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NICE as an ICER threshold-searcher: rationale and implications

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ABSTRACT

There has been much speculation about whether the National Institute for Health Clinical Excellence (NICE) has, or ought to have, a 'threshold' figure for the cost of an additional quality-adjusted life-year (QALY) above which a technology will not be recommended for use in the National Health Service (NHS). This paper argues that it is not constitutionally appropriate for NICE to set such a threshold, which is properly the business of parliament. Instead, the task for NICE is as a 'threshold-searcher' -- to seek to identify an optimal threshold incremental cost-effectiveness ratio (ICER), at the ruling rate of expenditure, that is consistent with the aim of the health service to maximize population health. This will involve the identification of technologies currently made available on the NHS that have estimated ICERs above the ratio, and alternative uses for those resources in the shape of technologies not currently provided that fall below the threshold.

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Introduction

The Quality-Adjusted Life-Year (QALY) is the outcome measure of choice for the National Institute for Health and Clinical Excellence (NICE) [1 p. 48]. There has been much speculation about whether NICE has a 'threshold' figure for the cost of an additional quality-adjusted life-year above which a technology will not be recommended for use in the National Health Service (NHS), and there has been some suggestion that NICE is dissembling in its denials that such a threshold exists [2 p. 27]. An early retrospective analysis of appraisal determinations in its first year of operation, summarised by Sir Michael Rawlins at NICE's annual public meeting in 2001, suggested that positive recommendations were in general associated with a cost per QALY of £30,000 or less; higher cost per QALY figures would receive approval only if there were special factors accepted as relevant by the Appraisal Committee (and the NICE Board) and not covered by the formal modelling [3 para 11].

Attempts to infer what any such threshold might be, based on published appraisal decisions, have identified a general concentration of estimates in the region of £20,000 - £30,000 in one study [2] and a suggestion that the threshold might be considerably higher than £30,000 in another [3]. In April 2004, the Institute confirmed that interventions with a cost per QALY below £20,000 were likely to be recommended; whilst the acceptability of therapies between £20,000 and £30,000 per QALY is more likely to depend upon other factors, such as the innovative nature of the therapy [1, page 33]. Prior to this, the only published specific threshold comes from the Department of

Health [4, para 12] in which a threshold of £36,000 was set, specific to a risk sharing agreement with the pharmaceutical industry over the provision of disease modifying drugs for people living with multiple sclerosis.

In this paper, we argue that there are good reasons why it is improper for NICE to apply a specific threshold. Rather, we characterise NICE's proper function as a "threshold searcher", seeking to identify the optimal threshold that lies somewhere between the least cost-effective technology currently provided and the most cost-effective technology not yet available routinely in the NHS.

It is not constitutionally proper for NICE to determine the threshold

NICE's function in relation to appraisals, as set out in the Framework Document issued by the Secretary of State for Health and the National Assembly for Wales, is

"to appraise the clinical benefits and the costs of such health care interventions as may be notified by the Secretary of State or the National Assembly for Wales … and to reach a judgement on whether on balance this intervention can be recommended as a cost-effective use of NHS and PSS resources" [5 p.28].

NICE does not, of course, set the NHS budget and, to our knowledge, no one has suggested that it would in any way be proper for it to do so. Parliament sets the NHS's budget and thus the ultimate financial constraint on the NHS.

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The logical implications of NICE's mandate can be made clear in the following way. Consider a rank ordering of all the technologies available to the NHS and the most efficient ways of spending NHS funding as shown in Figure 1. Those that have the largest possible impact on health per pound spent are plotted on the left with each addition to health gain falling as those with the best chances of being helped have already been helped. The downward slope depicted in Figure 1 continues until the point E is reached in Figure 1, at which the available NHS budget has been used up. The height of the line at this point (Ea) shows the marginal health gain from additional expenditure (mhg), given the current budget. Its inverse shows the marginal cost-effectiveness of NHS expenditure, or the threshold incremental cost-effectiveness ratio. The total health gain produced by this expenditure is the entire area under the curve. It is the greatest gain in health achievable, given the range of technologies available and the current NHS budget. It requires that this budget is effectively spent by the NHS so that none of the technologies with an mhg less than Ea are used.

