

**NATIONAL INSTITUTE FOR HEALTH AND  
CLINICAL EXCELLENCE**

# **SOCIAL VALUE JUDGEMENTS**

**Principles for the development of  
NICE guidance**

**Second edition**

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## **Preface**

This document describes the principles that NICE should follow in designing the processes it uses to develop its guidance (recommendations), and in developing individual pieces of guidance. It is mainly about the judgements that NICE and its advisory bodies should apply when making decisions about the effectiveness and cost effectiveness of interventions, especially where such decisions affect the allocation of NHS resources.

This document was developed by the board of NICE. It builds on the first edition of 'Social value judgements' [1], which was prepared in 2005.

All NICE guidance, and the procedures NICE uses to develop its guidance, should be in line with the Institute's legal obligations and the social value principles set out in this document. If any parts of NICE's guidance do not conform to these principles, NICE and its advisory bodies should identify them and explain the reasons why.

# 1 Introduction

## 1.1 Background

The National Institute for Health and Clinical Excellence (NICE) is an independent organisation responsible for providing national advice ('guidance') on promoting good health and preventing and treating ill health. NICE was established in 1999 to offer NHS healthcare professionals advice on how to provide their patients with the highest attainable standards of care. In 2005, its remit was expanded to include public health (that is, health promotion and disease prevention).

NICE has four programmes [2] that produce guidance (see Table 1). These include the development of clinical guidelines as well as recommendations on 'health technologies' (such as surgical interventions and pharmaceuticals) and public health. Much of the Institute's guidance takes into account both effectiveness<sup>1</sup> (how well it works) and cost effectiveness<sup>2</sup> (how well it works in relation to how much it costs). Some guidance just looks at efficacy<sup>3</sup> (how well it works under ideally controlled conditions).

When developing guidance for the NHS and the wider public health community, NICE bases its decisions on the best available evidence. This evidence is not always of good quality and is hardly ever complete. Those developing NICE's guidance are therefore inevitably required to make judgements. These judgements are of two types. Scientific value judgements are about interpreting the quality and significance of the evidence available; social value judgements relate to society rather than science.

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<sup>1</sup> **Clinical effectiveness:** the extent to which a specific treatment or intervention, when used under usual or everyday conditions, has a beneficial effect on the course or outcome of disease compared to no treatment or other routine care.

<sup>2</sup> **Cost effectiveness:** value for money; a specific health care treatment is said to be 'cost effective' if it gives a greater health gain than could be achieved by using the resources in other ways.

<sup>3</sup> **Efficacy:** the extent to which a specific treatment or intervention, under ideally controlled conditions, has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care.

<b>Table 1. NICE guidance programmes</b>		
<b>NICE programme</b>	<b>Provides guidance on</b>	<b>What the guidance takes into account</b>
<b>Technology appraisals</b>	The use of health technologies, which include: <ul style="list-style-type: none"> <li>• pharmaceuticals</li> <li>• devices</li> <li>• diagnostics</li> <li>• surgical and other procedures</li> <li>• health promotion tools.</li> </ul>	Clinical effectiveness and cost effectiveness.
<b>Clinical guidelines</b>	The appropriate treatment and care of patients with specific diseases and conditions.	Clinical effectiveness and cost effectiveness.
<b>Interventional procedures</b>	The safety of an 'interventional procedure' and how well it works. 'Interventional procedure' means any surgery, test or treatment that involves entering the body through skin, muscle, a vein or artery, or body cavity.	Clinical efficacy and safety of the intervention. It does not take cost effectiveness into account.
<b>Public health</b>	Activities to promote a healthy lifestyle and prevent ill health (for example, giving advice to encourage exercise or providing support to encourage mothers to breastfeed).	Effectiveness and cost effectiveness of public health activities.

## **1.2 Aim of this document**

This document describes the principles NICE should follow when applying social value judgements to the processes it uses to develop guidance as well as during the development of individual forms of guidance. It is particularly concerned with the social value judgements that NICE should adopt when making decisions about effectiveness and cost effectiveness.

## **1.3 Intended audiences for these principles**

The principles are intended for three audiences:

- those involved in designing or revising the processes for developing NICE guidance

- NICE’s advisory bodies responsible for developing individual items of NICE guidance
- NICE’s stakeholders<sup>4</sup> and the wider public, to enable them to understand the social values that underpin NICE guidance.

#### **1.4 Who has developed these principles?**

These principles are unusual in being the direct responsibility of the NICE board. Although the board is ultimately responsible for all NICE guidance, the content of individual forms of guidance is usually approved on behalf of the board by senior members of staff. The first edition of these principles [1] was prepared using the published literature, reports by NICE’s Citizens Council<sup>5</sup>, and the results of a survey conducted on behalf of NICE.

