The NICE Cost-Effectiveness Threshold
What it is and What that Means

Christopher McCabe,[1] *Karl Claxton*[2] and *Anthony J. Culyer*[3,4]

1　Academic Unit of Health Economics and NICE Decision Support Unit, Leeds Institute of Health Sciences, University of Leeds, Leeds, UK
2　Centre for Health Economics, Department of Economics and NICE Decision Support Unit, University of York, Heslington, York, UK
3　Centre for Health Economics, Department of Economics, University of York, Heslington, York, UK
4　Department of Health Policy Management and Evaluation, University of Toronto, Toronto, Ontario, Canada

Abstract

The National Institute for Health and Clinical Excellence (NICE) has been using a cost-effectiveness threshold range between £20 000 and £30 000 for over 7 years. What the cost-effectiveness threshold represents, what the appropriate level is for NICE to use, and what the other factors are that NICE should consider have all been the subject of much discussion. In this article, we briefly review these questions, provide a critical assessment of NICE's utilization of the incremental cost-effectiveness ratio (ICER) threshold to inform its guidance, and suggest ways in which NICE's utilization of the ICER threshold could be developed to promote the efficient use of health service resources.

We conclude that it is feasible and probably desirable to operate an explicit single threshold rather than the current range; the threshold should be seen as a threshold at which 'other' criteria beyond the ICER itself are taken into account; interventions with a large budgetary impact may need to be subject to a lower threshold as they are likely to displace more than the marginal activities; reimbursement at the threshold transfers the full value of an innovation to the manufacturer.

Positive decisions above the threshold on the grounds of innovation reduce population health; the value of the threshold should be reconsidered regularly to ensure that it captures the impact of changes in efficiency and budget over time; the use of equity weights to sustain a positive recommendation when the ICER is above the threshold requires knowledge of the equity characteristics of those patients who bear the opportunity cost. Given the barriers to obtaining this knowledge and knowledge about the characteristics of typical beneficiaries of UK NHS care, caution is warranted before accepting claims from special pleaders; uncertainty in the evidence base should not be used to justify a positive recommendation when the ICER is above the threshold. The development of a programme of disinvestment guidance would enable NICE and the NHS to be more confident that the net health benefit of the Technology Appraisal Programme is positive.

1. Background

The National Institute for Health and Clinical Excellence (NICE) is charged with the task of considering both the effectiveness and cost effectiveness of treatments and then making recommendations as to the provision of such treatments within the UK NHS. Cost-effectiveness analysis assesses two or more alternative courses of action in terms of their costs and benefits. The comparison is summarized using the expected incremental cost-effectiveness ratio (ICER). This is a measure of the additional cost per additional unit of health gain produced by one intervention compared with another. NICE's preferred form of cost-effectiveness analysis uses the QALY to describe the outcome of each intervention. By extension, the preferred form of ICER is the cost per QALY gained. Within the NICE appraisal process, the ICER for each technology is compared with a threshold value (generally accepted as having an upper limit of £30 000) to establish whether the technology represents an efficient use of limited NHS resources.

The objective of this article is to review the current state of knowledge regarding the cost-effectiveness threshold, the principles of its use in healthcare resource allocation decisions and any arguments for and against changing the threshold from the current range of £20 000–30 000.

Section 2 summarizes the statements in the 2004 *Guide to the Methods of Technology Appraisal* regarding the value and use of the cost-effectiveness threshold. Section 3 reviews the relevant literature on the use of the cost-effectiveness threshold in resource allocation decision making. Section 4 discusses key implications of using an ICER threshold to promote population health gain from the NHS budget. Section 5 considers the issue of whether the NICE threshold should change; and section 6 attempts to summarize the key observations of the paper.

2. What the Current *Methods Guide* Says

The 2004 *Methods Guide*[1] refers several times to the cost-effectiveness threshold. In chapter 6 (page 33), it states:

"The Appraisal Committee does not use a fixed ICER threshold above which a technology would automatically be defined as not cost effective or below which it would. Given the fixed budget of the NHS, the appropriate threshold is that of the opportunity cost of programmes displaced by new, more costly technologies. However, estimating this threshold would require complete information about the costs and QALYs from all competing healthcare programmes and the Committee does not have this information. Furthermore, the threshold will change over time as the budget for healthcare changes. Although the use of a threshold is inappropriate, comparisons of the most plausible ICER of a particular technology compared with other programmes that are currently funded are possible and are a legitimate reference for the Committee."[1]

This statement acknowledges the importance of considering the opportunity cost of implementing new treatments given a fixed threshold – whilst conversely suggesting that, since the data required to estimate the threshold quantitatively are not available, it is inappropriate to use a threshold. Our interpretation of this apparently contradictory statement is that it is use of a *particular* threshold that is to be avoided, hence NICE's emphasis on a range.

