LSHTM Health Economics Seminar 29 April 2015

Caveat emptor NICE: biased use of cost-effectiveness analysis is inequitable

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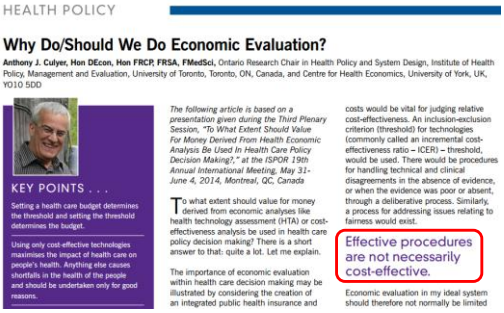

HEALTH POLICY

Why Do/Should We Do Economic Evaluation?

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KEY POINTS . . .

Setting a health care budget determines the threshold and setting the threshold determines the budget.

Using only cost-effective technologies maximises the impact of health care on people's health. Anything else causes shortfalls in the health of the people and should be undertaken only for good reasons.

The following article is based on a presentation given during the Third Plenary Session, "To What Extent Should Value For Money Derived From Health Economic Analysis Be Used In Health Care Policy Decision Making?," at the ISPOR 19th Annual International Meeting, May 31-June 4, 2014, Montreal, QC, Canada

To what extent should value for money derived from economic analyses like health technology assessment (HTA) or cost-effectiveness analysis be used in health care policy decision making? There is a short answer to that: quite a lot. Let me explain.

The importance of economic evaluation within health care decision making may be illustrated by considering the creation of an integrated public health insurance and costs would be vital for judging relative cost-effectiveness. An inclusion-exclusion criterion (threshold) for technologies (commonly called an incremental cost-effectiveness ratio – ICER) – threshold, would be used. There would be procedures for handling technical and clinical disagreements in the absence of evidence, or when the evidence was poor or absent, through a deliberative process. Similarly, a process for addressing issues relating to fairness would exist.

Effective procedures are not necessarily cost-effective.

Economic evaluation in my ideal system should therefore not normally be limited

ISPOR Value & Outcomes Spotlight March/April 2015 Vol. 1, No. 2

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HEALTH TECHNOLOGY ASSESSMENT
VOLUME 19 ISSUE 14 FEBRUARY 2015
ISSN 1366-5278

Claxton Report

Methods for the estimation of the National Institute for Health and Care Excellence cost-effectiveness threshold

Karl Claxton, Steve Martin, Marta Soares, Nigel Rice, Eldon Spackman, Sebastian Hinde, Nancy Devlin, Peter C Smith and Mark Sculpher

The most relevant 'central' threshold [in the NHS] is estimated to be £12,936 per QALY… if anything, likely to be an overestimate

Background: Cost-effectiveness analysis involves the comparison of the incremental cost-effectiveness ratio of a new technology, **which is more costly than existing alternatives,** with the cost-effectiveness threshold.

This indicates whether or not the health expected to be gained from its use exceeds the health expected to be lost elsewhere as other health-care activities are displaced. The threshold therefore represents the additional cost that has to be imposed on the system to forgo 1 quality-adjusted life-year (QALY) of health through displacement.

Claxton 2015, Abstract

The NICE advance has been bought at the price of biased use of the principle of cost-effectiveness and, as a corollary, biased support for innovative technologies.

These biases are built into its legal obligations. Its remit is to appraise the clinical and cost-effectiveness of technology x within its licensed indication for treating disease y.

To be considered in the scoping process for possible appraisal, the technology must be 'either new or an innovative modification of an existing technology with claimed benefits to **patients or the NHS** judged against the comparator(s).'

The purpose of the NICE appraisal is to decide whether the new technology
'works well' (is clinically effective)
and
'good value for money' (is cost-effective).

