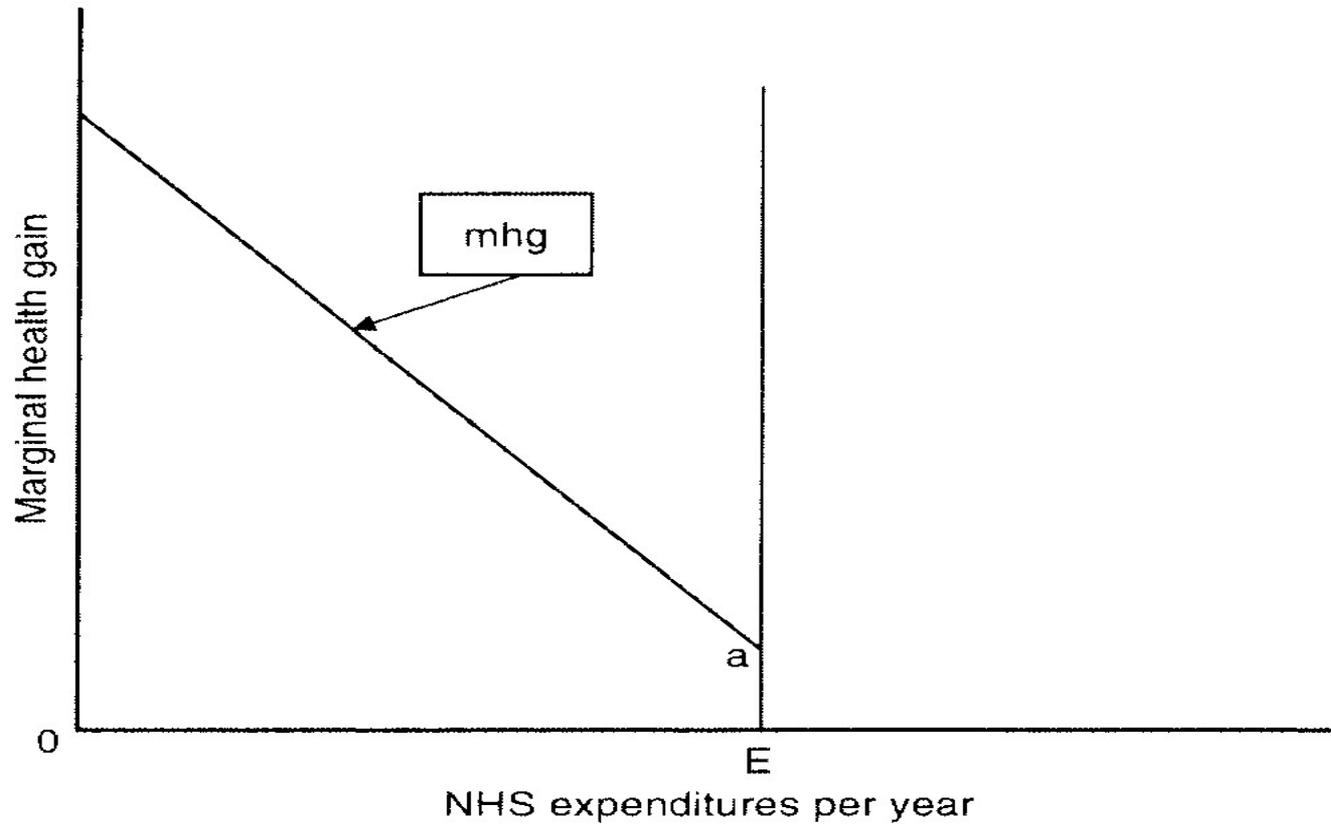
- Remove services that do not add value
- Remove inappropriate practice variations
- Consider whether the value added by services justifies any extra cost *

* The logic being that extra costs in one activity imply forgone benefits, or losses in quality, elsewhere, inside or outside the health care system

Efficiency and the Use of Economic Evaluation

- In order to determine the efficient use of health technologies, we need to compare the benefits added with the extra costs
- This is done by undertaking economic evaluations, such as *cost effectiveness analysis*
- The remit of the National Institute of Health and Clinical Excellence (NICE) in the UK is to consider '*clinical and cost-effectiveness*'
- The objective is to maximise the gain in health, typically measured in 'quality-adjusted life years' (QALYs), from the available budget

Efficient Use of Health Care Resources



Source: Culyer *et al.* *JHSRP* 2007.