The guide then goes on to consider a range of possible other factors to take into account in cases of technologies with ICERs at the lower and upper boundary of the range:

"Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on the cost-effectiveness estimate. Above a most plausible ICER of £20,000/QALY, judgements about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including:

- *the degree of uncertainty surrounding the calculation of ICERs*
- *the innovative nature of the technology*
- *the particular features of the condition and population receiving the technology*
- *where appropriate, the wider societal costs and benefits."*[1]

This approach echoes ideas advanced by Akehurst[2] in 2002, and seems to imply that NICE's 'effective threshold' is actually £20 000 per QALY. When cost-effectiveness ratios for a treatment exceed this, the Appraisal Committee considers

(i) whether the characteristics of the condition or population receiving the treatment would lead them to value the health gain produced by the intervention more highly than the estimate made in the analysis; (ii) whether innovative characteristics of the intervention are such as to require explicit consideration of the Secretary of State's instruction to give due weight to innovativeness, despite the excess opportunity cost from a purely efficiency perspective; and (iii) whether other benefits to society, outside of those considered by the cost-effectiveness analysis, are such that it is 'socially desirable' for the treatment to be made available.

The proposed role of uncertainty in decision making is unclear. The text may mean that when the ICER exceeds the lower bound of the threshold range, the committee will seek greater levels of certainty to support a positive recommendation. However, the text is also consistent with Akehurst's proposal[3] that when there is great uncertainty about an ICER in excess of the threshold value, it is appropriate to treat the estimate as not significantly different from the threshold value.

Use of additional criteria is not inconsistent with the operation of an explicit, single threshold value, nor is it inconsistent with much of the literature on social preferences over healthcare resource allocation.[3] However, as we discuss in section 4.2, there are substantive issues concerning the ways in which such additional considerations should be operationalized.

3. Setting the Threshold

There is significant argument about how the cost-effectiveness threshold should be determined. Three broad approaches have been proposed: (i) it should be inferred from previous decisions; (ii) it should be set so as to determine the optimal healthcare budget; and (iii) it should be set so as to exhaust an exogenously determined budget.[4]

3.1 Inferring the Value from Previous Decisions

Rawlins and Culyer[5] and Devlin and Parkin[6] made two attempts to infer NICE's cost-effectiveness threshold from reviews of previous decisions. The former was an essentially qualitative analysis,

whilst the latter treated NICE decisions as discrete choice experiments.

Rawlins and Culyer[5] identified an increasing likelihood of rejection as the ICER increased beyond £15 000, with few interventions being approved with an ICER >£30 000 (figure 1). Devlin and Parkin,[6] in contrast, estimated the threshold to be "somewhat higher than the £20,000 – £30,000 which NICE has publicly identified."

There are several problems with basing the current threshold on previous decisions. First, it is not necessarily desirable for current decisions to use the same decision rule as for previous ones; consistency of decision rule (the cost-effectiveness threshold) can conflict with consistency of objective (maximizing expected health gain). We discuss in more detail why the threshold might change over time in section 4. Second, this approach requires that previous decisions either took no account of any 'other' considerations or that any such consideration was judged not sufficient to have an impact on the decision, otherwise the linking of particular ICERs to a particular threshold value will have (largely unknowable) biases.

3.2 Setting to Determine the Optimal Healthcare Budget

Some have suggested that the appropriate process is to identify the marginal value that society attaches to health.[7] NICE itself has promoted two research projects to examine what value people in the UK attach to an additional QALY. If the cost-effectiveness threshold were set by such an empirically re-
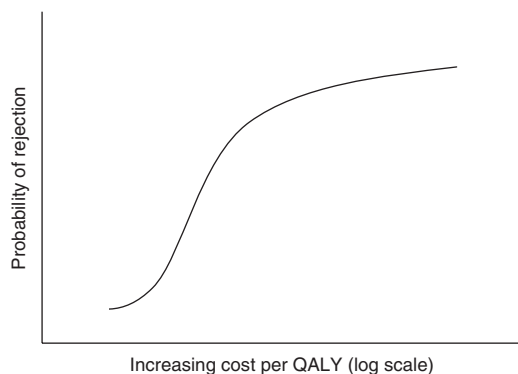

Fig. 1. Relationship between cost effectiveness and probability of rejection (reproduced from Rawlins and Culyer[5]).

vealed monetary value, the implication is that interventions having an ICER below that value should be approved. The healthcare budget would then be whatever sum was required to implement the purchases. Setting the threshold would thus effectively determine the NHS's budget.[8] The budget would be demonstrably consistent with the value that 'society' attached to health, and the state would be committed to increase the budget so long as the ICERs for new interventions fell below the threshold.

Three approaches have been suggested for quantifying the marginal value of health: (i) discovering the willingness to pay for health gain of a representative sample of society;[7] (ii) using the value of life/health employed in other areas of public sector resource allocation;[9] and (iii) setting it equal to GDP per capita.[10]

If there was a direct link between society's willingness to pay for health gain and the budget of the healthcare system, setting the threshold with reference to it would seem appropriate. However, in the UK, as in many other countries, the budget of the healthcare system is determined in large part by parliament and is done (doubtless imperfectly) by broad assessments of the marginal value of extensions of a wide variety of public programmes and of the value of purchasing power left in the pockets of consumers. The budget allocated to healthcare by parliament, therefore, already contains an implicit value of marginal health gain (MHG) – relative to alternative uses of public funds. It is difficult to see how experimental methods for revealing the social value of a QALY could capture these opportunity costs more effectively (or more legitimately) than parliament. To substitute the 'direct democracy' of public opinion for a parliamentary process plainly also raises constitutional issues well beyond the scope of this article.