At no stage of the scoping or appraisal process is an innovation that claims to be cost-effective and 'good value for money', but not 'clinically effective' in relation to the comparators, eligible for consideration

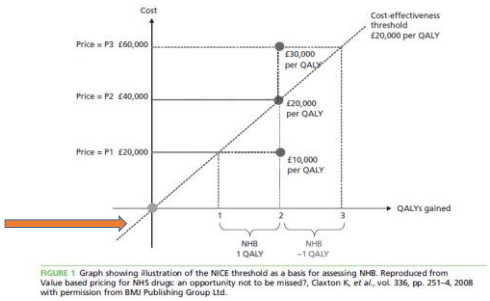
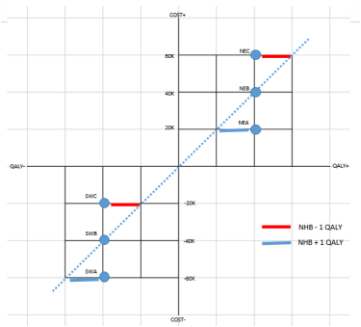


FIGURE 1 Graph showing illustration of the NICE threshold as a basis for assessing NHB. Reproduced from Value based pricing for NHS drugs: an opportunity not to be missed?, Claxton K, *et al.*, vol. 336, pp. 251–4, 2008 with permission from BMJ Publishing Group Ltd.

The full 4 quadrant CE Plane

with Claxton NE quadrant rotated and placed in SW quadrant



So

- All innovations below linear ICER are Cost-effective
- If threshold is infinite (ICER line Vertical), no SW innovations are cost-effective, only those in Eastern hemisphere
- If threshold is zero (ICER line horizontal) all SW innovations are cost-effective and none of those in Northern hemisphere

Terminology

- 'Incrementally CE' if in NE quadrant
- 'Decrementally CE' if in SW quadrant
- BUT both are CE
- May be helpful for operational reasons to characterise the differing origins of CE, but the two cannot be separated for policy purposes without abandoning the CE principle.
- Separating incremental and decremental cost-effectiveness is as meaningful as separating right-handed and left-handed ambidexterity

This argument is not an empirical one

- about the NICE threshold (whether 20 or 30k), or
- about the NHS threshold (whether 12xxx or some other number), or
- about where 'displacement' occurs in order to fund a new, more expensive innovation

It is not dependent on use of the QALY

The argument applies whatever the metric of effectiveness, but does assume there is one !

Reasons advanced for not going SW (beneath a linear ICER)

- Infringes rights
- Harms health ('lossaversionitis') (Gandjour)
- Can't show will actually produce benefits (Sendi, Gafni, Birch)
- Kinked ICER (O'Brien) or MAD (Kent)
  WTA ≠ WTP valid at societal level
- Prospect Theory (Tversky& Kahneman) and 'Psychic numbing' (Slovic) are legitimate at societal level

Infringes rights

- *"SW interventions are simply **wrong** because they take away from them something people already have."*
- …. even if it were to be agreed that *current* recipients would not be forced to move on to the less effective treatment because it is now the cost-effective one, this argument lacks any justification when extended to those who acquire the same condition *in the future.*
- Having never enjoyed the effectiveness of the old treatment, they cannot have a right to it taken away from them.
- Those who become ill later cannot ethically be favoured, in relation to other sufferers, simply because they suffer from this disease or condition, rather than from some other one.

Harms health

- *"SW interventions will produce ill health which will require treatment and impose extra costs"*
- Gandjour argues that even prospect of SW interventions will create depression, anxiety etc.
- He may be right, but if 'lossaversionitis' is produced then treatment for it needs to be entered into the allocation system and the cost-effectiveness of interventions for it assessed.

Required proof can't be provided

- "*SW interventions should not occur unless it can be shown that there will be a net increase in health*"
- 'NICE cannot be expected to reflect what is likely to be marked variation between local commissioners and providers in how they react to an effective reduction in their budget as a result of positive guidance. Given NICE's remit, it is the expected health effects (in terms of length and QoL) of the average displacement within the current NHS (given existing budgets, productivity and the quality of local decisions) that is relevant to the estimate of the threshold.' p.8
- We see no justification for imposing higher specificity requirements regarding displacement on SW interventions than on NE ones.

Kinked ICER

- *"Some SW interventions are acceptable, but only those **under** a (very) kinked ICER"*

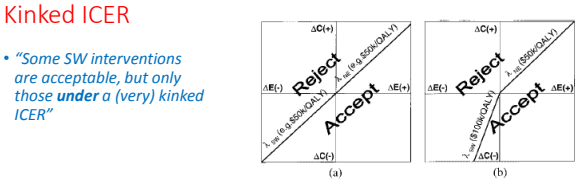


Figure 1. The space of incremental cost (ΔC) and incremental effect (ΔE) – here presented as quality-adjusted life-year QALYs are shown. In (a) the arbitrary threshold of \$50k per QALY is a straight line through the north-east to south-west quadrant; in (b) the threshold is kinked, with the 'selling price' of a QALY being higher (set to \$100 k for illustration only)

HEALTH ECONOMICS
HEALTH ECONOMICS LETTERS

Is there a kink in consumers' threshold value for cost-effectiveness in health care?

