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# Education and debate

## National Institute for Clinical Excellence and its value judgments

Michael D Rawlins, Anthony J Culyer

NICE has to make both scientific and social value judgments when appraising health technologies and developing clinical guidelines for the NHS. Here, its chair and previous vice chair explain the rationale behind the decisions

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The National Institute for Clinical Excellence (NICE) offers health professionals in England and Wales advice on providing NHS patients with the highest attainable standards of care.<sup>1</sup> NICE gives guidance on individual health technologies, the management of specific conditions, and the safety and efficacy of interventional diagnostic and therapeutic procedures. Guidance is based on the best available evidence. The evidence may not, however, be very good and is rarely complete. Those responsible for formulating the NICE's advice therefore have to make judgments both about what is good and bad in the available science (scientific value judgments) and about what is good for society (social value judgments). In this article we focus on the scientific and social judgments forming the crux of the institute's assessment of cost effectiveness. Scientific value judgments and those relating to clinical effectiveness are considered elsewhere.<sup>2</sup>

### NICE's approach to economic evaluation

On its own, clinical effectiveness is insufficient for maintaining or introducing any clinical procedure or process. Cost must also be taken into account. When good evidence exists of the therapeutic equivalence between two or more clinical management strategies, the cheaper option is preferred (box 1).

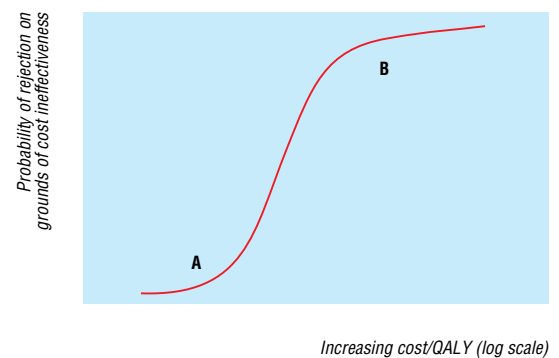
#### Incremental cost effectiveness ratio

However, in most instances NICE is confronted with a clinical management strategy that is better than

#### Box 1: Cost minimisation

Oral and intravenous fludarabine are equivalent as second line treatments for chronic lymphatic leukaemia.<sup>3</sup>

The total (acquisition plus administration) costs over four cycles are £3000 (£2700+£300) for oral administration and £5300 (£2700+£2600) for intravenous administration. Thus using oral fludarabine rather than intravenous saves £2300 over four cycles and the oral formulation is preferred.



Relation between likelihood of a technology being considered as cost ineffective plotted against the log of the incremental cost effectiveness ratio

current standard practice but which costs more. NICE must then decide what increase in health (compared with standard practice) is likely to accrue from the increase in expenditure. This is the incremental cost effectiveness ratio. Such ratios can be expressed in many ways. NICE's preferred measure is the cost per quality adjusted life year (QALY), but if appropriate data on quality of life are not available, it uses alternatives such as the cost per life year gained.

NICE rejects the use of an absolute threshold for judging the level of acceptability of a technology in the NHS for four reasons:

- There is no empirical basis for deciding at what value a threshold should be set
- There may be circumstances in which NICE would want to ignore a threshold
- To set a threshold would imply that efficiency has absolute priority over other objectives (particularly fairness)
- Many of the technology supply industries are monopolies, and a threshold would discourage price competition.

Rather than apply an arbitrary threshold, NICE makes its decisions on a case by case basis, as shown stylistically in the figure. As the incremental cost effectiveness ratio increases, the likelihood of rejection on grounds of cost ineffectiveness rises. The critical issues

**Box 2: Cost ineffectiveness****Anakinra for rheumatoid arthritis**

Anakinra seems to be less effective than etanercept or infliximab for rheumatoid arthritis.<sup>8</sup> It costs £7450/year for each patient. The incremental cost effectiveness ratio for anakinra is estimated to be £69 000/QALY for rheumatoid arthritis, which is an unacceptable opportunity cost.

**Interferon beta and glatiramer acetate for multiple sclerosis**

Interferon beta and glatiramer acetate reduce the frequency and severity of relapse in relapsing-remitting multiple sclerosis.<sup>9</sup> The mid-range estimates of the incremental cost effectiveness ratios (£/QALY) depend on the time horizon examined:

- 5 years = £580 000
- 10 years = £308 000
- 20 years = £70 000

The opportunity costs for each of these scenarios are unacceptable.

**Box 3: Cost effectiveness**

Imatinib is licensed for the treatment of chronic myeloid leukaemia in the chronic phase (after failure of interferon alfa)<sup>10</sup> and in the accelerated and blast crisis phases (for those not treated earlier with imatinib).

The mid range estimates of the incremental cost effectiveness ratios (£/QALY) are:

- 37 000 for the chronic phase
- 38 400 for the accelerated phase
- 49 000 for the blast crisis phase.