The healthcare system is not the only area of public policy concerned with promoting health. For example, transport investment decisions typically take account of the expected impact on injury and death rates when appraising road building schemes. It is therefore intuitively appealing that the value of health ought to be consistent across public sector activities. Loomes[9] has suggested that the cost-effectiveness threshold should be set at a level con-

sistent with the value attached to a life in other parts of the public sector. Whilst health and life are the primary (although not sole) objectives of the NHS, they are not the primary objectives of other public sector activities. The budgets allocated to these different activities by parliament imply a relative valuation of these objectives as well as the impact on health and length of life. It would be a major task to isolate the 'health component' in these other activities. Currently, only transport uses an explicit value and, as one of the authors of this briefing paper has previously observed, "NICE simply does not have (and nor is it mandated to acquire) the kind of information about outputs in non-health sectors that it would need to form necessary judgements about the marginal costs and benefits of health spending versus spending in other areas of public services."[4] Thus, although it may be intuitively appealing, it is not feasible for the threshold to be set (by NICE) by reference to other public sector activities.

Williams[10] suggested that a 'common sense' value for the threshold would be per capita GDP. At the time of lecture, this was somewhat lower than the bottom of the threshold range used by NICE. The appeal of this proposal is that, if every member of society were to be given a 'fair share' of a nation's wealth, they would receive the per capita GDP. The maximum they could therefore spend on health gain in any one year would be the per capita GDP. Three significant problems present themselves. First, the approach implies that the society might be willing to devote all its wealth to healthcare, which is manifestly not the case. Second, the same thought experiment will yield the same 'maximum' for *any* good or service in GDP and so provides no basis whatever for choosing between any of them. Third, the *average* cost effectiveness of healthcare can be at or below per capita GDP with the cost effectiveness of *marginal* programmes being markedly higher thanks to diminishing marginal returns. NICE has to establish whether a new intervention is more cost effective than the marginal interventions that would have to be displaced in order to pay for it from a constant budget. Use of an arbitrary average risks rejecting interventions that were more cost effective than those already provided.

3.3 Setting to Optimally Exhaust a Budget

From the beginning, NICE's use of cost-effectiveness analysis has been perceived as a means of promoting the efficient use of available NHS resources.[11,12] The cost-effectiveness threshold ought thus to be the cost per QALY of the least efficient funded treatment (i.e. the intervention with the highest cost per QALY). For a new intervention to add to health, it must be more efficient per unit of resource than the least efficient currently funded intervention and ought to displace it, in whole or part, so that the marginal productivity of each intervention in terms of health was everywhere equalized. Here too, however, is another evident informational challenge. If identifying the marginal interventions for disinvestment is too difficult, the threshold requires an alternative justification.[12] Here, we need to tread with care. On the one hand, there is an issue of principle: what the threshold ought to represent, a value judgement; and on the other, an empirical question: the value it should take in any specific context.

In figure 2, the range of technologies in O–E embodies those extant and provided in the NHS. Let us assume that all provide positive MHG and that the least productive one has an MHG of E–a. However, 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, labelled c–f. A composite MHG curve is the horizontal sum of the two lines, H–d–e, which combines all
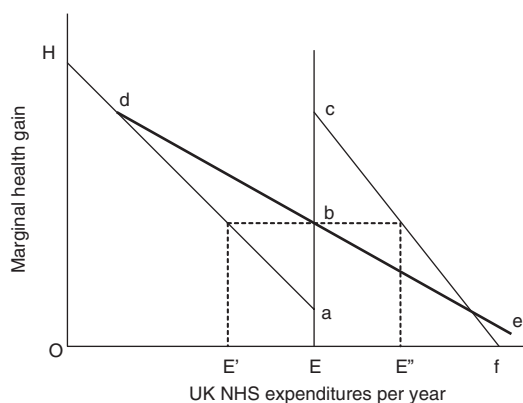
available technologies: those in use as well as those that could be used but are not, ordered by contribution to health gain.

It is immediately apparent that NICE confronts three potentially interesting MHGs, the size of none of which it can be sure. E–a 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 resources are used. E–c is the health gain to be achieved from adopting the best technology not currently in use in the NHS. E–b 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 an MHG above E–b would represent an increase in health outcomes as long as it displaces a technology with a lower MHG (in the range E'–E). The optimal solution is plainly to cease using all those technologies in the range E'–E on H–a and substitute for them all those in the range E–E" (= E'–E) on c–f.