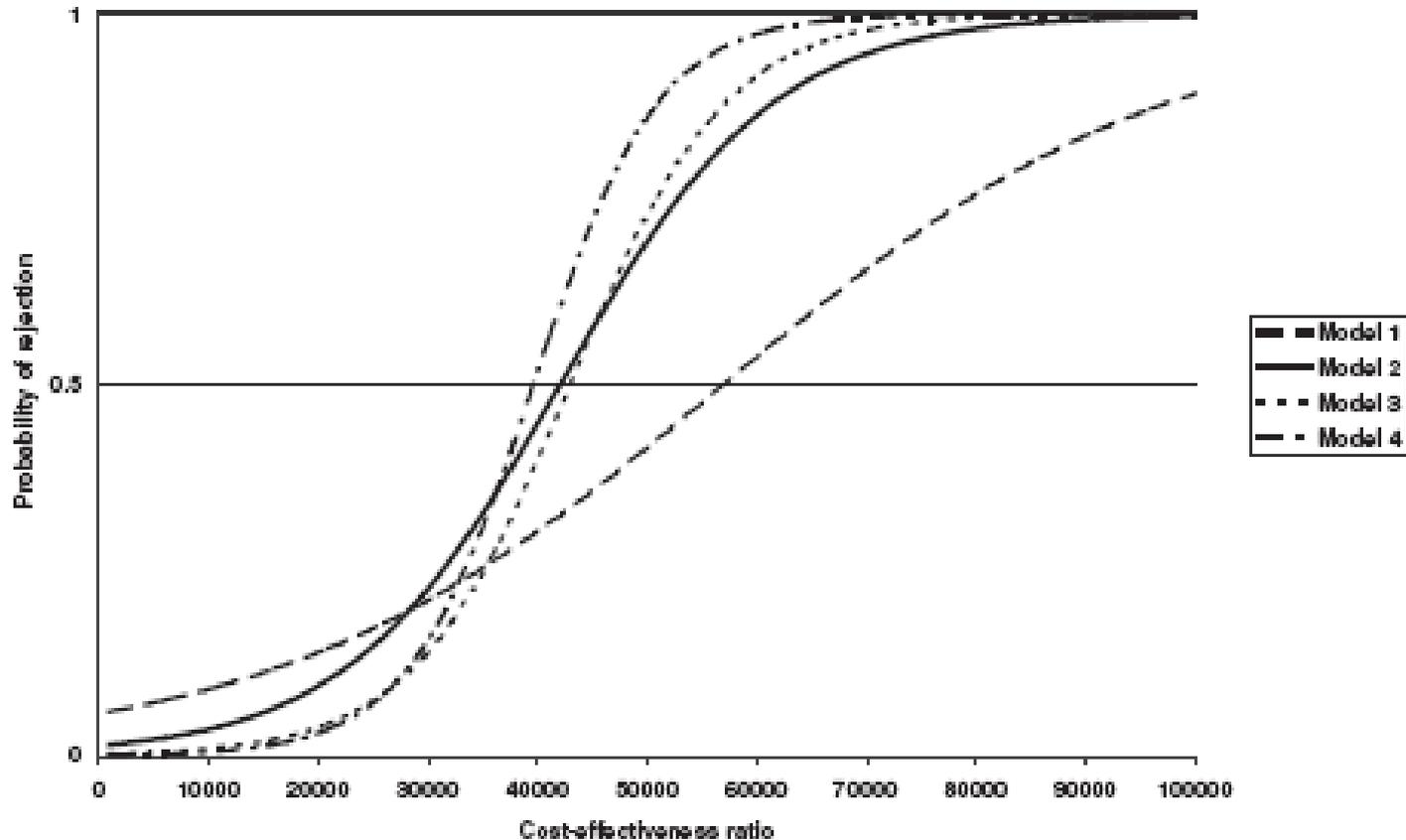
Challenges in Designing an Efficient Health Insurance Package