If the objective is indeed to maximize the impact of health services on health then one can approach the defining characteristic of this objective in either one of two ways. One can speak either of a budget that is to be efficiently spent, which entails using all the technologies embodied in the figure up to 0E, which implies the threshold mhg of Ea; or one can speak of a threshold QALY gain per unit of expenditure - Ea, which entails using all technologies whose mhg is higher than Ea, which will (just) require a budget of 0E. The two are equivalent: one may either spend the budget to maximise health (which

implies the threshold), or purchase all technologies up to the threshold (which implies the budget). Both produce exactly the same outcome – and NICE is constitutionally qualified to determine neither of them!

Determining the budget is Parliament's business. NICE is neither mandated nor qualified to make judgments about the relative value of public money spent on health care versus the other possibilities – education, defence, environment, etc. and, of course, private consumption. But, since determining the threshold is logically equivalent to determining the budget (given the available technologies embodied in the curve), then NICE cannot be qualified to pronounce on that either.

Therefore, information about how much an individual or society values improvements in health outcome (i.e. their willingness to pay for a QALY) is not at all relevant to the NICE remit. These values could only be used as the appropriate threshold by NICE if it were also given responsibility to set the NHS budget. However, NICE has commissioned independent research into the social value of QALY [6]. Whilst this information may have a bearing on political judgments concerning the level of resources the NHS ought to receive, it is unlikely to correspond to the threshold required to maximize health gain from a budget constraint given by Parliament.

NICE as a threshold-searcher

The information demands of optimizing NHS expenditure are manifestly huge. NICE has incomplete and uncertain information on the mhg function in figure 1 and, therefore, does not know the value of the threshold. The threshold is neither taken by NICE (from government) nor made by NICE. NICE is neither a threshold taker nor a threshold maker. NICE is, in effect, a threshold-searcher, where the threshold is logically implied by the combination of the technologies that are available and the budget, but is not readily visible.

Figure 1 assumes the NHS is able to allocate its budget on programmes in order of their health gain per pound spent. Figure 2 explores the more realistic analytical problem for NICE when the current budget is not allocated in this efficient manner . In Figure 2, the range of technologies in 0E embodies those extant in the NHS. Let us assume that all are positive and that the least productive one has, as before, a mhg of Ea. However, we now assume that there are many technologies either extant or emergent that are not currently provided within the NHS. These technologies are ranked in a separate downward-sloping function to the right of E labeled cf. A composite mhg curve is the horizontal sum of the two lines, Hde. which combines all available technologies: those in use as well as those that could be used but are not, and again orders them by contribution to health gain. It is immediately apparent that NICE confronts three potentially interesting marginal health gains, the size of none of which it can be sure. Ea is the actual mhg implied by current use in the NHS. It is what the current 'threshold' would appear to be if a comprehensive assessment were to be made of the ways in which current NHS resource are used. Ec is

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the health gain to be achieved from adopting the best technology not currently in use in the NHS. Eb is the threshold above which technologies ought to be adopted and below which they ought not.

The incorporation of any technology not in current use with a mhg above Eb would represent an increase in health outcomes as long as it displaces a technology with a lower mgh (in the range E'E). The optimal solution is plainly to cease using all those technologies in the range E'E on Ha and substitute for them all those in the range EE" (= E'E) on cf. The search strategy for NICE is to work within the "zone of substitution" defined by E'E", identifying technologies in current use that are the least productive uses of current NHS resources, and identifying better value technologies that are not currently provided.