If the function of NICE is to substitute more efficient interventions for less efficient ones, it can do this through specifying a 'working' cost-effectiveness threshold, reflecting the Institute's estimate of the ICER of the least cost-effective activity undertaken by the NHS. This working estimate can be drawn from (i) the incomplete evidence base on the cost effectiveness of interventions that the NHS does provide; and (ii) stakeholders' personal and professional knowledge of the likely value of funded interventions, for which formal evaluations are not available.[1,8] Over time, this 'working' ICER can be adjusted in a casuistical fashion reflecting developments in the published evidence base and evidence on the efficiency of disinvestments made to fund the recommended interventions, and changes in the healthcare budget and in judgments about the efficiency of healthcare production.

Although the 'threshold-searcher' model of Culyer et al.[8] describes how resource allocation processes can utilize ICERs for healthcare resource allocation decisions at the margin, the authors did not address the frequently cited criticisms of Birch and Gafni,[13-16] who have repeatedly argued that decision makers cannot maximize health gain from limited resources by using ICERs in isolation from information on budget impact. To do so, they say, is

Fig. 2. The National Institute for Health and Clinical Excellence as a threshold searcher (reproduced from Culyer et al.,[8] with permission).

a recipe for "continued expansion of expenditure."[13-16] Their argument is that the opportunity cost of a positive decision is determined by the total budgetary impact, not the ICER. It is possible for the total budget for an existing health intervention to be less than that for the new intervention even though the new intervention has a lower ICER. If the new intervention is mandated on the basis of the ICER alone, then extra funds would need to be found.[14]

3.4 Relationship with Budget Impact

The threshold-searcher model[8] can be used to explore the relationship between budget impact and the cost-effectiveness threshold. The threshold is the inverse of the MHG per unit of expenditure of the least efficient intervention in current use. In figure 2, the substitution of a more for a less efficient intervention causes the MHG of the least efficient intervention to rise. Thus, in figure 2, after the process of substituting more efficient technologies for less efficient ones, the MHG is E–b. Future interventions will have to have an MHG ≥E–b, rather than E–a, to justify incorporation into the portfolio of funded treatments. As a result, the threshold for future decisions decreases. The next candidate intervention will need to be even more efficient in order to justify its inclusion as a funded intervention. This is the case even if the budget impact of the substitution is neutral, i.e. when the budget impact of the new intervention is identical to the budget impact of the displaced intervention. Thus, the cost-effectiveness threshold is, as a matter of logic, endogenous once one allows for dynamic interactions, even though, in an overall sense, it is constrained by the budget determined by parliament.

To the extent that the total cost of the new intervention is greater than that of the procedure it replaces, a positive recommendation requires more disinvestment until the budgetary impact of successive substitutions is neutral and the budget constraint holds. This means that the cost-effectiveness threshold for an intervention with a large budgetary impact should be lower than that for an intervention with a small impact (i.e. because the lower the threshold the higher the MHG; and when the greater the budget impact, the greater the amount of current activity that has to be displaced to fund the new technology and therefore more efficient current

technologies will have to be displaced). In this way, allocation processes based on a cost-effectiveness threshold can fully capture the opportunity cost of both positive and negative investment recommendations.

The rate of change in the productivity of healthcare also matters. Thus, when productivity is rising through the use of relatively efficient technologies, the substitution of generics for branded products, and so on, the health production function is displaced upwards (i.e. greater returns in health are obtained from healthcare inputs). As the budget increases, the cost-effectiveness threshold should also increase, i.e. less efficient interventions should be incorporated into the portfolio of treatments provided by the NHS, provided that the productivity of existing healthcare activities grows at a slower rate than the budget (in figure 2, an expansion in the budget is represented as an extension of the line H–a to the right – the MHG of the least efficient intervention that can be funded is lower the further to the right you go and thus the threshold is higher). In times of rapid expansion of the NHS budget, such as have been seen over the past 7 years, the countervailing effects of the implementation of new treatments and increases in the budget may have made the adoption of a cost-effectiveness range a (fortuitously) appropriate approach. Conversely, when budgetary growth is less than the net budget impact of investment and disinvestment decisions, the cost-effectiveness threshold should fall to reflect the increased efficiency of the marginal intervention. These relative rates of growth of the budget and productivity of healthcare also have implications, which do not concern us here, for discounting.[17]

3.5 Summary

The budget of the NHS is set by parliament. NICE is charged "to appraise the clinical benefits and 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 as to whether, on balance, this intervention can be recommended as a cost effective use of NHS and Personal and Social Services (PSS) resources."[18] It is clear that NICE is not mandated to determine the budget of the NHS, and since setting a threshold independently of the budget is logically equivalent

to determining the budget, NICE cannot be mandated to do that either. The appropriate approach to NICE's cost-effectiveness threshold is therefore to see it as an equilibrating variable that promotes the efficient (health maximizing) use of a fixed budget.