This second edition has been prepared using:

- further reports from the Citizens Council [3–7]
- publications commenting on the first edition of ‘Social value judgements’
- the results of a survey of members of NICE’s advisory bodies on how the principles set out in the first edition of ‘Social value judgements’ have been used and how they could be improved
- comments by NICE’s technical staff on the Citizens Council reports listed above
- legislation on human rights, discrimination and equality as reflected in NICE’s equality scheme
- a report from a roundtable discussion that explored the principles in the first edition in relation to contemporary bioethics and political philosophy
- a consultative workshop on social value judgements involving members of the Institute’s staff, its advisory bodies and outside experts.

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<sup>4</sup> The Institute’s stakeholders include relevant professional bodies, patients and patient–carer organisations, health-related industries and the wider public health community.

<sup>5</sup> The 30 members of the Citizens 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. See the glossary for further details.

## **1.5 *Outline of the document***

Chapter 2 discusses ethical principles concerning decisions on healthcare and how decisions can be made, and chapter 3 sets out the fundamental principles underlying NICE and its processes. Chapter 4 covers the principles NICE applies when developing guidance and chapter 5 explains how NICE responds to comments and criticisms. Chapter 6 examines how NICE aims to avoid discrimination and promote equality. Particular considerations that apply to public health guidance are discussed in chapter 7. Chapter 8 looks briefly at reducing inequalities, and the final chapter discusses how NICE should follow these principles.

This second edition also includes a glossary of terms.

## 2 Principles of bioethics

### 2.1 *Moral principles*

NICE subscribes to the widely accepted moral principles [8–13] that 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 [14]. NICE also recognises that there are tensions both within and between these principles; and it 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 them within the context of the social value judgements that NICE and its advisory bodies have to make.

**Respect for autonomy** recognises the rights of individuals to make informed choices about healthcare, health promotion and health protection. From this arises the concept of ‘patient choice’. The moral principle of respect for autonomy cannot, however, be applied universally or regardless of other social values. For example, some people may be unable to make informed choices because of mental or physical incapacity; and some public health measures must be imposed on whole populations (such as smoking bans in enclosed spaces).

**Non-maleficence** involves an obligation not to inflict harm (either physical or psychological) and is associated with the maxim ‘first, do no harm’. As any treatment or intervention can potentially have adverse consequences, it may be necessary to balance the benefits and harms when deciding whether an intervention is appropriate.

**Beneficence** is closely related to non-maleficence and involves an obligation to benefit individuals. But no clinical or public health intervention is always beneficial for everyone. In the context of the work of NICE, it is the balancing of benefits and harms that is usually more relevant.

**Justice**, as it relates to healthcare, is concerned with providing services in a fair and appropriate manner. This is a particular problem in healthcare because of the inevitable mismatch between demands and resources (see section 2.2).

## **2.2 *Distributive justice***

The mismatch between demands and resources in healthcare leads to the problem of 'distributive justice', or how to allocate limited healthcare resources fairly within society. There are, broadly, two approaches that can be taken to resolve such problems in publicly funded healthcare systems.

The **utilitarian approach** involves allocating resources to maximise the health of the community as a whole. It allows an efficient distribution of resources, but sometimes at the expense of fairness. It can allow the interests of minorities to be overridden by the majority; and it may not help in eradicating health inequalities.

The **egalitarian approach** involves distributing healthcare resources to allow each individual to have a fair share of the opportunities available, as far as is possible. It allows an adequate, but not necessarily maximum, level of healthcare, but raises questions as to what is 'fair'. But an egalitarian approach cannot be fully applied when there are limits on resources.

There is no consensus as to which approach provides the more ethical basis for allocating resources [8, 14, 15]. Each has strengths and weaknesses, and NICE does not subscribe fully to either approach. Rather, NICE seeks to apply the principles that underpin the NHS through an emphasis on 'procedural justice' [15]. This focuses on ensuring that the processes by which healthcare decisions are reached are transparent, and that the reasons for the decisions

are explicit. It does not attempt to resolve the conflicts between these different approaches.

### **2.3 Procedural justice**

Procedural justice provides for ‘accountability for reasonableness’. For decision-makers to be ‘accountable for their reasonableness,’ the processes they use to make their decisions must have four characteristics [15]: publicity, relevance, challenge and revision, and regulation.

#### **Publicity**

Both the decisions made about limits on the allocation of resources, and the grounds for reaching them, must be made public.

#### **Relevance**

The grounds for reaching decisions must be ones that fair-minded people would agree are relevant in the particular context.