NICE's search strategies

It is not feasible for NICE to examine the cost-effectiveness of all interventions to reveal the location of Hde. Instead, NICE adopts a number of strategies consistent with the behaviour to be expected of a threshold searcher. In collaboration with the Department of Health, it engages in horizon scanning to explore technologies that probably lie in the zone of substitution.   NICE also relies upon a broad consultation process with all stakeholders, including the general public, to identify technologies for both investment and disinvestment. [7]   The proposals obtained through the consultation process are reviewed by two expert committees; the Advisory Committee on Topic Selection (ACTS)

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and the Joint Planning Group, [7] who bring their broad knowledge of the efficiency of a wide range of NHS interventions to the consideration of which therapies to put forward for review. Within the review process the

> "appraisal committee's judgments on the cost effectiveness of a new technology must include judgments on the implications for health care programmes for other patient groups…how the cost effectiveness of the technology being appraised relates to other intereventions/technologies currently being applied in the NHS."

If this system were to work well, we would expect to see a mixture of investment and disinvestment opportunities being reviewed by NICE. However, in practice almost all NICE appraisals have considered opportunities for investment. [8] As a result, disinvestment opportunities have had to be considered at local provider level. Whilst some local commissioners have established formal processes for considering local disinvestment and investment decisions [9], [10], [11], there is evidence of substantial variation in both the quality and the degree of transparency in local health commissioning processes [12]. Methods for identifying and evaluating local investment and disinvestment opportunities do exist; for example Programme Budgeting and Marginal Analysis, (PBMA). [13]. However, the widespread adoption of a common evaluative framework, producing information on the cost effectiveness of a much larger range of NHS interventions may help to provide a bridge between local commissioning processes and NICE. For example, NICE could be asked to work with local commissioners to identify programmes and technologies for which there exists a *prima facie* case for disinvestment. It could then

appraise these over time together with emerging technologies, in the expectation of imposing a more balanced set of investment and disinvestment requirements on local decision-makers

Conclusions

In this paper, we have argued that it is not NICE's constitutional role to determine the value of an additional QALY since the setting of the NHS budget is properly a matter for parliament. NICE nonetheless needs a criterion on which to judge the cost-effectiveness of technologies that pass through its appraisal process and it is the *search* for the threshold implied by the prevailing NHS budget that is the appropriate task for NICE. This will require NICE to grasp the disinvestment nettle and include within its current appraisal process technologies that should no longer be provided by the NHS as well as candidate technologies to replace them.