## 4. Implications of Setting the Threshold to Optimally Exhaust a Fixed Budget

4.1 Considering Innovation

Figure 3[19] shows the total health gain to the NHS population under three scenarios. Consider an intervention costing £20 000 per patient for a health gain of 2 QALYs. At this price, the ICER is below the cost-effectiveness threshold and the net health benefit of the intervention is 1 QALY per person. At a price of £40 000 and 2 QALYs gained, the ICER is exactly equal to the threshold, and at this point, the net benefit from the new intervention is zero, the loss of health from displaced technologies being the same as the gain.

However, if the new treatment is more effective than existing treatments, setting the price at a level that produces an ICER equal to the cost-effective-

ness threshold implies that the full value of the innovation (greater efficacy) is captured by the manufacturer. As the manufacturers are typically profit maximizers, they will seek to price as close to this point as possible. Strictly, what is happening is that the cost-effectiveness information is information not previously available to manufacturers about the maximum willingness to pay of the demanders and makes the task of perfect price discrimination, or the use of an 'all-or-nothing' demand curve, more readily achievable by producers.[20]

While it is appropriate for manufacturers to appropriate a share of the value of innovations, it would be unwise to create a system under which they extract it all. The public sector subsidises R&D in a number of ways, through publicly funded research, tax incentives and research infrastructure investment. Therefore, even if society were unconcerned about who benefits from innovation (NHS patients or the pharmaceutical industry), it would not be efficient to allow full appropriation of the value of innovation by the manufacturer. However, society is most certainly concerned about this distribution, and it is reasonable that at least some of the benefits of innovation should accrue to NHS pa-
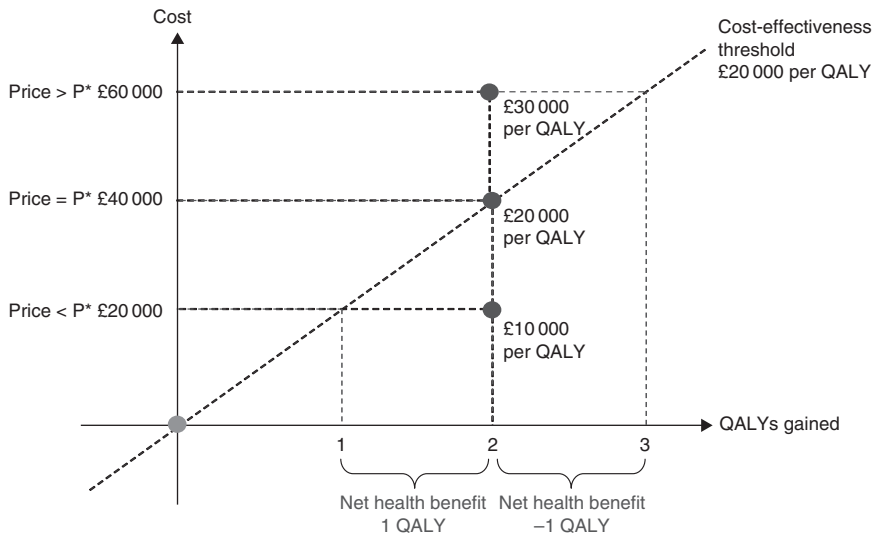
Fig. 3. Threshold and health gain (reproduced from Claxton et al.[19]). **P*** = maximum price the NHS can afford or the value of the technology.

tients. In pharmaceuticals, as in other industries where innovation is protected, society currently permits monopoly rents during patent protection, but does not allow full appropriation by, for example, facilitating perfect price discrimination.

Such concerns as this are somewhat tangential to those of the Institute. However, of direct relevance for NICE is the use of innovation as an argument for recommending interventions having ICERs above the threshold. When the ICER is close to, or at, the threshold value, the full value of the innovation is already being paid to the manufacturer. To recommend an intervention when the ICER is above the threshold is to pay more for the innovation than it is worth (in terms of the population's health). Promoting population health is consistent only with recommending treatments with ICERs that are below the threshold. It seems inappropriate for NICE to seek to honour its obligations to promote innovation through such a subsidy and at possible cost to NHS patients. NICE's contribution to innovation is more likely to be realized effectively through clarity and consistency in the criteria that it uses to make its recommendations. The ultimate benefit is to bring the desire of the NHS to use interventions that are no more costly than they need be into the research plans of manufacturers, so that the market is not disrupted by unforeseen changes in requirements and innovation is of the sort that maximizes and properly rewards industry's contribution to the nation's health.

4.2 Equity Arguments

The threshold represents the opportunity cost of the implementation, i.e. the health gain forgone by other patients. While the threshold is critical to the determination of the most efficient (i.e. health maximizing) use of NHS resources, the Appraisal Committee also considers whether there is any ground in equity for weighting the health gains and losses of different people differentially or for recommending technologies with relatively high ICERs on grounds of their beneficial impact on equity.[1]

While efficiency, in the sense of health maximization, is a major concern of NICE's Appraisal Committee, it is not the only one; nor, indeed, is it possible to identify efficiency without making assumptions about the relative value of additional QALYs to different people. Interpersonal comparisons are therefore inherent in the process of establishing efficiency.[21] An important further consideration relates to the wider opportunity cost of Appraisal Committee decisions. When the threshold is being used to allocate a fixed budget, there is not one category of patient interest but two: those patients who would receive the new treatment or some alternative and those patients who bear the opportunity cost of its provision (i.e. those whose service availability is reduced by virtue of the expenditure on the new treatment).