In the absence of any effective alternative treatment (apart from bone marrow transplantation) imatinib was considered to be cost effective in the chronic phase after interferon alfa. Denial of imatinib in the accelerated phase was considered to be inconsistent because the ratio was similar to that for the chronic phase.

Denial of imatinib to patients in the blast cell phase was considered unfair. Patients at this advanced stage could reasonably have expected, in view of the decisions made already, to have had the opportunity of treatment with imatinib at an earlier stage of their condition. The fact that they were not given this chance would have been due to failings in the healthcare system. On grounds of equity, therefore, it was considered that imatinib should be available to patients in the blast cell phase of chronic myeloid leukaemia who had not previously been treated with the drug.

are the values of incremental cost effectiveness ratios at inflexions A and B.<sup>4-6</sup> Clinical management pathways with ratios to the left of A would generally be regarded as cost effective. Those with ratios to the right of B would, if adopted, be likely to deny other patients (with different conditions) access to more cost effective treatments.

There is no empirical basis for assigning particular values to A or B,<sup>7</sup> but NICE and its advisory bodies have taken the view that inflexion A occurs at around £5000-£15 000/QALY and inflexion B at around £25 000-£35 000/QALY. NICE would be unlikely to reject a technology with a ratio in the range of £5000-£15 000/QALY solely on the grounds of cost ineffectiveness but would need special reasons for accepting technologies with ratios over £25 000-£35 000/QALY as cost effective. The main considerations in making judgments about cost effectiveness for ratios of £25 000-£35 000/QALY are:

- The degree of uncertainty surrounding the estimate
- The particular features of the condition and population using the technology
- The innovative nature of the technology
- When appropriate, the wider societal costs and benefits
- When appropriate, reference to previous appraisals.

The phrase "particular features of the condition and the population using the technology" incorporates matters that include the availability and clinical effectiveness of other interventions for the condition, particular public health issues (such as communicable diseases), and special considerations of equity. Boxes 2 and 3 show examples of the application of some of these principles.

Judgments about whether incremental cost effectiveness ratios can be considered "reasonable" are made by the independent members of NICE's advisory committees (particularly the appraisal committee) and the guideline development groups. Membership is drawn from clinicians and health managers working in the NHS, technical experts (statisticians and health economists), and patients or patient advocates.

**Affordability**

NICE does not take affordability into account when making judgments about cost effectiveness. The term is not a technical one, but we use it to mean that a particular activity should be funded by increasing the total funds available for health care rather than from existing resources. This would imply increasing taxation, borrowing on the markets, or diversion of funds from another publicly funded activity. Affordability, in this sense, is a matter for the government when deciding the annual budget for the NHS. It is NICE's job to judge whether something ought to be purchased from within the resources made available to the NHS.

The government could therefore judge a particular intervention unaffordable for the NHS (because of the large numbers who would be eligible for treatment) even though NICE had judged it cost effective. In such circumstances the government could respond in one of two ways: the Department of Health and the Welsh Assembly Government might formally advise the NHS to ignore NICE's advice; alternatively, ministers might invoke one of the clauses in its directions to NICE stating that (in this particular case) it is required to take account of "advice from ministers on available resources." So far, neither of these potential government responses have been proposed or threatened.

**Social value judgments**

Social value judgments have a critical role if resources are to be distributed with efficiency and equity. NICE and its advisory bodies, however, have no particular legitimacy to determine the social values of those served by the NHS. To ensure that these values resonate broadly with the public, NICE has formed a Citizens Council.<sup>11 12</sup>

### Efficiency

A fundamental value judgment is that efficiency in health care involves maximising the health of the population subject to the resources available. The main social value judgments regarding efficiency relate to the measure of health used and to the scope of costs and benefits. NICE uses the QALY as the principal measure of health outcome. This measure embodies the important social value judgment that to count only gains in life expectancy, without considering the quality of the additional life years, omits important dimensions of human welfare.<sup>11</sup> The QALY has the advantage of having been extensively validated in experimental conditions.<sup>13-17</sup> The main value judgments embodied in QALYs are that health related quality of life can reasonably be captured in terms of physical mobility, ability to self care, ability to carry out activities of daily living, absence of pain and discomfort, and absence of anxiety and depression.

NICE believes that, while differential productivity at work should be considered, it ought not be used to disadvantage people who are not in regular paid employment, including children and those who are retired.<sup>11</sup> It needs to explore how best to reflect productivity effects without causing inequity in the ways in which services are allocated.

It is sometimes held that NICE ought to give a higher priority to novel treatments for conditions for which no alternative specific forms of therapy are currently available, or to conditions associated with social stigma such as mental illness or sexually transmitted diseases.<sup>11</sup> These, too, are social value judgments that need to be considered in more detail in the future.