- It is not feasible to assess the cost-effectiveness of every single treatment or technology
- The cost-effectiveness of treatment can vary by sub-groups of the patient population
- It is important to determine the 'cost-effectiveness threshold' in one's jurisdiction
- Other factors may be important alongside cost-effectiveness

THE COST-EFFECTIVENESS THRESHOLD

- Originally NICE denied having a maximum amount it was willing-to-pay (for a QALY).
- Research into NICE's decisions identified the implicit threshold (Devlin and Parkin, 2004).
- NICE now says its critical range is £20,000 to £30,000 per QALY (Rawlins and Culyer, 2004).
- Current research into what the appropriate threshold should be.

DOES NICE HAVE COST-EFFECTIVENESS THRESHOLD?



Source: Devlin and Parkin. *Health Economics* 2004; 13: 437-452.

PROS AND CONS OF AN EXPLICIT THRESHOLD

Advantages:

- Encourages consistency in decision-making.
- More transparent.
- An implicit threshold would be inferred anyway.

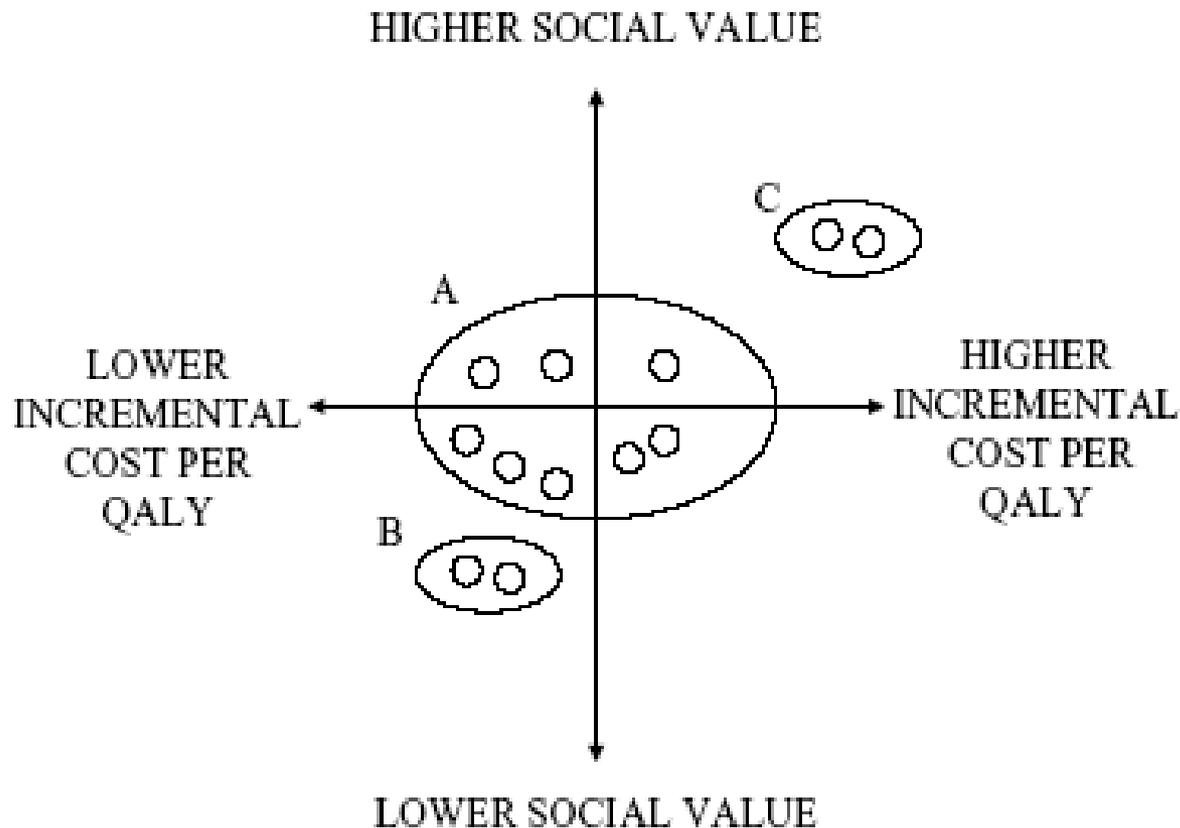
Disadvantages:

- Hard to determine what the threshold should be.
- Does not tell us the opportunity cost of adopting a new technology.
- Other considerations may come into play.

QALYS AND SOCIAL VALUES

- Health economists' chosen measure of health gain is the quality-adjusted life-year (QALY).
- Methodological problems with QALYs.
- Equal weighting of QALYs may not be appropriate.
- The QALY may not capture all the elements of social value.

THE RELATIONSHIP BETWEEN SOCIAL VALUE AND INCREMENTAL COST PER QUALITY-ADJUSTED LIFE-YEAR (QALY)



FACTORS OFTEN CONSIDERED ALONGSIDE COST-EFFECTIVENESS

- Lack of, or inadequacy of, alternative treatments.
- Seriousness of the condition.
- Affordability from the patient perspective.
- Overall financial implications for government.
- Equity objectives.

Lessons From Overseas: What Do we Need?

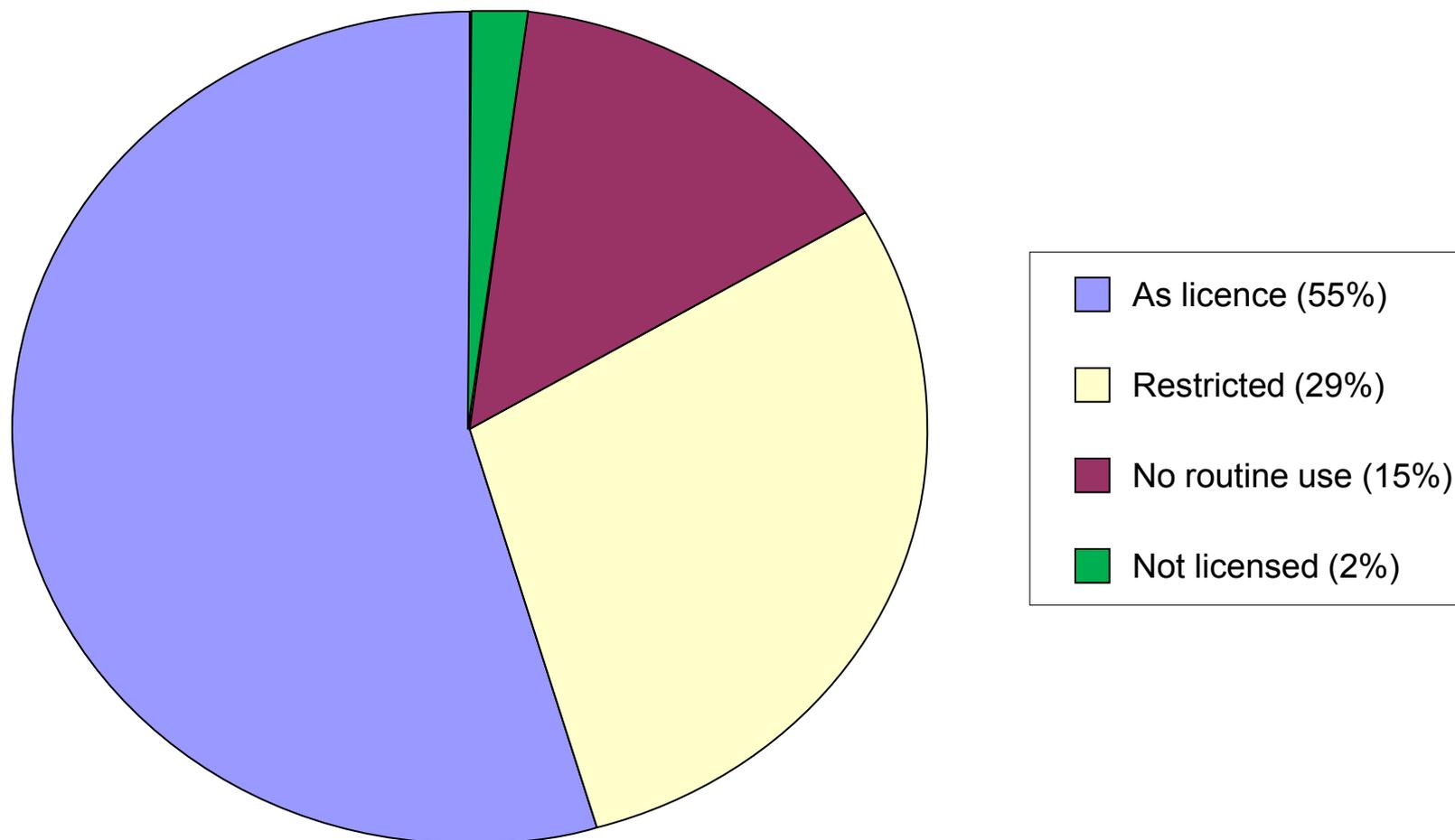
- A way of targeting new and expensive treatments to those who will benefit the most
- A way of looking broadly across different areas of medicine
- A debate about the cost-effectiveness threshold
- A way of introducing other considerations into decision-making
- Reliable structures and processes for making and implementing decisions