We have already observed that NICE does not know, and probably can not know, which patients bear the opportunity cost of its appraisal guidance. If NICE recommends an intervention on equity grounds, it necessarily has to make assumptions about the characteristics of those patients who bear the opportunity cost. Specifically, in making a positive recommendation, it must assume that the health gain forgone by those who bear the opportunity cost is valued less than that of those who receive the benefit.

Procedural justice would seem to require that the character of the claims of the anonymous bearers of the opportunity cost be properly considered in NICE appraisals. In particular, when claims are made by advocacy and other groups about the special nature, need, etc., of the people they represent, NICE must do their best to assess the extent to which these claims carry greater weight than the claims that could be made by those bearing the opportunity cost. Given the typical pattern of NHS expenditure, the typical bearer of the opportunity cost is, for example, likely to be elderly and in the last year of life. It does not therefore appear intuitively plausible to suppose that the weight to be attached to beneficiaries' health gains must necessarily be higher than that attached to the anonymous losers. Plainly this is an area in which information is poor and broad generalizations will, for some time, have to substitute for more specific identification of the characteristics of 'typical' displaced health gain. The matter is ripe for research.

4.3 Monitoring and Recommending Disinvestment

The 2004 *Methods Guide* avoids defining an explicit threshold on the grounds that the correct figure cannot be known. However, both the previously suggested casuistry (building up of specific cases) and the threshold searching model imply that it may be reasonable for NICE to utilize explicit thresholds that might converge over time on a 'best estimate'. A crucial part of this search process would be the identification of activities for disinvestment or, when there is budgetary growth, to identify other planned investments that ought to be abandoned in order to fund NICE recommendations.

There has been little research on either selecting or implementing disinvestments in the NHS. NICE has commissioned research from Brunel and City Universities, which is yet to be published.[22] Should it turn out that actual disinvestments have tended to be more cost effective than the NICE recommended interventions, there would be *prima facie* evidence for supposing either that the current threshold is too high or that NHS trusts and commissioners were making poor decisions at their levels. Discovering which the case was would plainly be an important piece of work. However, it will not be easy to discover. Local commissioners' choices will be determined by several factors, including their total budgets, cost structures, the case mixes of the populations they serve and even the ease of implementation. As these factors vary across Primary Care Trusts (PCTs), the threshold is also likely to vary by PCT, and therefore whether NICE appraisal guidance has a positive or negative impact on the efficiency of local healthcare will also vary by PCT.

Martin et al.[23] examined the actual changes in programme budgets and health across PCTs and estimated the average budget elasticity of health, that is, the proportionate changes in health resulting from marginal changes to programme budgets. They provided empirical estimates of the cost-effectiveness threshold expressed as life-years gained. They reported a range from £7397 for respiratory problems to £26 453 for diabetes mellitus (year 2005–6 values). The threshold estimates for cancer and circulation problems were £13 931 and £8426, respectively. These figures need to be interpreted with

some care as they take no account of the many interventions that impact on quality of life rather than survival. This said, the results are consistent with a central estimate across all programme budgets around the lower limit of the current range.

The variation in thresholds between programme budgets has implications for NICE. It implies that the opportunity cost of a NICE recommendation also varies depending upon where it falls, so it may be efficient or inefficient dependent on local circumstance. The risk of NICE guidance being inefficient will depend *inter alia* on (i) the degree to which national resource allocation captures geographical variation in health needs; (ii) the degree to which local resource allocation processes reflect variations in health needs between patient groups; and (iii) whether the technology appraisal programme is focussed on those areas with the greatest potential for increasing the efficiency of NHS activity. Local commissioners will almost certainly need guidance on how best to identify and then manage disinvestments and postponement of planned investments following NICE recommendations. It seems obvious that the criteria they use ought not to conflict with those used by NICE (though doubtless supplemented by further criteria).

Culyer et al.[8] suggested that NICE should actively make both disinvestment and investment recommendations. The Institute has started to explore this possibility.[24] External organizations have also started to recommend that the NHS, via NICE or other routes, should disinvest from activities not having a robust evidence base.[25] Most recently, the House of Commons Select Committee recommended that NICE should appraise potential candidates for disinvestment, commenting that it was unacceptable that the Institute had ignored the Committee's earlier recommendation to this effect.[26] Unfortunately, the catalogue of procedures for which the evidence base is poor or absent is very long and, where there is advantage to be had from disinvestment, it is unlikely to be the case that the scale of disinvestment required entails the entire elimination of a procedure. So the task of specifying disinvestment guidance is by no means easy.