#### **Challenge and revision**

There must be opportunities for challenging decisions that are unreasonable, that are reached through improper procedures, or that exceed the proper powers of the decision-maker. There must be mechanisms for resolving disputes; and transparent systems should be available for revising decisions if more evidence becomes available.

#### **Regulation**

There should be either voluntary or public regulation of the decision-making process to ensure that it possesses all three of the above characteristics.

It is particularly important for NICE to be ‘accountable for its reasonableness’ because it provides advice to the NHS. The NHS is funded from general taxation, and it is right that UK citizens have the opportunity to be involved in the decisions about how the NHS’s limited resources should be allocated.

The features of the processes used to develop NICE guidance that relate to procedural justice are discussed in chapter 3.

### 3 Fundamental operating principles

There are legal obligations and fundamental principles underlying the processes by which the Institute produces its guidance and NICE must always adhere to them.

#### 3.1 *Legal obligations*

NICE is bound by its Establishment Order [16], any Directions from the Secretary of State for Health [17], and legislation on human rights, discrimination and equality.

##### **NICE's Establishment Order [16]**

The Institute's Establishment Order states that:

'Subject to and in accordance with such directions as the Secretary of State may give, the Institute shall perform –

(a) such functions in connection with the promotion of clinical excellence, and the effective use of available resources in the health service,

(b) such functions in connection with the promotion of excellence in public health provision and promotion and in that connection the effective use of resources available in the health service and other available public funds,

(c) such other functions

as the Secretary of State may direct'.

### **Secretary of State's Directions to NICE [17]**

The Secretary of State's Directions to the Institute require that (among other matters) in the appraisal of the clinical benefits and the costs of interventions, NICE should consider the following factors.

- (a) The broad balance of clinical benefits and costs.
- (b) The degree of clinical need of patients with the condition or disease under consideration.
- (c) 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.
- (d) The potential for long-term benefits to the NHS of innovation.

The Secretary of State's Directions limit the interventional procedures programme to considerations of safety and efficacy.

NICE is committed to promoting equality, eliminating unlawful discrimination, and actively considering the implications of its guidance for human rights. It therefore aims to comply fully with legislation on human rights, discrimination and equality. The Institute's 'Equality Scheme and Action Plan 2007–2010' describes in detail how it meets these commitments and fulfils its obligations [18].

Assessing the impact of its guidance on equality is now an integral part of NICE's guidance development process. All guidance centres record the impact of equality issues at all stages of the guidance development. NICE also tries to involve in guidance development the widest possible range of organisations concerned with particular forms of inequality. It uses public consultation to seek a diverse range of views on the potential impact of guidance on equality.

### **3.2 Procedural principles**

Although each type of NICE guidance is developed using a different process, all these processes follow the same procedural principles. They therefore share common features arising from these principles:

- scientific rigour
- inclusiveness
- transparency
- independence
- challenge
- review
- support for implementation
- timeliness

These features relate to the procedural justice requirement for ‘accountability for reasonableness’ described in section 2.3 above. They give legitimacy to NICE guidance, and therefore should also apply to any future forms of guidance.

#### **Scientific rigour**

NICE’s guidance development processes should be scientifically rigorous. Guidance should be based on a systematic review of the relevant published literature as well as, when appropriate, unpublished literature.

#### **Inclusiveness**

The development of NICE guidance should include all parties with a legitimate interest in the guidance. This includes relevant professional bodies, patients and patient–carer organisations, health-related industries and the wider public health community. They should be involved in determining the scope of the guidance at the start of the development process, and have an opportunity to comment on drafts of the guidance.

#### **Transparency**

NICE publishes descriptions of all its guidance development processes to ensure that its work is as transparent as reasonably possible. Most evidence

supporting its recommendations is published. Only in exceptional circumstances does NICE accept unpublished evidence that must remain 'confidential' to protect the commercial or academic interests of a company or organisation. 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 tries to explain the reasons for the advice and the way NICE has interpreted the available evidence.

### **Independence**

All NICE guidance is developed by members of its independent advisory bodies. The members of these bodies are drawn from the NHS, academia, individuals with experience of the relevant industries, and patient–carer organisations. All members have to declare any relevant interests both annually and at each meeting they attend.

### **Challenge**

All four guidance programmes allow consultees and stakeholders to comment on drafts of guidance. In the technology appraisals programme, consultees have rights of appeal to a panel appointed by the Institute's board. All appeals are open to the public. The interventional procedures programme has a resolution process. Because NICE is a public body, its guidance can also be challenged in the courts.

### **Review**

The need to review NICE guidance is assessed between 3 and 4 years after publication. This may happen sooner if significant new information becomes available.

### **Support for implementation**

In 2004 NICE launched an implementation strategy to support the uptake of its guidance. It aims to ensure that there are mechanisms for implementing guidance recommendations as part of quality improvement throughout the NHS and partner organisations.