NICE's Technology Appraisals of New Cancer Drugs: May 2000-March 2008

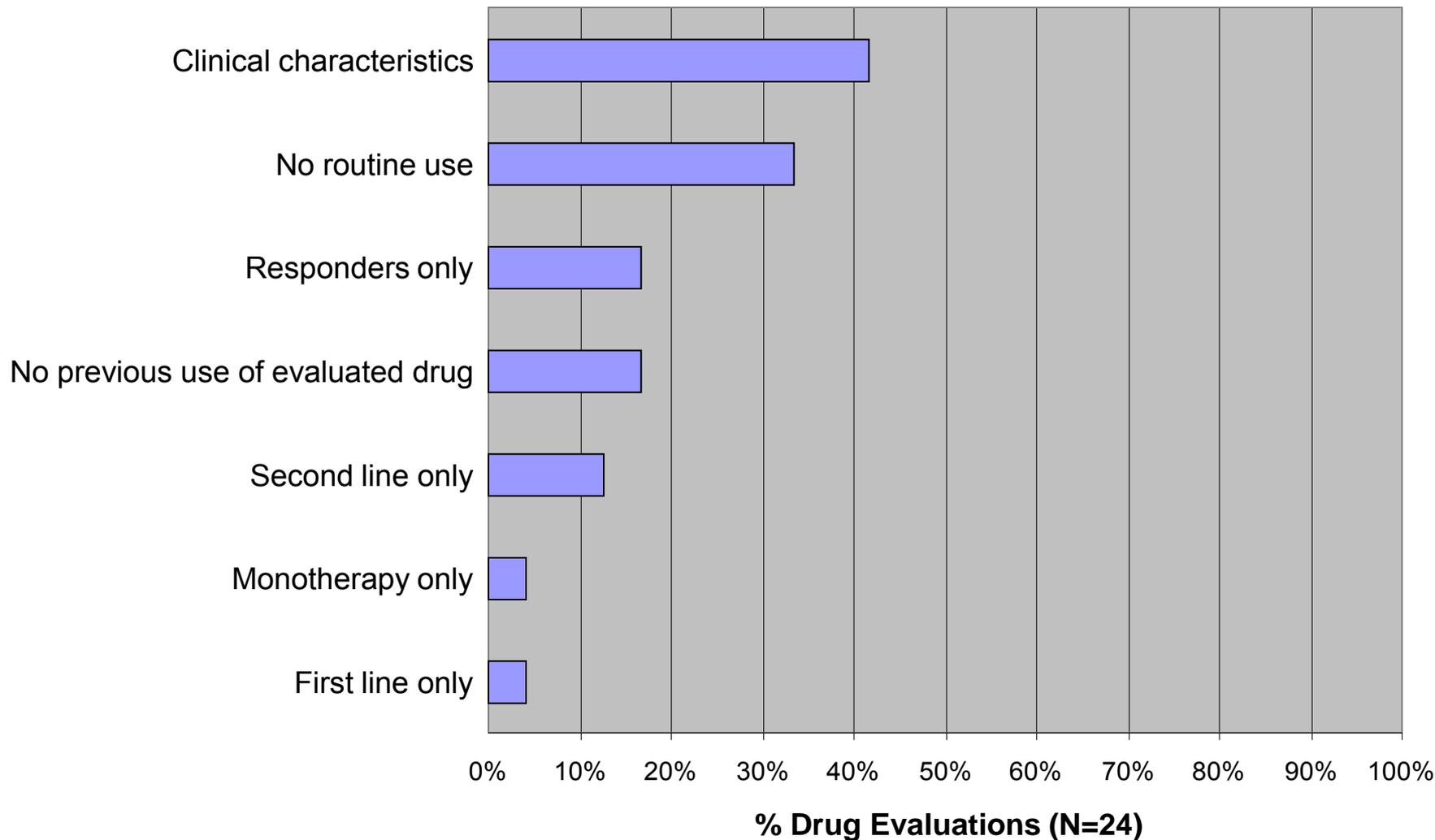
- *Data sources*
 - NICE published technology appraisals on cancer drugs
 - EMEA/MHRA licences/SPCs
- *Data extraction*
 - Drug, indication, recommendations
 - Stated justifications for guidance:
uncertainty; methodological issues; trial evidence; ICER
- *Analysis of guidance*
 - compare recommendation with licence
 - classify recommendation as:
per licence; restricted; no routine use