### Equity

Equity lies at the heart of the NHS. Lack of equity (in the form of so called postcode prescribing) was one of the reasons why NICE was established. Much of the philosophical literature on equity is far from being applicable to the real world.<sup>18, 19</sup> NICE has therefore had to make its own judgments. For NICE, equity also refers to fairness in the ways in which the costs and benefits of available care are distributed among all those who use the NHS.<sup>19-21</sup> NICE's recommendations are intended to apply across the whole of England and Wales, regardless of where people live or work. Thus, NICE has made the social value judgment that local variations in cost ought not to result in variations in availability of health care.<sup>11</sup>

Value judgements about equity are often implicit within both clinical and cost effectiveness analyses. An assumption that underlies most of NICE's technology appraisals has been that "a QALY is a QALY is a QALY." By this NICE means that a QALY gained or lost in respect of one disease is equivalent to a QALY gained or lost in respect of another. It also means that the weight given to the gain of a QALY is the same, regardless of how many QALYs have already been enjoyed, how many are in prospect, the age or sex of the beneficiaries, their deservedness, and the extent to which the recipients are deprived in other respects than health. The decision to give no differential weight is the result of a social value judgment that an additional adjusted life year is of equal importance for each person.<sup>12</sup>

### Summary points

NICE exists to give health professionals advice on providing their NHS patients with the highest clinical standards of care

It undertakes its economic assessments using a cost utility approach (cost per quality adjusted life year)

Decisions about cost effectiveness are made on a case by case basis

Judgment is needed to balance the tensions between efficiency and equity

The Citizens Council has also considered how NICE might take account of age in its considerations of clinical and cost effectiveness.<sup>12</sup> The council recommends that age should be taken into account when it is an indicator of either risk or benefit. It does not recommend, though, that NICE should be more generous in its judgments of cost effectiveness merely because of individuals' social roles or age.

### Conclusions

The scientific value judgments made by NICE remain, ultimately, those developed and enunciated by the knowledge, experience, and expertise of the board members and its independent advisory bodies (the appraisal committee, the interventional procedures advisory committee and the guideline development groups). NICE hopes that the NHS's scientific and clinical community will agree with the basis for these judgments. Similarly, it hopes that the social value judgments will resonate acceptably across the whole community.

In the absence of other relevant information, NICE will have to make its own social value judgments and be held accountable for them. Explicit discussion of the key issues will greatly aid in this process. Underlying all the decisions, however, is one fundamental social value judgment: that advice from NICE to the NHS should embody values that are generally held by the population that the NHS serves.

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## Challenges for the National Institute for Clinical Excellence

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So far NICE has focused on evaluating new technologies rather than existing ones. But this approach is creating inflationary pressure that the NHS cannot afford

Even with recent large increases in NHS expenditure, acute funding difficulties continue to emerge. It is essential that a national mechanism to prioritise new and existing technologies is available to inform decision making. The National Institute for Clinical Excellence (NICE) was created to meet this need.<sup>1</sup> However, despite Rawlins and Culyer's essay on consultation and equity,<sup>2</sup> NICE has yet to mature into the efficient prioritisation mechanism that is required to ensure the best use of NHS resources.

### Rationing

Rawlins has stated that there is "no role for NICE in the rationing of treatments to NHS patients."<sup>3</sup> These weasel words belie the inevitability of healthcare rationing, which is ubiquitous in all healthcare systems. Rationing involves depriving patients of care from which they may benefit and which they wish to have<sup>4</sup>; this is inescapably the business of NICE. Indeed, rationing is the inevitable corollary of prioritisation, and NICE must fully inform rationing in the NHS.

The issue is not whether but how to ration. The criteria determining access to care depend on the health

goals society is seeking to achieve. Are we solely interested in efficient use of resources—maximising health from a given budget? Or does society seek efficiency and equity and, if so, is it prepared to sacrifice some efficiency to achieve equity goals? The central nature of NICE as a prioritisation (and hence rationing) body means that four fundamental challenges emerge. These challenges need to be managed carefully and robustly if NICE is to prosper, as we discuss below.

### Restricting access to NHS funding

Currently the role of NICE is too peripheral to the NHS. For instance, the government should make it impossible for the NHS to adopt expensive new technologies until they are approved by NICE. The additional benefits of most technologies are small—for example, taxanes may add only a few more months to life and have adverse side effects for cancer patients. The function of NICE is to reach a consensus about clinical and economic evidence. This does not imply that only cost effective treatments should be funded but that decisions to fund interventions under the NHS should be taken after careful consideration of the best possible information. Such consideration should be done before, not after, the introduction of new technologies.

### Equity and efficiency trade-offs

Society is clearly not concerned only with efficiency and using NHS budgets to maximise improvements in population health. The NHS, in its usual fragmented and implicit way, illustrates different value systems—for example, by investing "inefficiently" in low birthweight babies because our society values highly the lives of the newly born. In some cases NICE has also operated a rule of rescue approach to its recommendations rather than one based solely on effectiveness or cost effectiveness.<sup>5</sup>

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