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COMMENTARY

No Room for Kinkiness in a Public Healthcare System

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Egalitarian-ethical-equitable argument at a societal level
– and BTW efficient in terms of maximising health gain

OR
Individual self interest argument based on Rawlsian rationality:
… someone who does not know which, from the wide range of possible conditions, they or their significant others will personally suffer from, should clearly favour the wider distribution of benefits that comes from applying the cost-effectiveness decision rule consistently in the SW as well as NE quadrant

WTA ≠ WTP (loss aversion)

- *"People require much greater compensation for a given loss than they are willing to pay for the same gain"*
- Not in dispute at individual level
- Reproduced in studies aggregating individual preferences
- But why should we accept the societal inequity that will result by using this in public policy?

'Psychic numbing' is legitimate

Figure 9. A model depicting psychic numbing—the collapse of compassion—when valuing the saving of lives.

"If I look at the mass I will never act": Psychic numbing and genocide

Paul Slovic[1]
Decision Research and University of Oregon

Judgment and Decision Making, vol. 2, no. 2, April 2007, pp. 79-95.

1 Qal **Year** for 1 person

= 1 Qal **Day**

- for 365 persons?
- for 3,650 persons?
- for 36,500 persons?
- for 365,000 persons?
- for 3,650,000 persons?

1 Qal **Year** for 1 person

= 1 Qal **Half Year**

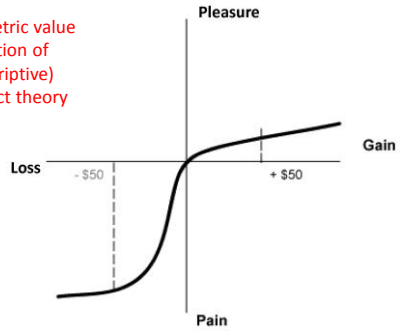
- for 2 persons?
- for 20 persons?
- for 200 persons?
- for 2,000 persons?
- for 20,000 persons?

1 Qal **Year** for 1 person

= 1 Qal **Month**

- for 12 persons?
- for 120 persons?
- for 1,200 persons?
- for 12,000 persons?
- for 120,000 persons?

Asymmetric value function of (descriptive) prospect theory



SW innovations are everywhere!

- Just presented as SE ones!

Even NICE goes SW without admitting it

- NICE implemented a SW innovation in its own operations by its introduction of the cheaper Single Technology Appraisal, where the manufacturer is responsible for the analysis and an independent team is paid only to critique it, not conduct a full-scale Multi Technology Assessment using all appropriate comparators
- It seems unacceptable to admit that the quality of an STA is less than an MTA, even though clearly it is (any dissent?)
- But the reduction could be relatively small and the cost- saving large, thereby releasing resources for other uses - the essence of the SW argument!

Innovation support – yes,but only if dearer

- NICE is charged with objectives other than maximising the increase in public health and among its other obligations is to support innovation.
- But this turns out to be biased support, in that no support can be provided for the development of technologies which are simply cost-effective.
- No innovation in the SW quadrant can meet the filter test of clinical effectiveness administered prior to the test of cost-effectiveness.
- So while NICE has a remit to support the adoption of innovative new technologies, in practice the support is confined to those that will cost more.

Claxton spot on … except for SW blind spot

> One explanation for… 'Acceptance creep' (in the NICE appraisal process) is that the broad selection of stakeholders who contribute to the NICE process excludes a key constituency: those unidentified NHS patients who bear the true opportunity costs of NICE decisions. NICE undoubtedly faces extensive pressure from the direct beneficiaries of a positive recommendation, including manufacturers, the patients who might benefit and their clinicians. [but NICE] is failing to uphold this critical responsibility to all NHS patients. (p.2)
>
> …it is the unidentified and unrepresented NHS patients who bear the true (health) opportunity costs. Although finding reasons to approve new drugs is undoubtedly politically expedient, this cannot be ethically literate, because the interests of NHS patients, whether they are identifiable or not, are just as real and equally deserving of the type of care and compassion that can be offered by a collectively funded health care system. It is to be hoped that NICE will begin to place the unidentified NHS patients who bear the real opportunity costs at the heart of its deliberative process… (p.6)

Thanks for attending