

**National Institute for Health and Clinical
Excellence**

SOCIAL VALUE JUDGEMENTS

**Principles for the development of NICE
guidance**

Thursday 8th December 2005

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Preface

These guidelines have been produced to help the Institute and its advisory bodies in developing NICE guidance. It is a 'living document' that will be updated to reflect developments within the academic world, the work of the Citizens Council, and the Institute's own emerging experience as it continues to develop guidance for the NHS and the wider public health community.

The guidelines will be formally reviewed in 2007 but earlier if the need arises. At that time we anticipate that important additional areas will be incorporated. These include the problem of comorbidity, the so-called "rule of rescue", approaches to the trade-off between risk and benefit within the interventional procedures programme, and the question of how NICE should approach the requirement to foster innovation. In addition, future editions will examine the social value judgements that should inform NICE's public health guidance.

Summary of principles

These guidelines describe the social value judgements that should, generally, be incorporated into the processes used to develop NICE guidance and be applied when preparing individual items of NICE guidance. The Institute recognises, however, that there will be circumstances when – for valid reasons – departures from these general principles are appropriate. When departures from these principles are made, the reasons should be explained (section 1.2).

Principle 1

The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance (section 3.3).

Principle 2

For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations (sections 4.1 and 6.1).

Principle 3

NICE guidance should not support the use of interventions¹ for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached (section 4.1).

Principle 4

In the economic evaluation of particular interventions, cost–utility analysis is necessary but should not be the sole basis for decisions on cost effectiveness (section 4.1).

Principle 5

NICE guidance should explain, explicitly, reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio in excess of £20,000 to £30,000 per QALY (section 4.3).

Principle 6

NICE clinical guidance should only recommend the use of a therapeutic or preventive intervention for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups that cannot be identified by any other means (section 5.1).

¹ The term ‘intervention’ is used in these guidelines to encompass health technologies and any other measure used to influence the course of a particular condition.

Principle 7

In setting priorities there is no case for the Institute or its advisory bodies to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of preventative or therapeutic interventions (section 5.2).

Principle 8

In developing clinical guidance for the NHS, no priority should be given based on individuals' income, social class or position in life and individuals' social roles, at different ages, when considering cost effectiveness. Nevertheless, in developing its approach to public health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status (section 5.3).

Principle 9

NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention that cannot be identified by any other means (section 5.4).

Principle 10

NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account (section 5.5).

Principle 11

Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective (section 5.6).

Principle 12

It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance (section 5.7).

The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures (section 5.7).

Principle 13

Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses (section 6.5).

1 Introduction

1.1 *Background*

When developing advice to the National Health Service (NHS) and, since 1 April 2005 to the wider public health community, the Institute bases its conclusions on the 'best available' evidence. The best available evidence is not always very good and is rarely (if ever) complete. It may be of poor quality, lack critical elements, or both. Those responsible for formulating the Institute's advice about efficacy, effectiveness, cost effectiveness and safety are therefore inevitably required to make judgements.

These judgements fall broadly into two categories. Scientific value judgements are concerned with interpreting the significance of the available scientific, technical and clinical data. Social value judgements relate to society rather than to basic or clinical science: they take account of the ethical principles, preferences, culture and aspirations that should underpin the nature and extent of the care provided by the NHS. Nevertheless, the distinction is not absolute: there is a scientific dimension to the measurement and understanding of social value judgements, but this does not form part of this document.

1.2 *Aim of these guidelines*

This document describes the Institute's approach to incorporating social value judgements into the processes used to develop NICE guidance, as well as the principles that should be applied in developing individual items of guidance. It is primarily, though not exclusively, concerned with those social value judgements that are involved in developing conclusions about cost effectiveness and particularly those judgements that have implications for priority setting and resource allocation.

The Institute recognises, however, that there will be circumstances when – for valid reasons – departures from these general principles are appropriate. When this happens, however, the Institute expects the reasons for doing so to be explained in the guidance.

1.3 *Areas outside the remit of these guidelines*

There are four important areas that are not included in these guidelines.

Firstly, the guidelines do not cover the social value judgements required in evaluating the balance between the risks and benefits of interventional procedures. The Institute intends to include such considerations in future editions of the guidelines. They have been omitted from this document, partly because the bioethical literature is generally weak in the area and partly because the Institute has not as yet undertaken (or commissioned) work relating to this topic.

Secondly, the guidelines do not, in the main, consider the social value judgements concerned with developing public health advice. This issue will also be addressed in future editions.

Thirdly, the guidelines do not describe the social value judgements that should be applied in developing guidance on the use of 'ultra-orphan'² health technologies. NICE is currently formulating its position on the appraisal of these technologies and its conclusions are not yet available.

Finally, the guidelines do not cover the social value judgements required of those undertaking the National Confidential Enquiries (1) because on 1 April 2005 the National Patient Safety Agency took over responsibility for this programme.

1.4 *Intended audiences for these guidelines*

These guidelines are intended for three audiences.

They are addressed at those involved in constructing, or revising, the processes and procedures that determine the way NICE guidance is developed.

The guidelines are especially relevant to the Institute's advisory bodies (see the glossary) that are responsible for developing individual forms of NICE guidance.

They also attempt to help the Institute's stakeholders³ and the wider public, to understand the social values that underpin NICE guidance.

1.5 *Who has developed these guidelines?*

Although the Institute's board takes ultimate responsibility for the content of all NICE guidance, senior members of the Institute's staff have devolved powers to approve documents on the board's behalf. These guidelines, however, are unusual in being the direct responsibility of the board. They take account (as described below) of the views of the Institute's advisory bodies and, in particular, of advice from its Citizens Council. They have also been revised in the light of comments on an earlier draft from a wide range of interested groups and individuals.

1.6 *Methods used to develop these guidelines*

These guidelines are based, primarily, on evidence from three sources – the published literature, two reports of the Citizens Council (2, 3), and the results of a survey (4, 5) conducted on behalf of the Institute.

² So-called 'ultra-orphan' health technologies are defined by NICE as those used to treat conditions with a prevalence of less than 1 in 50,000 in the UK.

³ The Institute's stakeholders include professional bodies, industries, patients/carers and their representative organisations relevant to particular forms of NICE guidance.

1.6.1 The literature

The aim of the review of the literature was to identify, and synthesise, published material that might inform the board's approach to developing its social value judgements. Publications relating to three particular areas were sought:

- general principles of bioethics
- bioethical considerations of resource allocation and priority setting
- reports of relevant studies of professional and public attitudes to resource allocation, priority setting and rationing.

Publications relating to all three areas were identified from the peer-reviewed literature (through Medline, Embase, Science Citation Index, Social Science Citation Index, Arts and Humanities Citation Index), books and monographs, as well as the 'grey' literature.