The use of a cost-effectiveness threshold is, at its core, about matching investment and disinvestment to increase the total health produce by the health

service. To date, NICE has focussed its efforts on investment. Knowing what in fact is disinvested from can provide some insight into whether, on average, NICE appraisal guidance is improving the efficiency of the NHS. In the future, a programme of disinvestment guidance, to balance the investment guidance, might give the public and the NHS greater confidence that the net benefit of the NICE Appraisal Programme was positive.

5. The Changing Threshold

The Chair of NICE recently observed that the current threshold range has been utilized for 7 years and noted that the methods review process would need to consider whether the range should change or remain the same.[27]

5.1 Empirical Estimation

The House of Commons Health Committee thought that the choice of threshold was "of serious concern."[26] The grounds for this concern were that, "it is not based on empirical research and is not directly related to the NHS budget. It seems to be higher than the threshold used by PCTs for treatments not assessed by NICE."[26]

The Institute's response to the Health Committee's comments identified 17 technology appraisals that had produced costs savings and stressed that most of the recommendations from the clinical guidelines programme – if implemented – would save the NHS money.[28] It went on to highlight the range of knowledge-promotion activities it is pursuing to promote efficiency in clinical practice and commissioning. Whilst these are important and valuable activities, it would seem appropriate, given the mandatory nature of guidance from the Technology Appraisal Programme, that the value of the threshold gives the NHS and the people it serves confidence that the opportunity cost of the programme is less than the value of the health gain it produces.

5.2 Should the Threshold Change?

A disadvantage of using a moving/converging threshold, or one that was subject to periodic adjustment, is that it would evidently introduce an additional uncertainty and provide a less secure environment for industrial innovation. Whether this additional source of uncertainty would be significant, given all the other major uncertainties facing industry (such as the high failure rates in phase III drug development), is unclear. Current pricing arrangements allow companies to amortize the cost of these failures through the price of future successes, so the system may even encourage unnecessarily high-risk investments. Changes in the threshold could be used to signal to the pharmaceutical industry and others the changes in the efficiency in the NHS that the Institute was established to promote, and allow the industry to incorporate these changes into its investment appraisal processes. This in turn would reduce the risk of treatments coming to market that did not deliver sufficient additional health gain to justify the price consistent with an acceptable return on investment. What would also help would be the wide promulgation of the principles upon which changes in the threshold would be made, thus enabling future changes to be anticipated.

The empirical evidence of Martin et al.[23] indicated that even the lower end of the current cost-effectiveness range may be too high and likely to lead to less efficient treatments being implemented at the cost of more efficient ones. The Select Committee report observes that the current threshold is higher than the ICER used by PCTs in their commissioning processes.[26] Thus, there is a *prima facie* case for considering reducing the threshold. However, it maybe premature to substantially change the threshold on the basis of the current narrow range of studies.

The efficiency of NICE guidance may be promoted without changing the threshold. The 2004 *Methods Guide* indicated that £20 000 is the threshold at which criteria other than the ICER come into play. A substantial proportion of the treatments approved by NICE have been in this range. Modifying the utilization of these 'other factors' in line with the arguments we have set out would have the effect of strengthening the lower bound of the current range as the effective threshold, and thus promote the efficiency of future NICE guidance.

6. Conclusions

The incremental cost-effectiveness threshold, as used by NICE, is a means for promoting the optimum allocation of a fixed budget. It is not necessari-

ly an expression of society's willingness to pay for health. Using the threshold-searcher model described by Culyer et al.[8] to explore the implications of this, we conclude the following:

1. It is feasible and probably desirable to operate an explicit single threshold rather than the current range.

2. The threshold should be seen as a threshold at which 'other' criteria are taken into account beyond the ICER itself.

3. Interventions with a large budgetary impact may need to be subject to a lower threshold as they are likely to displace more than the marginal activities.

4. Reimbursement at the threshold transfers the full value of an innovation to the manufacturer. Positive decisions above the threshold on the grounds of innovation reduce population health.

5. The value of the threshold should be reconsidered regularly to ensure that it captures the impact of changes in efficiency and budget over time.

6. The use of equity weights to sustain a positive recommendation when the ICER is above the threshold requires knowledge of the equity characteristics of those patients who bear the opportunity cost. Given the barriers to obtaining this knowledge and knowledge about the characteristics of typical beneficiaries of NHS care, caution is warranted before accepting claims from special pleaders.

7. Uncertainty in the evidence base should not be used to justify a positive recommendation when the ICER is above the threshold.

8. The development of a programme of disinvestment guidance would enable the Institute and the NHS to be more confident that the net health benefit of the Technology Appraisal Programme was positive.