NICE Cancer Recommendations

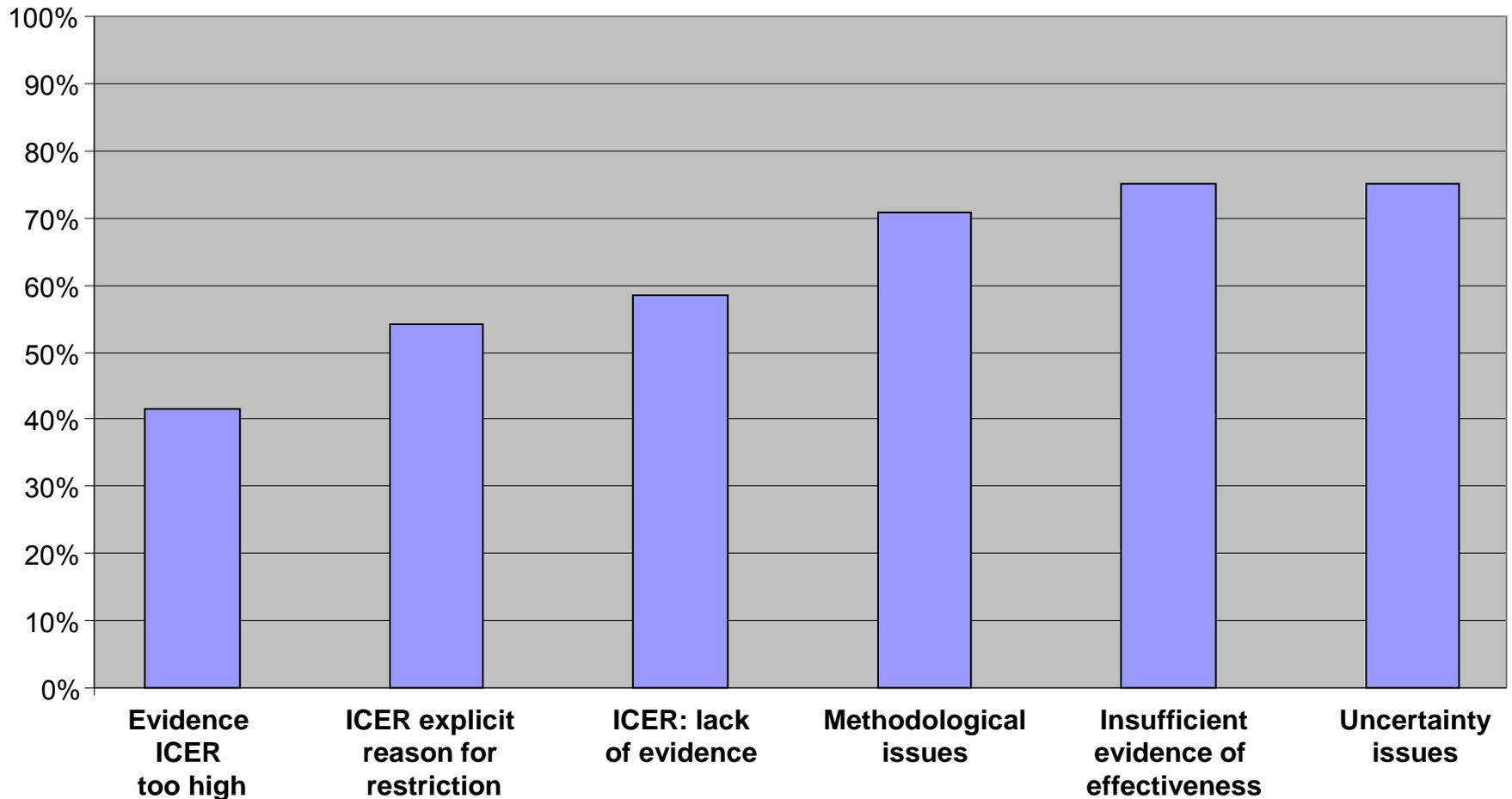
% cancer drug evaluations (N=55)



NICE Cancer Recommendations: Types of Restriction



Reasons for NICE Restrictions: % Drug Evaluations (N=24)



Technology Appraisals versus Clinical Guidelines

- ***Technology appraisals***

Deal with new technologies; narrow focus; many concern a single technology (eg a drug in a given indication); mandatory on the NHS.

- ***Clinical guidelines***

Deal with existing care; broader focus; aim is to improve existing care patterns; adoption is voluntary.

NICE's Clinical Guidelines Programme

- Guidelines also consider 'clinical and cost-effectiveness'
- To date 153 have been published
- Discuss discontinuation or modification of existing practices, as well as the use of new technologies
- Cover broad areas of medicine or health conditions:
 - # 150 Headaches
 - # 151 Neutropenic Sepsis
 - # 152 Crohn's Disease
 - # 153 Psoriasis

NICE's Process of Developing Clinical Guidelines

- Topics prioritised by the Ministry
- Scoping undertaken by NICE
- Guideline Development Group (GDG) appointed by the appropriate National Coordinating Centre (based in royal colleges of medicine)
- GDG is multidisciplinary, including methods experts in epidemiology and economics
- GDG considers available literature and clinical opinion
- Often original economic modelling is conducted
- The draft report is circulated for stakeholder comment
- The guideline is published by NICE, along with a lay version; the full report of the GDG is available on the web
- Several implementation strategies are employed, including advice on local implementation and the production of a costing template