1.6.2 The Citizens Council

The members of NICE's advisory bodies are appointed for their competence in making scientific value judgements but neither they, nor the board, can legitimately impose their own social value judgements on the NHS and the patients that it seeks to serve.

The Institute therefore established the Citizens Council as a formal committee of the Institute to help develop the broad social values that NICE should adopt in preparing its guidance. The 30 members of the Council reflect the age, gender, socioeconomic status and ethnicity of the people of England and Wales. Councillors serve for a period of 3 years, with one third retiring each year. They do not represent any particular section or sector of society; rather, they bring their own personal attitudes, preferences, beliefs and prejudices (6). They and their families have experience of the NHS as patients, but none of the members is a healthcare professional.

At each meeting, the Council is asked for its views on an issue about which the Institute seeks advice. Meetings are facilitated by an independent organisation and members have the opportunity to hear, and cross-examine, expert witnesses as well as to engage in discussion and deliberation in both plenary and small-group sessions. The Council's conclusions are contained in a report that is presented to the Institute's board.

1.6.3 The ICM survey

In March 2004 a telephone survey was conducted by ICM, on behalf of NICE, amongst a sample of 1010 people in the UK. The questions related to:

- awareness of the existence and functions of the Institute (4)
- attitudes about priority setting, particularly in relation to patients' age (5).

The ICM survey is a useful source of information about the public's perceptions, but NICE recognises that polling, like all methods for seeking 'public opinion', has two major limitations. Firstly, the results are very sensitive to the way questions are 'framed'. Secondly, responses are instantaneous replies without the benefit, necessarily, of learning about the underlying

issues. NICE therefore triangulates the results of polling data with the reports of the Citizens Council and the relevant literature.

More information about the ICM poll can be found at www.nice.org.uk/page.aspx?o=268902.

2 Principles of bioethics

2.1 *Moral principles*

The Institute subscribes to the widely accepted moral principles (7–11) that are expected to underpin clinical and public health practice:

- respect for autonomy
- non-maleficence
- beneficence
- distributive justice.

These so-called ‘four principles’ have been adopted by NICE because they provide a simple, accessible, and culturally neutral approach that encompasses most of the moral issues that arise in healthcare (12). In accepting these principles, the Institute also recognises (7) that there are tensions both within and between them; it also accepts that no one principle has an overriding priority over another. Indeed, these guidelines are, to a considerable extent, concerned with attempting to resolve the inherent tensions between these moral principles within the context of the social value judgements that the Institute and its advisory bodies have to make.

2.1.1 **Respect for autonomy**

Respect for autonomy acknowledges the rights of individuals to make informed choices in relation to healthcare, health promotion and health protection. It is inherent in the concept of ‘patient choice’. It cannot, though, be applied universally. By virtue of mental or physical incapacity, for example, some people may be unable to make informed choices; public health measures must sometimes be necessarily imposed on whole populations (such as smoking bans in enclosed spaces); and providing a few people with very expensive treatments, on the basis of personal preference, could deprive many others of more cost-effective interventions.

2.1.2 **Non-maleficence**

Non-maleficence asserts an obligation not to inflict damage (either physical or psychological) and has often been associated with the maxim ‘first, do no harm’. Yet no intervention⁴ is free from the potential to cause adverse consequences: it is the balance between the benefits and harms that determines (at least in part) whether an intervention is appropriate.

2.1.3 **Beneficence**

Beneficence, which is closely related to non-maleficence, refers to the obligation to benefit individuals. Moral philosophers distinguish between ‘positive beneficence’ and ‘utility’, with the former describing benefits that can be accrued and the latter attempting to balance benefits and harms. Yet no clinical or public health intervention is invariably beneficial for everyone; and,

⁴ The term ‘intervention’ is used in these guidelines to encompass health technologies and any other measure used to influence the course of a particular condition.

in the context of the work of NICE, it is respect for utility that is usually more relevant.

2.1.4 Distributive justice

'Distributive justice', as it relates to healthcare, is concerned with the provision of services in a fair and appropriate manner in the light of what is due, or owed, to people. Problems of distributive justice have become particularly manifested in healthcare, because of the universal mismatch between demands and resources. It is one of the most debated topics in bioethics, and is probably the most culture-specific.

The traditional, paternalistic approach to distributive justice has been the 'need principle'⁵. This claims that priorities should be set solely on the basis of clinical need as defined by the current degree of ill health (13); in practice, the need principle has largely been based on the premise 'doctor knows best'. This principle, however, takes no account of other issues and provides no solution to problems relating to a healthcare system as a whole. The need principle, as defined here, has some relevance to the 'rule of rescue' but is not otherwise considered further. Of the other main theories of distributive justice (7), two are especially relevant to the British healthcare system⁶: utilitarianism and egalitarianism.

Utilitarianism⁷ seeks to maximise overall good (or public utility). In its purest form, the utilitarian approach considers distributive justice to be best served by maximising social utility. It is often expressed, in shorthand, as 'the greatest good for the greatest number'.

Egalitarianism seeks fairness either in equality of opportunity (the 'fair opportunity' rule) or in equality of outcomes. Egalitarians seek healthcare to be distributed, so far as is possible, so that each person can achieve a fair share of the opportunities available in the particular society.

There is no consensus about which of these (and other) competing theories of distributive justice most appropriately captures the bioethical basis of the fair allocation of healthcare resources (7,13,14). Utilitarianism can allow the interests of minorities to be overridden by the majority, and it has little or nothing to offer in eradicating health inequalities. On the other hand, the notion of 'utility' places a premium on the 'efficiency' of a healthcare system, and provides a compelling warning about the dangers of ignoring opportunity costs (section 4). Egalitarianism emphasises fairness, and access to an adequate (though not necessarily maximum) level of healthcare. Its

⁵ The 'need principle' is sometimes described as the Marxist approach to distributive justice.

⁶ A third, widely held theory of distributive justice is 'libertarianism'. This espouses a free-market solution for the distribution of healthcare. Since, in the UK, over 90% of all healthcare is provided through the NHS and funded from general taxation, libertarianism is irrelevant to these guidelines.

⁷ Since classical utilitarianism is concerned with maximising happiness (a concept which is not concerned solely with health) some (11) prefer to describe the approach, in healthcare, as the 'maximising principle' but the term 'utilitarianism' will be retained in this discussion.

implications, though, remain uncertain (7). There is lack of clarity both in the definition of 'adequate' healthcare, and in the distinctions between what is fair and unfair or between what is unfair and what is unfortunate.

Both theories of distributive justice clash, at some point, with the considered moral convictions of most people. Each, however, articulates ideas that most would be reluctant to relinquish; and where one theory is weak, the other is often strong and some compromise has to be found (9). This is uncomfortable and has been described, by one commentator (15), as 'muddling through elegantly'.