Acknowledgements

References

1. NICE guide to the methods of health technology appraisal. London: NICE, 2004
2. The use of thresholds: discussion. In: Towse A, Pritchard C, Devlin N, editors. Cost effectiveness thresholds: economic and ethical issues. London: King's Fund and Office of Health Economics, 2002: 38
3. Dolan P, Shaw R, Tsuchiya A, et al. QALY maximisation and people's preferences: a methodological review of the literature. Health Economics 2005 Feb; 14 (2): 197-208
4. Culyer AJ. Introduction. In: Towse A, Pritchard C, Devlin N, editors. Cost effectiveness thresholds: economic and ethical issues. London: King's Fund and Office of Health Economics, 2002: 9-15
5. Rawlins MD, Culyer AJ. National Institute for Clinical Excellence and its value judgements. BMJ 2004; 329: 224-7
6. Devlin N, Parkin D. Does NICE have a cost effectiveness threshold and what other factors influence its decisions? A binary choice analysis. Health Econ 2004; 13: 437-52
7. Smith RD, Richardson J. Can we estimate the 'social value' of a QALY? Four core issues to resolve. Health Policy 2005; 74 (1): 77-84
8. Culyer AJ, McCabe CJ, Briggs AH, et al. Searching for a threshold not setting one: the role of the National Institute for Health and Clinical Excellence. J Health Serv Res Policy 2007 12; 1: 56-8
9. Loomes G. Valuing life years and QALYs: transferability and convertibility of values across the UK public sector. In: Towse A, Pritchard C, Devlin N, editors. Cost effectiveness thresholds: economic and ethical issues. London: King's Fund and Office of Health Economics, 2002: 46-55
10. Williams A. What could be nicer than NICE? London: Office of Health Economics, 2004
11. Hutton J, Maynard A. A NICE challenge for health economics. Health Econ 2000; 8: 89-93
12. Devlin N. An introduction to the use of cost effectiveness issues in decision making: what are the issues? In: Towse A, Pritchard C, Devlin N, editors. Cost effectiveness thresholds: economic and ethical issues. London: King's Fund and Office of Health Economics, 2002: 16-25
13. Birch S, Gafni A. Cost effectiveness/utility analyses: do current decision rules lead us to where we want to be? J Health Econ 1992; 11: 279-96
14. Gafni A, Birch S. Guidelines for the adoption of new technologies: a prescription for uncontrolled growth in expenditures and how to avoid the problem. CMAJ 1993; 148: 913-7
15. Birch S, Gafni A. On being NICE in the UK: guidelines for technology appraisal for the NHS in England and Wales. Health Econ 2002; 11 (3): 185-91
16. Sendi P, Gafni A, Birch S. Opportunity costs and uncertainty in the economic evaluation of health care interventions. Health Econ 2002; 11: 23-31
17. Claxton K, Culyer AJ, Sculpher M, et al. Discounting and cost effectiveness in NICE: stepping back to sort out a confusion [editorial]. Health Econ 2006; 15 (1): 1-4
18. National Institute for Health and Clinical Excellence. Framework document [online]. Available from URL: http://www.nice.org.uk/NICEmedia/pdf/appendixB_framework.pdf [Accessed 2008 Jul 18]
19. Claxton K, Briggs A, Buxton MJ, et al. Value based pricing for NHS drugs: an opportunity not to be missed? BMJ 2008 Feb; 336: 251-4

20. Friedman M. Lectures in price theory. Chicago (IL): Aldine, 1971

21. Culyer AJ. The bogus conflict between efficiency and equity. Health Econ 2006; 15: 1155-8

22. Appleby J, Devlin N, Parkin D, et al. Searching for local NHS cost effectiveness thresholds: a feasibility study. NICE conference; Manchester; 2007 Dec 5-6 [online]. Available from URL: http://www.nice2007.co.uk/ApplebyDevlin.pdf [Accessed 2008 Jul 17]

23. Martin S, Rice N, Smith P. Further evidence on the link between health care spending and health outcomes in England [CHE discussion paper 32]. York: University of York, 2007

24. National Institute for Health and Clinical Excellence. NICE launches commissioning guides as part of an initiative to help NHS reduce spend on ineffective treatments [online]. Available from URL: http://www.nice.org.uk/newsevents/infocus/nice_launches_commissioning_guides_as_part_of_an_initiative_to_help_nhs_reduce_spending_on_ineffective_treatments.jsp [Accessed 2008 Jul 17]

25. Association of Directors of Public Health. Letter from the President: patient charges for treatment. ADPH 2007 Jan [online]. Available from URL: http://www.adph.org.uk/press_releases/20070131.php?PHPSESSID=1jftq9htaji5qglme2i3a01nlh5 [Accessed 2008 Jul 17]

26. House of Commons Health Committee. National Institute for Health and Clinical Excellence: first report of session 2007-08. Vol. 1. London: The Stationary Office, 2008 Jan

27. Rawlins M. The future for NICE (National Institute for Health and Clinical Excellence). Pharm J 2007; 278 (7452): 589

28. National Institute for Health and Clinical Excellence. NICE response to the committee's first report of the session 2007-2008 HSC 550. London: The Stationary Office, 2008 Jun

Correspondence: Professor *Christopher McCabe*, Academic Unit of Health Economics, Leeds Institute of Health Sciences, University of Leeds, Charles Thackrah Building, 101 Clarendon Rd, Leeds, LS2 9LJ, UK.
E-mail: c.mccabe@leeds.ac.uk