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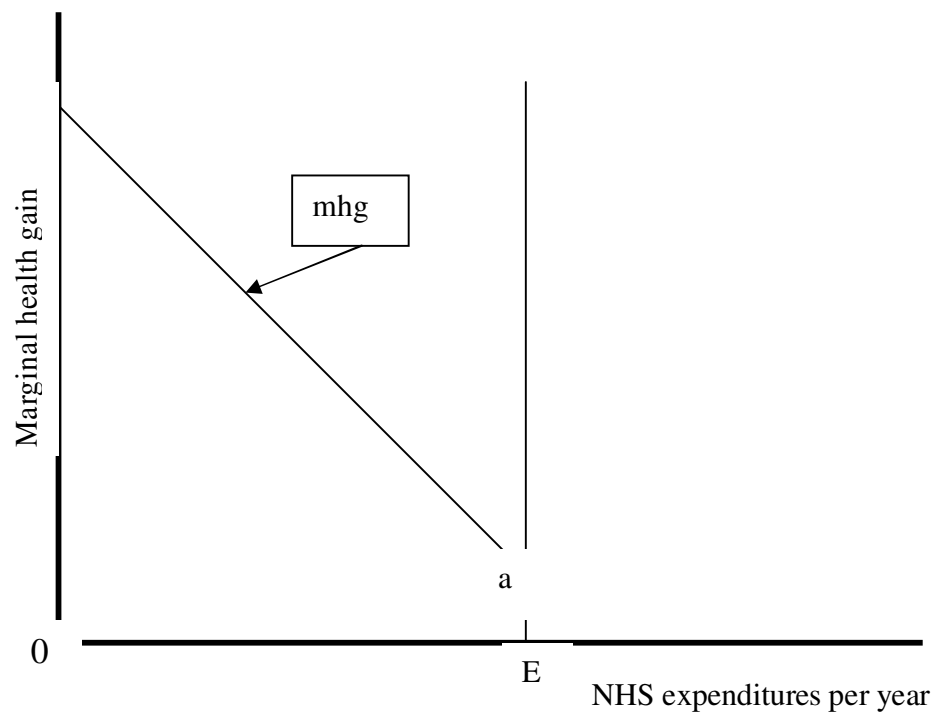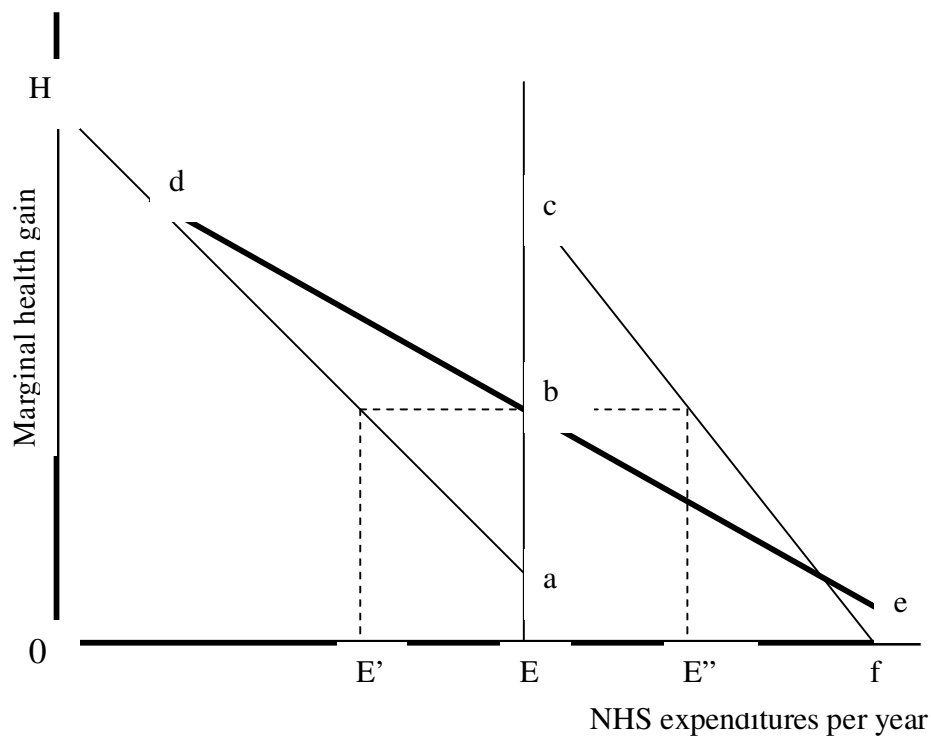
Figure 1 Marginal health gain

Figure 2 Three thresholds for NICE

Conflict of Interest

AJC was Vice Chair of NICE until 2003 and is a member of the NICE Research and

Development Committee.

CM receives funding from NICE for the NICE Decision Support Unit.

AHB has no conflicts of interest.

KC is a member of the NICE Appraisal committee and has received research funding

from NICE.

MB has no conflicts of interest.

RA has no conflicts of interest.

MS is a member of the NICE Appraisal Committee and receives NHS R&D
funding to undertake technology assessments for NICE'

JEB has no conflicts of interest.

Contribution

AJC, CM, AHB KC, MB, RLA, MS and JB were jointly responsible for the ideas

presented in this paper. They jointly drafted and reviewed the paper. They have all

approved the final version of the paper. AJC acts as guarantor for the paper.

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