This compromise is not a synthesis of the conflicting demands of utilitarianism and egalitarianism but a procedural device that allows the resolution of divergent values in order to provide 'accountability for reasonableness'. Decisions about social value judgements that are either implicit, or explicit, in NICE guidance should focus on the acceptable implications of each theory of distributive justice without necessarily, or invariably, choosing one over another. Inevitably, some people will be dissatisfied (16), for not everyone's claims will be met. Procedural justice, however, places a premium on ensuring that the processes by which decisions are reached have legitimacy (14, 17–20).

2.2 Strategies for setting priorities

There is a groundswell of opinion amongst bioethicists and political philosophers that, if there is to be confidence in the legitimacy of decisions, the procedures adopted should have all four of the following characteristics:

- publicity
- relevance
- revision and appeals
- regulation.

2.2.1 Publicity

Decisions about limits on the allocation of resources must be public. This includes not only the decisions themselves, but also the grounds for making them. It does not, however, require that all the criteria for decision-making should be established in advance: rather, there should be room for the development of 'case-law'.

2.2.2 Relevance

'Relevance' means that the grounds for decisions are ones that fair-minded people would agree are relevant to meeting healthcare needs, especially when there are constraints on resources. In particular, 'relevance' focuses on the importance of deliberation about the limits of the common good and acknowledges that such 'deliberative democracy' should involve both the decision-makers themselves and those whom the decisions may affect.

2.2.3 Revision and appeals

There must be opportunities for challenging decisions and mechanisms for resolving disputes. There should be systems in place for revising decisions when new, or additional, evidence becomes available or new arguments are put forward.

2.2.4 Regulation

There should be either voluntary or public regulation of the process of decision-making to ensure that it has all three of the above characteristics (publicity, relevance and opportunities for revisions and appeals).

2.2.5 Accountability for reasonableness in decision-making

Ensuring that procedures have all four of these characteristics makes decision-makers 'accountable for their reasonableness' (14, 17–20) (see section 2.1.4). Critics (7) claim that majority preferences – however well informed and fair – will sometimes lead to unjust outcomes, that deliberative democracy in action will 'most certainly' conflict with the principles of justice, and that 'deep suspicion is warranted about procedural strategies for setting priorities'. Such criticisms have some merit: yet no reasonable theoretical or practical alternatives have been proposed to resolve the conflicting theories of distributive justice.

For the NHS, there is a further reason for ensuring broad 'accountability for reasonableness' (14). The NHS is constructed on the principle of social solidarity. It provides healthcare for all UK citizens, at times of need, and irrespective of their ability to pay. Because the NHS is funded from general taxation, it must be right for UK citizens to have the opportunity to be engaged in the broad principles by which the NHS's priorities are set. They are, after all, the ultimate providers – through their taxes – of the services that are available.

3 Applying principles through process

3.1 The Institute's guidance programmes

The National Institute for Clinical Excellence (NICE) was established in 1999 to offer NHS healthcare professionals guidance on providing their patients with the highest attainable standards of care⁸. It has done this through three major programmes (1).

3.1.1 Health technology appraisals programme

The Institute advises on the use of individual, or classes of, health technologies. These include pharmaceuticals, devices, diagnostics, surgical and other procedures, and health promotion techniques. NICE's advice is based on considerations of both the clinical and cost effectiveness of the particular technology (or class of technologies) under examination.

3.1.2 Clinical guidelines programme

The Institute advises on the clinical management of specific conditions or disorders by developing and disseminating 'clinical guidelines' defined as: 'Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances'. As with its appraisals of health technologies, NICE's clinical guidelines take account of both the clinical and cost effectiveness of various clinical management options.

3.1.3 Interventional procedures programme

The Institute advises on the safety and efficacy of new and established interventional procedures for use within the NHS. The Institute defines interventional procedures as: 'those used for diagnosis or treatment that involve incision, puncture, entry into a body cavity or the use of ionising, electromagnetic or acoustic energy'.

In its assessment of interventional procedures, NICE takes account of the efficacy (rather than effectiveness) of the procedure and whether its safety (in relation to its efficacy) is compatible with its benefits. This programme, unlike the appraisals and clinical guidelines programmes, is not concerned with cost effectiveness although procedures that are regarded as safe and efficacious may undergo subsequent appraisals.

⁸ The National Institute for Clinical Excellence (NICE) was renamed on 1 April 2005, when it took on the functions of the Health Development Agency and became the National Institute for Health and Clinical Excellence. The organisation will produce public health guidance (on the promotion of good health and the prevention of ill health) for those working in the NHS, local authorities and the wider public and voluntary sector as well as the clinical guidance that it has been developing since its establishment in 1999. However, this document deals only with the clinical guidance for which NICE is responsible.

3.2 Legal requirements underpinning NICE guidance

In developing its guidance, NICE is obliged, by law, to conform to the provisions laid out in its Establishment Orders (21–23), and in its Directions from the Secretary of State for Health (24).

3.2.1 NICE's Establishment Orders

The Institute's original Establishment Order (21) provided that: 'The Institute shall perform such functions in connection with the promotion of clinical excellence in the health service as the Secretary of State may direct'. To avoid any misunderstanding about whether economic considerations should be taken into account, the Order was later amended (22) to: 'The Institute shall perform such functions in connection with the promotion of clinical excellence **and with the efficient use of available resources** in the health service as the Secretary of State may direct'.

The Institute is thus legally obliged to take account of both clinical and cost effectiveness in developing guidance in its technology appraisals and clinical guidelines programmes. The Establishment Order restricts the perspective of NICE's clinical guidance to the NHS and personal social services (PSS). In developing its public health guidance, however, the Institute's perspective has been extended to include 'other available public funds' as well as the NHS and PSS (24). This recognises the fact that responsibility for implementing public health measures extends beyond the NHS (for example, to local authorities). These 'cost-effectiveness' provisions do not apply to NICE's interventional procedures programme, which covers only safety and efficacy.

3.2.2 Directions to the Institute

The Secretary of State's Directions (24) to NICE require that, in appraising the clinical benefits and the costs of interventions, the Institute should have regard to the following factors.

- 1 The broad balance of benefits and costs.
- 2 The degree of clinical need of patients with the condition or disease under consideration.
- 3 Any guidance issued to the NHS by the Secretary of State that is specifically drawn to the attention of the Institute by the Secretary of State and any guidance issued by the Secretary of State.
- 4 The potential for long-term benefits to the NHS of innovation.

3.3 Essential features of NICE guidance

The Institute has adopted, and published, process documents for each form of NICE guidance (25–27). Although, inevitably, the process documents for each programme differ in detail they all have common features:

- methodological robustness
- inclusiveness
- transparency
- independence
- appeals
- review.

NICE guidance should also be timely. This means that it should be available at a time when it is of greatest use to its intended audiences.