Ways of Determining the Cost-Effectiveness Threshold

- Analysis of existing investments in health care
 - project currently being undertaken for the Ministry of Health in the UK
 - main issue concerns the availability of data on health outcomes
- Community surveys of willingness-to-pay for a QALY
 - two research projects commissioned in the UK
 - EuroVAQ project commissioned by the EU

Considering Other Factors Alongside Cost-Effectiveness

- ‘Deliberative’ decision-making
(eg Rawlins and Culyer, British Medical Journal, 2004)
- Assigning different weights to QALYs
(eg NICE’s ‘End-of-Life’ Guidance)
- Formal approaches to decision-making,
such as ‘Multi-Criteria Decision Analysis’

NICE'S SUPPLEMENTARY GUIDANCE FOR 'END OF LIFE' THERAPIES

If the therapy:

- is for a small patient population with life expectancy of less than 24 months;
- where the therapy adds three months or more to life expectancy.

Then:

- the QALYs gained should assume full quality of life in the added months;
- in addition the Committee can consider that the QALYs gained should be weighted sufficiently high for the therapy to be approved, given NICE's current threshold.

Value-Based Pricing in the UK

- Office of Fair Trading Report in 2007
- More flexibility in pricing introduced through *Patient Access Schemes*
- Caution over the *outcomes-based* schemes and perceived success of the *finance-based* schemes
- Government discomfort with the fallout from some of NICE's recommendations

Examples of UK Patient Access Schemes

- b-IFN and glatiramer for multiple sclerosis – 2002
 - Prospective cohort – managed by DH
- Bortezomib for multiple myeloma – 2007
 - Money back guarantee based on response (M-protein)
- Ranibizumab for AMD – 2008
 - Dose capping scheme (<14 injections per eye)
- Erlotinib for SCLC – 2008
 - Cost capping scheme (same overall cost as docetaxel)
- Sunitinib for advanced RCC – 2009 DRAFT
 - First time EOL guidance informed decision
 - 1st cycle of treatment free to NHS patients
- Lenalidomide for multiple myeloma – 2009 DRAFT
 - Dose capping scheme (<26 cycles/2yrs)

Value-Based Pricing Proposal in the UK

- Would apply to new branded medicines launched from January 1, 2014
- Recognition that new arrangements may be required for already-existing medicines
- The negotiation would consider:
 - the 'basic' cost-per QALY threshold
 - the burden of illness and unmet need that the medicine focuses on
 - the extent of therapeutic innovation
 - the wider societal benefits (eg impact on carers)

Value-Based Pricing Proposal (2)

- A full assessment of these factors will be used to determine the VPB
- If the company's price is higher than the VBP, it would be asked to lower its price, or provide extra justification
- *'If the company were not prepared to do either of these, it would be the company's responsibility to explain to the public why it was not prepared to offer that drug at an appropriate price'*

Reliable Structures and Processes

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Key principles for the improved conduct of health technology assessments for resource allocation decisions

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Issues to Consider

- Structure and independence of HTA organizations
- Range of technologies evaluated
- Types of evidence considered
- Quality of the review process
- Level of stakeholder involvement
- Transparency in HTA processes
- Communication and implementation of HTA results

Implementation of Guidance or Policies

- Most jurisdictions struggle with this, although it is central to the effort to obtain more clinical and cost-effectiveness
- In the UK, evidence on the implementation of NICE guidance is mixed
- In all cases, it is important to win over the hearts and minds of healthcare practitioners
- Many of the more effective approaches are linked to payment systems
- The most appropriate strategies need to be developed for each jurisdiction and may not easily be transferable

Conclusions

- The cost-effectiveness of health treatments and technologies can be assessed, thereby considering both the quality of care and resource use
- Designing an efficient health insurance package presents a number of challenges
- Solutions need to be developed locally, but it is worthwhile considering lessons from overseas