3.3.1 Methodological robustness

The Institute's guidance is invariably based on a systematic review of the relevant published, and unpublished, literature. Although NICE is prepared to accept unpublished data it does so with reluctance: it believes that the data on which its guidance is based should be in the public domain (that is, accessible in print or electronic formats). Only in this way can there be professional and public confidence in its guidance. Nevertheless, refusal to accept unpublished data might disadvantage patients and breach the principles of non-maleficence and beneficence. In addition, rejection of relevant data would probably be unacceptable to the Courts.

3.3.2 Inclusiveness

The development of NICE guidance involves all those who have, or might have, an interest as either 'consultees' or 'commentators' (for technology appraisals) or 'stakeholders' (for clinical guidelines). These include relevant professional bodies, patients and patient-carer organisations, and (in the case of manufactured technologies) healthcare industries. All are involved with determining, at the start of the process, the scope of the guidance; all have an opportunity to comment on initial drafts of guidance; and all have the opportunity to make representations about the proposed final version of the guidance.

3.3.3 Transparency

The documentation supporting all NICE guidance is freely available on the Institute's website apart from data submitted as 'commercial in confidence' or 'academic in confidence'. Initial and final drafts of all forms of guidance are published, and interested parties may comment even if they are not registered as stakeholders or consultees. NICE guidance attempts to explain the reasons for the Institute's advice and the interpretation that its advisory bodies have placed on the available data.

3.3.4 Independence

All NICE guidance is developed by the independent members of the Institute's advisory committees (the appraisals committee and the interventional procedures advisory committee) and guideline development groups. They are drawn from the NHS, academia, the industries and patient-carer organisations. Their conclusions are reached only after extensive deliberation.

All members of the Institute's board, its staff, and members of its advisory bodies are required to make annual declarations (25) of any financial links they may have with the pharmaceutical, devices or diagnostics industries (19). Members of the board and advisory bodies are asked, in addition, to declare again their relevant interests at the start of each agenda item in a meeting (28).

3.3.5 Appeals

All three programmes provide consultees and stakeholders with the opportunity to comment on draft forms of NICE guidance. In the technology appraisals programme, consultees have additional rights of appeal to a panel appointed by the board (25). As the Institute is a public body, its guidance can be challenged in the UK (and EU) courts.

3.3.6 Review

When it is published, each of NICE's appraisals and clinical guidelines has a review date, which is the date at which NICE's Guidance Executive will consider the options for review of the guidance. These review dates are usually 3 and 4 years after publication (for appraisals and clinical guidelines, respectively) but if significant new data are anticipated or emerge the review dates may be brought forward.

3.3.7 Implementation

At the time NICE was proposed (29) its role did not include responsibility for implementing the guidance it produced. Recently, however, the Institute's Directions have been amended to provide a legal framework for an implementation programme (24). A number of practical measures have been introduced to support the implementation of NICE guidance. First, NHS trusts have a legal obligation (30) to make available resources to provide patients with technologies recommended in NICE's appraisals guidance. Secondly, NICE guidance is highlighted in the Department of Health's outline (31) of the standards that patients can expect to receive from the NHS. Thirdly, the Institute itself has established an implementation programme (32).

3.3.8 Legitimacy

These arrangements, collectively, offer 'accountability for reasonableness' (15, 17–20) (see section 2.1.4). They provide NICE guidance with a legitimacy that would otherwise be lacking, and have been commended on both scientific and technical (33), as well as political (34), grounds. Daniels and Sabin (12) acknowledge that NICE's processes embody key elements of accountability for reasonableness although they have reservations about the Institute's engagement with the public⁹. Empirical evidence is now emerging to suggest that this approach is acceptable to the public (35).

The principles that underpin the processes by which NICE guidance is currently developed should, therefore, be maintained and applied to future forms of advice (for example, public health guidance).

Principle 1

The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance.

⁹ At the time that Daniels' and Sabin's comments were made, the Citizens Council had been planned (32) but not yet implemented.

4 Cost effectiveness and setting priorities

4.1 *The Institute's approach to economic evaluation*

The Institute accepts that, for both legal and bioethical reasons, in undertaking technology appraisals and developing clinical guidelines it must take account of economic considerations. Decisions about the total resources available for healthcare are, rightly, the responsibility of parliament and inevitably compete with other demands such as education, defence and transport. Within the allocations made by parliament, the resources for the NHS are finite, and the use of cost-ineffective interventions in one area of practice will deny the availability of cost-effective interventions in another. The Institute thus recognises that both it, and its advisory bodies, have a responsibility to avoid issuing guidance that would incur 'opportunity costs' that would lead to the substitution of one form of inequality by another one.

Principle 2

For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations.

Economic evaluation in healthcare requires that the particular intervention under consideration has been shown to be clinically effective. Although there are various ways in which clinical effectiveness can be established, the requirement to do so is not only intellectually compelling and essential for a quantitative approach to economic evaluation, but also strongly supported by the British public (5). The Institute recognises the distinction between 'evidence of lack of effectiveness' and 'lack of evidence of effectiveness', but nevertheless considers that, in general, NICE and its advisory bodies should avoid promoting the use of interventions for which evidence of clinical effectiveness is either absent or is too weak for reasonable conclusions to be reached. This expectation should not, however, be overinterpreted. There will be circumstances, particularly where evidence is weak or entirely lacking, where judgement and experience strongly suggest that particular strategies (such as 'good clinical practice') provide patients with benefits in a cost-effective manner.

Principle 3

NICE guidance should not support the use of interventions for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.

The Institute's preferred approach (25, 37) to the economic evaluation of clinical interventions is cost–utility analysis. In developing its clinical guidance, NICE is required (section 3.2.1) to confine its estimation of costs to those falling on the NHS and PSS. In its public health guidance, however, the

Institute is expected to expand the cost base to include other available public funds as well as those of the NHS and PSS. The principal measure of health outcome adopted by the Institute is the quality-adjusted life year (QALY). This embodies the important social value judgement that to count only gains in life expectancy, without considering the quality of the additional life years, omits important dimensions of human welfare (37).

Value judgements embodied in health-related quality-of-life measures can be reasonably 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.

There are also value judgements in the ways in which these elements are combined (37) and the scoring given to the various combinations of levels of functioning.

The use of cost–utility analysis in resource allocation has aroused a substantial debate (7–9, 38–43). Charges of discrimination against children, elderly and disabled people, and people who are terminally ill, have led some to conclude that the use of QALYs leads to impermissible trade-offs in setting priorities. Nevertheless, most bioethicists and political philosophers are generally prepared to accept cost–utility analyses provided that they are used to inform, rather than direct, decisions about setting priorities, and that other considerations are available to constrain morally offensive trade-offs (7, 13, 14). The Institute’s own position is that while it endorses the use of cost–utility analysis in the economic evaluation of particular interventions, such information is a necessary, but not sufficient, basis for decision-making.

Suggestions have been made that social value judgements in cost–utility analyses could be identified empirically, and embedded within mathematical models (43, 44). Equity weights for age and gender are, for example, included in the calculation of disability-adjusted life years (DALYs) (45). Equity weighting, though intellectually attractive, is premature in the light of the available evidence (43, 44). NICE does not include equity weighting in its approach to cost–utility analysis (25) but does not exclude the possibility for the future.

Principle 4

In the economic evaluation of particular interventions, cost–utility analysis is necessary but should not be the sole basis for decisions on cost effectiveness.

4.2 Efficiency versus equity

The tensions between the utilitarian and egalitarian theories of distributive justice (section 2) are reflected in the debate amongst health economists about the balance between efficiency and equity (46).

Cost–utility analyses provide measures of health benefits in terms of anticipated health gains, and their associated costs are assessed from estimates of resource expenditure. The goal is utilitarian: it seeks to ensure the greatest health benefits for the money expended; it unashamedly attempts to achieve efficiency. In its strictest interpretation it expounds a value judgement that seeks the most ‘efficient’ use of the resources available to the NHS and prizes the maximisation of the overall health of the population above all else. The limitations of the quest for pure efficiency were, for example, apparent in the initial (draft) prioritised list of healthcare services in the Oregon scheme (47). This was based on a rank order of cost utilities but produced unacceptable trade-offs: tooth-capping, for example, was ranked above emergency surgery for both acute appendicitis and ectopic pregnancy.

The Institute’s rejection of both a strictly utilitarian (efficiency) approach to the economic evaluation of healthcare interventions and quantitative attempts to incorporate equity weighting into estimates of QALYs has important implications. Firstly, despite the Institute’s rejection of efficiency as the sole criterion for deciding cost effectiveness, NICE and its advisory bodies nevertheless require some indication of the range of cost per QALY values that are acceptable. Without such information, inconsistencies between different forms of NICE guidance, and different advisory bodies, would be inevitable. Secondly, if it is accepted that the Institute and its advisory bodies should have latitude in their interpretation of the cost effectiveness of particular interventions, some indication of the nature of the social value judgements they should adopt is necessary. Guidance on the nature of the social value judgements that should be adopted is essential to ensure fairness as well as, again, to avoid inconsistencies between the decisions of different advisory bodies (or even the same body on different occasions).

4.3 Limits to cost effectiveness

Where one intervention appears to be more effective than another, the Institute and its advisory bodies have to determine whether the increase in cost associated with the increase in effectiveness represents reasonable ‘value for money’. This is generally done by calculating the incremental cost-effectiveness ratio. For the reasons already stated (see section 4.1) the preferred approach is the cost (£) per QALY (33), although in some instances it has been necessary to use the cost (£) per life year gained or (particularly for anti-cancer drugs) the cost (£) per disease-free life year.

There is no empirical basis for assigning a particular value (or values) to the cut-off between cost effectiveness and cost ineffectiveness (37). The consensus amongst the Institute’s economic advisors is that the Institute should, generally, accept as cost effective those interventions with an incremental cost-effectiveness ratio of less than £20,000 per QALY and that

there should be increasingly strong reasons for accepting as cost effective interventions with an incremental cost-effectiveness ratio of over £30,000 per QALY. These reasons (25,37) include the degree of uncertainty surrounding the estimate of the incremental cost-effectiveness ratio and, where appropriate, reference to previous appraisals. The Institute and its advisory bodies will also wish to consider social value judgements, including consideration of the nature of the condition, the particular patient population, and the intervention itself. These are discussed in separate sections of these guidelines (section 5).

The Institute is reassured by independent evidence (48, 49) that its advisory bodies have not adopted a rigid incremental cost per QALY 'threshold'. NICE is aware, however, that some commentators have criticised the Institute's range of acceptable incremental cost-effectiveness ratios as too generous. Williams (45), for example, has suggested that the 'common sense' approach would be to base the incremental cost-effectiveness ratio on the per capita gross domestic product. This, in the context of the UK, would represent an incremental cost per QALY 'threshold' value of £18,000 per QALY (50).

Suggestions such as these, however, rely on 'judgements' that carry no more (or less) authority than the collective judgement of the Institute's economic advisors. The Institute therefore wishes its advisory bodies to continue with the current range of acceptable incremental cost-effectiveness ratios, albeit with two provisos: first, that advisory bodies should explain, explicitly, their reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio in excess of £20,000–£30,000 per QALY; and, second, that NICE will review this in the light of research currently being conducted through the NHS Research and Development's Methodology Programme.

Principle 5

NICE guidance should explain, explicitly, reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio in excess of £20,000 to £30,000 per QALY.

5 Social value judgements – service users

The NHS seeks to provide comprehensive healthcare for the population of the UK that is free at the point of need. Patients should not be denied access to NHS treatment simply because of their age, disability, faith, gender, sexual orientation, socioeconomic status or race, because their illness may be self-inflicted, or because of some other ‘non-health indicator’. However, for reasons previously discussed, on both bioethical and economic grounds, limits have to be placed on healthcare provision that take account of both efficiency and equity.

The board is conscious that discrimination can sometimes occur inadvertently (51) and asks the Institute and its advisory bodies to be especially vigilant in avoiding all forms of discrimination.

5.1 Age

- The issue of whether, or how, an individual’s age should be taken into account in allocating healthcare resources has roused considerable debate.

NICE’s Citizens Council concluded that (3):

- health should not be valued more highly in some age groups than in others
- individuals’ social roles, at different ages, should not influence considerations of cost effectiveness
- however, where age is an indicator of benefit or risk, it is appropriate to take it into account.

The Institute’s general principle is that patients should not be denied NHS treatment simply because of their age. NICE acknowledges that treatments can produce different benefits at different ages and that age itself may be the only identifiable indicator. Nonetheless, wherever practical, NICE’s advisory bodies should avoid issuing guidance that refers to age if this is being used as a presumed proxy for some aspect of patients’ health status.

Where NICE guidance refers to age it should only occur when all the following conditions are met:

- the evidence indicates that age is a good proxy for some aspect of patients’ health status and/or the likelihood of adverse effects of the treatment, and
- there is no practical way of identifying patients other than by their age (there is, for example, no routinely available diagnostic test to measure the relevant aspect of their health status), and
- it is logically and/or biologically plausible that, because of their age, patients will respond differently to the treatment in question.

In such instances NICE and its advisory bodies should explain within the guidance the reasons for using age as an indicator. The use of arbitrary age

cut-offs intended to indicate (for example) 'old age', 'childhood' or 'adolescence' should be avoided. Where it is necessary to indicate an age cut-off, and where the treatment is appropriate only for people in a particular age group, then a reason for using this specific cut-off should be provided.

Principle 6

NICE clinical guidance should only recommend the use of a therapeutic or preventive measure for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups that cannot be identified by any other means.

5.2 Gender and sexual orientation

Principle 7

In setting priorities there is no case for the Institute or its advisory bodies to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of preventative or therapeutic interventions.

5.3 Socioeconomic status

The Citizens Council considered that no priority should be given based on individuals' income, social class or position in life (2). Nor did the Council consider that individuals' social roles, at different ages, should influence considerations of cost effectiveness (2, 3).

The Institute supports these conclusions, as they relate to NICE's clinical guidance, and wishes its advisory bodies to take note of them in developing advice for the NHS. Nevertheless, in developing its approach to public health guidance, the Institute wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status.

Principle 8

In developing clinical guidance for the NHS, no priority should be given based on individuals' income, social class or position in life, and individuals' social roles, at different ages, should not influence considerations of cost effectiveness. Nevertheless, in developing its approach to public health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status.

5.4 Race (ethnicity)

There is no general case for limiting healthcare on racial (ethnic) grounds (51). NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of

differences between the groups in the clinical effectiveness of the intervention that cannot be identified by any other means. For example, it would be acceptable to restrict the use of the combination of hydralazine and isosorbide dinitrate (BiDi) for heart failure to Afro-Caribbeans, because of the absence of benefit in other ethnic groups (53).

Principle 9

NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention that cannot be identified by any other means.

5.5 Self-inflicted conditions

The Citizens Council considered that in developing its guidance NICE should not take into consideration whether or not a particular condition was self-induced (2). There were two reasons for reaching this conclusion: firstly, the Council believed it was impossible – at least in circumstances such as ischaemic heart disease – to decide whether an individual's condition was 'self-inflicted' or due to some other factor(s); secondly, the Council rejected the notion of 'deservedness' in priority setting within the NHS (2).

The board accepts that NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account.

Principle 10

NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account.

5.6 Patient choice

The Citizens Council emphasised in its first report (2) the importance of respecting individuals' systems of values, as well as their cultural attitudes and religious views. The Council also drew attention to the importance of individual choice. However, it recognised that individual choice would sometimes be necessarily limited in the interests of the population as a whole.

The Institute endorses the Council's sentiments, which reach to the heart of the requirement to respect an individual's autonomy. Nevertheless, while respect for autonomy and individual choice are important for the NHS and its users, this should not have the consequence of disadvantaging NHS users as a whole by having an unacceptable opportunity cost or promoting the use of interventions that are clinically and/or cost ineffective.

Principle 11

Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.

5.7 Responding to criticism

The Institute's processes both allow and encourage the involvement of consultees and stakeholders (section 3.3). The board considers it to be incumbent on the Institute and its advisory bodies to respond, objectively, to the comments of stakeholders and consultees and, where appropriate, to change their views.

The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to ignore such attempts.

Principle 12

It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance.

The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures.

6 Social value judgements – conditions

Just as there are social value judgements relating to users of the NHS (section 5) that the Institute and its advisory bodies should take into account when developing NICE guidance, so there are social value judgements relating to the condition.

6.1 Quality and quantity of life

As discussed previously (section 4), the board considers that NICE guidance should incorporate wherever possible in its cost–utility analyses the influence of particular interventions on both the quality and quantity of life. It is for this reason that the board’s preferred metric for health gain is the QALY.

The Institute is conscious, however, that incremental cost-effectiveness ratios may not adequately incorporate important features. In particular, QALYs may undervalue or even ignore the effect of a particular disease on pretreatment health status or the prognosis of the condition. Equally, conventional cost–utility analysis, and its emphasis on ‘capacity to benefit’, may lead to treatments not being recommended for subcategories of patients or conditions for which they would be clinically effective and cost-effective treatments.

6.2 Communicable diseases

As recognised by the Citizens Council (1), treatments used to control, or cure, communicable diseases may have benefits that extend far beyond those affected by the condition. It may not always be practical to incorporate these into the cost–utility analysis of the particular intervention and where this applies, or if the estimates are subject to substantial uncertainties, the board suggests that the Institute and its advisory bodies consider taking a more generous view of cost effectiveness.

6.3 Conditions associated with stigma

Some conditions, especially mental illness and sexually transmitted diseases, are associated with a stigma. The Citizens Council considered that some priority should be given for the treatment of such disorders (2).

Some diseases with attached stigmas have, in the past, been given a lower priority than they deserved within the NHS. There may therefore be a case for such interventions, particularly in the fields of mental health and sexually transmitted diseases, to be given some priority. The board, however, urges the Institute and its advisory bodies to be sparing in the use of special considerations and to do so only if there is reasonable evidence that those who suffer have additional psychological burdens, due to the associated stigma, that have not been taken into account in the cost–utility analyses.

Principle 13

Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses.

References

1. National Institute for Clinical Excellence (2004) *A Guide to NICE*
www.nice.org.uk/page.aspx?o=203748
2. National Institute for Clinical Excellence (2003) Report of the Citizens Council: determining clinical need.
www.nice.org.uk/pdf/FINALNICEFirstMeeting_FINALReport.pdf
3. National Institute for Clinical Excellence (2004) NICE Citizens Council: report on age. www.nice.org.uk/pdf/boardmeeting/brdjan04item2.pdf
4. National Institute for Clinical Excellence (2004) Results of an ICM 'omnibus' poll: attitudes to NICE. Unpublished.
5. National Institute for Clinical Excellence (2004). Results of an ICM 'omnibus' poll: age. Unpublished.
6. Davies C, Wetherall M, Barnett E, Seymour-Smith S. *Opening the Box: Evaluating the Citizens Council of NICE*. Open University: Milford Keynes. 2005
7. Beauchamp TL, Childress JF (2001) *Principles of Biomedical Ethics*. Oxford and New York: Oxford University Press.
8. Gillon R (1985) *Philosophical Medical Ethics*. Chichester: Wiley.
9. Gillon R, editor (1994) *Principles of Health Care Ethics*. Chichester: Wiley.
10. Beauchamp TL (1994) The 'four principles' approach. In: Gillon R, editor. *Principles of Health Care Ethics*. Chichester: Wiley, p3–12.
11. Gillon R (1994) The four principles revisited. In: Gillon R, editor. *Principles of Health Care Ethics*. Chichester: Wiley, p319–334.
12. Gillon R. (1994) Medical ethics: four principles plus attention to scope. *British Medical Journal* 309:184-188.
13. Cookson R, Dolan P (2000) Principles of justice in health care rationing. *Journal of Medical Ethics* 26:323–329.
14. Daniels N, Sabin JE (2002) *Setting Limits Fairly: Can we Learn to Share Medical Resources?* Oxford and New York: Oxford University Press.
15. Hunter D (1993) Rationing dilemmas in health care. National Association of Health Authorities and Trusts (NAHAT): Research paper No. 8. Birmingham: NAHAT.
16. Gillon R (1994) Preface: medical ethics and the four principles. In: Gillon R, editor. *Principles of Health Care Ethics*. Chichester: Wiley, pxxi–xxxi.

17. Daniels N, Sabin JE (1997) Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philosophy and Public Affairs* 26:303–50.
18. Daniels N (2000) Accountability for reasonableness. *British Medical Journal* 321:1300–01.
19. Daniels N, Sabin J (1998) The ethics of accountability in managed care reform. *Health Affairs* 17:50–64.
20. Gutmann A, Thompson D (1996) *Democracy and Disagreement*. Cambridge, Massachusetts: The Belknap Press of the Harvard University Press.
21. Statutory Instrument 1999 No. 220 The National Institute for Clinical Excellence (establishment and constitution) order 1999
22. Statutory Instrument 1999 No. 2219 The National Institute for Clinical Excellence (establishment and constitution) amendment order 1999
23. Statutory Instrument 2005 No. 497 The National Institute for Clinical Excellence (establishment and constitution) amendment order 2005
24. Secretary of State for Health (2005) *Directions and Consolidating Directions to the National Institute for Health and Clinical Excellence*.
25. National Institute for Clinical Excellence (2004) *Guide to the Methods of Technology Appraisal*. www.nice.org.uk/pdf/TAP_Methods.pdf
26. National Institute for Clinical Excellence (2004) *The Guideline Development Process – An Overview for Stakeholders, the Public and the NHS*.
www.nice.org.uk/pdf/GDP_An_Overview_for_Stakeholders_the_Public_and_the_NHS.pdf
27. National Institute for Clinical Excellence (2004) *The Interventional Procedures Programme: Programme Manual*.
<http://www.nice.org.uk/pdf/ip/IPProgrammeManual.pdf>
28. National Institute for Clinical Excellence (2002) Code of practice on declaration of interests. www.nice.org.uk/pdf/brdsep02item8.pdf
29. Department of Health (1998) *A First Class Service: Quality in the New NHS*. London: Department of Health.
30. Department of Health (2004) Directions to Primary Care Trusts and NHS trusts in England concerning arrangements for the funding of technology appraisal guidance from the National Institute for Clinical Excellence (NICE). www.dh.gov.uk/assetRoot/04/07/56/86/04075686.pdf
31. Department of Health (2004) Standards for better care.
www.dh.gov.uk/assetRoot/04/08/66/66/04086666.pdf

32. Rawlins MD (2004) NICE work – providing guidance to the British National Health Service. *New England Journal of Medicine* 351:1383–5.
33. World Health Organization (2003) *The Technology Appraisal Programme of the National Institute for Clinical Excellence*. Copenhagen: World Health Organization.
www.nice.org.uk/pdf/boardmeeting/brdsep03itemtabled.pdf
34. Guttman A, Thompson D (2002) Deliberative democracy beyond process. *Journal of Political Philosophy* 10:153–74.
35. Dollan P, Edlin R, Tsuchiya A, Wailoo A (2005) It ain't what you do. It's the way that you do it: Characteristics of procedural justice and their importance in social decision-making. In press.
36. Department of Health (2000) *The NHS Plan*. London: Department of Health.
37. Rawlins MD, Culyer AJ (2004) National Institute for Clinical Excellence and its value judgements. *British Medical Journal* 329:224–6.
38. Harris JR (1985) *The Quality of Life*. London: Routledge and Kegan.
39. Brock D (1998) Ethical issues in the development of summary measures of health status. In: *Summarising Population Health: Directions for the Development and Application of Population Metrics*. Washington DC: National Academy Press, p73–86.
40. Nord E (1999) *Cost-Value Analysis in Health Care: Making Sense out of QALYs*. Cambridge: Cambridge University Press.
41. Ubel P (2000) *Pricing Life*. Cambridge, MA: MIT Press.
42. Johannesson M, Johannsson P-O (1997) Is the valuation of a QALY gained independent of age? Some empirical evidence. *Journal of Health Economics* 16:589–99.
43. Powers M, Faden R (2000) Inequalities in health, inequalities in health care: four generations of discussion about justice and cost-effectiveness analysis. *Kennedy Institute of Ethics Journal* 10:109–27.
44. Williams A (1994) Economics, society and health care ethics. In: Gillon R, editor. *Principles of Health Care Ethics*. Chichester: Wiley, p 829–42.
45. Murray CJL, Acharya AK (1997) Understanding DALYs. *Journal of Health Economics* 16:703–30.
46. Williams A, Cookson R (2000) Equity in health. In: Culyer AJ, Newhouse JP, editors. *Handbook of Health Economics (Volume 1B)*. Amsterdam: Elsevier, p1863–1910.

47. Hadorn DC (1991) Setting health care priorities in Oregon. Cost-effectiveness meets the rule of rescue. *Journal of the American Medical Association* 265:2218–25.
48. Towse A, Pritchard C (2002) Does NICE have a threshold? An eternal view. In: Towse A, Pritchard C, Devlin N, editors. *Cost-Effectiveness Thresholds: Economic and Ethical Issues*. London: Kings Fund and The Office of Health Economics, p25–30.
49. Devlin N, Parkin D (2004) Does NICE have a cost-effectiveness threshold and what other factors influence its decisions? A binary choice analysis. *Health Economics* 13:437–52.
50. Williams A (2004) *What Could Be Nicer than NICE?* London: Office of Health Economics.
51. Bhopal R (1998) Spectre of racism in health and health care: lessons from history and the United States. *British Medical Journal* 316:1970–3.
52. Sassi F, Archard L, Le Grand J (2001) Equity and the economic evaluation of healthcare. *Health Technology Assessment* 5:1–138.
53. Food and Drug Administration (2005) FDA News: FDA approves BiDil heart failure drug for black patients. Press release 23 June 2005. www.fda.gov/bbs/topics/NEWS/2005/NEW01190.html
54. Culyer AJ (2005) *The Dictionary of Health Economics*. Cheltenham: Edward Elgar.

Glossary of terms

Academic in confidence See 'In confidence material' (25).

Advisory bodies The Institute's advisory bodies involved in the construction of NICE guidance comprise the two technology appraisal committees, the Interventional Procedures Advisory Committee, the subject-specific guideline development groups and their guideline review groups.

Technology appraisal committee A standing advisory committee of the Institute that develops guidance, for the NHS, on the clinical and cost effectiveness of individual (or groups of related) health technologies. Its members are drawn from the NHS, patient/carer organisations, relevant academic disciplines and the pharmaceutical and medical devices industries.

Beneficence Beneficence refers to the obligation to benefit individuals (see section 2.1.3).

Bioethics The ethics of medical and biological research and practice.

Capacity to benefit In health economics this refers to the potential increase in the health of an individual or group (see also 'Health gain') that might be achieved through the use of health services (54).

Carer (caregiver) Someone (usually a relative or close friend), other than a health professional, involved in caring for a person with a medical condition.

Citizens Council The Citizens Council is a formal committee of the Institute consisting of 30 members drawn from the population of England and Wales. The council exists to help develop the broad social values that NICE should adopt in preparing its guidance (see section 1.6.2).

Clinical efficacy The extent to which an intervention is active when studied under controlled research conditions (25).

Clinical effectiveness The extent to which an intervention produces an overall health benefit in routine practice (25).

Clinical guideline Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.

Clinician A healthcare professional providing healthcare. Examples include doctors, nurses, pharmacists, paramedics and physiotherapists.

Commercial in confidence See 'In confidence material'.

Communicable diseases An infectious disease due to an infectious agent (such as a bacterium, virus or parasitic worm) that arises through its transmission from another infected person, animal or reservoir (swamps, contaminated needles etc.) to a susceptible host (55).

Consultees Stakeholders within the technology appraisals programme. They include relevant healthcare professionals, patients or patient advocacy groups, and representatives of the particular manufactured technology.

Cost-effectiveness analysis An economic study in which the consequences of different interventions are measured using a single outcome, usually in 'natural' units (for example, life years gained, deaths avoided, heart attacks avoided, cases detected). Alternative interventions for the same condition are then compared in terms of cost per unit of effectiveness (54).

Cost-effectiveness model An explicit mathematical framework that is used to represent clinical decision problems and incorporate evidence from a variety of sources so that the costs and health outcomes can be estimated (25).

Cost-utility analysis A form of cost-effectiveness analysis in which the units of effectiveness are expressed as quality-adjusted life years (QALYs) (54).

Declarations of interests The requirement for members of the NICE board, the staff, and the members of its advisory groups to indicate their financial interests any technology, or business, under consideration.

Directions Legally binding instructions to the Institute (or other NHS bodies), from the Secretary of State, on the conduct of its affairs.

Disability-adjusted life year (DALY) A measure of the burden of disability-causing disease and injury (54).

Distributive justice A term used by philosophers to indicate how resources might be most appropriately be distributed in a society. For healthcare, it is concerned with the provision of services in a fair, equitable and appropriate manner in the light of what is due, or owed, to people (section 2.1.4).

Effectiveness See 'Clinical effectiveness'.

Efficacy See 'Clinical efficacy'.

Efficiency In healthcare efficiency, at its simplest level, involves using the available resources in a manner that maximises the health of the population as a whole (37), but more complicated accounts are available (54).

Egalitarianism An egalitarian considers that should get the same, or be treated the same, or be treated as equals. Egalitarian doctrines tend to express the idea that all human persons are equal in fundamental worth or moral status.

Equity For NICE, equity refers to fairness in the ways in which the costs and benefits of available care are distributed among all those who use the NHS (37) but more extensive accounts are available (54).

Establishment orders (NICE's) The legal instruments establishing the Institute, authorising its legal powers, and indicating the arrangements for its governance.

Evidence Information on which a decision or guidance is based. Evidence is obtained from a range of sources including randomised controlled trials, observational studies, expert opinion (of clinical professionals and/or patients) (25).

Guideline development group A multidisciplinary group, usually involving 12 to 15 people, with responsibility for developing a clinical guideline for NICE.

Grey literature Reports that are unpublished or have limited distribution, and are not included in the common bibliographic retrieval systems.

Health economics The application of economic theory to phenomena and problems associated with health (54).

Health-related quality of life A combination of an individual's physical, mental and social well-being; not merely the absence of disease (25).

Health technology Any method used by those working in health services to promote health, prevent and treat disease and improve rehabilitation and long-term care. Technologies in this context are not confined to new drugs or sophisticated equipment, but include surgical procedures, devices and other forms of therapeutic intervention such as physiotherapy and psychology.

In confidence material Information (for example, the findings of a research project) defined as 'confidential' because its public disclosure could have an impact on the commercial interests of a particular company or the academic interests of a research or professional organisation (25).

Incremental cost-effectiveness ratio (ICER) The ratio of the difference between the costs of two alternatives and the difference between their effectiveness (54).

Interventional Procedures Advisory Committee A standing committee of the Institute's board responsible for advising on the safety and efficacy of interventional procedures.

NICE guidance NICE guidance includes technology appraisals guidance, clinical guidelines, and interventional procedures guidance. It will also, in the future, include public health guidance.

Non-maleficence This asserts an obligation not to inflict either physical or psychological damage (section 2.1.2).

Opportunity cost The opportunity cost of investing in a healthcare intervention is the other healthcare programmes that are displaced by its introduction. This may be best measured by the health benefits that could have been achieved had the money been spent on the next best alternative healthcare intervention.

Outcome Measure of the possible results that may stem from exposure to a preventive or therapeutic intervention. Outcome measures may be intermediate endpoints or they can be final endpoints (25).

Public health The science and art of preventing disease, prolonging life and promoting health through organised efforts of society.

Quality-adjusted life year (QALY) A generic measure of health-related quality of life that takes into account both the quantity and the quality of life generated by interventions.

Quality of life See 'Health-related quality of life'.

Social value judgement An ethical opinion made either implicitly or explicitly that a particular course of action, institutional arrangement or method of analysis ought to be implemented, or is itself good (54).

Stakeholder Those with an interest in the use of a technology under appraisal or a guideline under development. Stakeholders include manufacturers, sponsors, healthcare professionals, and patient and carer groups (25).

Synthesis of evidence A generic term to describe methods used for summarising (comparing and contrasting) evidence into a clinically meaningful conclusion in order to answer a defined clinical question. This can include systematic review (with or without meta-analysis), and qualitative and narrative summaries (25).

Systematic review Research that summarises the evidence on a clearly formulated question according to a predefined protocol using systematic and explicit methods to identify, select and appraise relevant studies, and to extract, collate and report their findings. It may or may not use statistical meta-analysis (25).

Technology See 'Health technology'.

Technology appraisals Recommendations on the use of new and existing medicines and other treatments within the NHS in England and Wales, such as: medicines (for example, drugs), medical devices (for example, hearing aids and inhalers), diagnostic techniques (tests used to identify diseases), surgical procedures (for example, repair of hernias), and health promotion activities (for example, patient education models for diabetes) (25).

Technology assessment The process of evaluating the clinical, economic and other evidence relating to the use of a technology so that guidance on its most efficient use can be formulated (25).

Utilitarianism This is an ethical doctrine which specifies 'utility' as the principal good characteristic of society: what humankind as a whole ought to maximise (54).

Utility Utility is number assigned to entities (usually benefits or things presumed to be the objects of people's preferences) according to a rule. This enables the entities to be quantified and ranked according to preference, desirability or choice (54).