## **Timeliness**

Parliament, the public, patients and the NHS expect NICE to publish guidance in a timely manner. But the desire for rapid guidance development sometimes conflicts with the need for guidance to be based on robust evidence and subject to appropriate consultation. Appropriate arrangements are required for guidance to be developed at the time it is needed without compromising its quality.

## 4 Evidence-based decision-making

NICE guidance is evidence based. NICE assesses the clinical, public health and cost effectiveness of interventions before deciding whether and how to recommend their use.

### 4.1 *Clinical and public health effectiveness*

NICE expects its advisory bodies to use their scientific and clinical judgement in deciding whether the available evidence is sufficient to provide a basis for recommending or rejecting particular clinical or public health measures. The Institute recognises, however, that there is a difference between 'evidence of lack of effectiveness' and 'lack of evidence of effectiveness'. In general, therefore, NICE's advisory bodies should avoid recommending interventions where evidence of their effectiveness is absent or too weak for reasonable conclusions to be drawn.

NICE's advisory bodies may sometimes recommend that an intervention is used only within a research programme. They should consider whether the intervention is reasonably likely to benefit patients and the public, how easily the research can be set up or whether it is already planned or in progress, how likely the research is to provide further evidence, and whether the research is good value for money.

#### **Principle 1**

NICE should not recommend an intervention (that is, a treatment, procedure, action or programme) if there is no evidence, or not enough evidence, on which to make a clear decision. But NICE's advisory bodies may recommend the use of the intervention within a research programme if this will provide more information about its effectiveness, safety or cost.

## **4.2 Cost effectiveness**

Except in the case of interventional procedures, NICE and its advisory bodies have to consider whether interventions are cost effective before recommending their use in the NHS.

Deciding which treatments to recommend involves balancing the needs and wishes of individuals and the groups representing them against those of the wider population. This sometimes means treatments are not recommended because they do not provide sufficient benefit to justify their cost.

### **Principle 2**

Those developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them.

### **Assessing cost effectiveness**

NICE assesses the cost effectiveness of an intervention by comparing its cost against the gain in health outcome (benefit) it is expected to provide. This is known as cost–utility analysis. The main health outcome measure that NICE uses is the quality-adjusted life year (QALY). A QALY is a unit that combines both quantity (length) of life and health-related quality of life into a single measure of health gain.

NICE uses the QALY as an outcome measure because it takes into account not only the increased life expectancy from an intervention, but also the quality of the increased life. In addition to recognising that much of healthcare is concerned with improving people's quality of life, it also reflects the value judgement that mere survival is an insufficient measure of benefit; and that the expected quality of life years gained also needs to be considered. Balancing life years gained and quality involves social value judgements, some of which may be very difficult to make. The QALY also provides a 'common currency' which allows different interventions to be compared for different conditions. This allows NICE to make its decisions consistently, transparently and fairly.

Cost–utility analysis cannot, however, be the sole basis for NICE’s decisions and the Institute expects its advisory bodies to use their judgement when considering the results of cost-effectiveness analyses.

NICE interventional procedures guidance does not address cost effectiveness. Therefore, principles 3 and 4 do not apply to it.

### **Principle 3**

Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone. NICE must consider other factors when developing its guidance, including the need to distribute health resources in the fairest way within society as a whole.

### **Comparing the cost effectiveness of different interventions**

Where one intervention appears to be more effective than another, the Institute must decide whether the increased cost, associated with the increased effectiveness, represents reasonable ‘value for money’ for the NHS. NICE generally compares interventions by calculating the incremental cost-effectiveness ratio (ICER). The ICER is the ratio of the difference in the mean costs of an intervention compared with the next best alternative (which could be no action or treatment) to the differences in the mean health outcomes. ICERs are expressed as cost (in £) per QALY gained.

NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, in general, interventions with an ICER of less than £20,000 per QALY gained are considered to be cost effective. Where advisory bodies consider that particular interventions with an ICER of less than £20,000 per QALY gained should not be provided by the NHS they should provide explicit reasons (for example that there are significant limitations to the generalisability of the evidence for effectiveness). Above a most plausible ICER of £20,000 per QALY gained, judgements about the acceptability of the intervention as an effective use of NHS resources will specifically take account of the following factors.

- The degree of certainty around the ICER. In particular, advisory bodies will be more cautious about recommending a technology when they are less certain about the ICERs presented in the cost-effectiveness analysis.
- The presence of strong reasons indicating that the assessment of the change in the quality of life inadequately captured, and may therefore misrepresent, the health gain.
- When the intervention is an innovation that adds demonstrable and distinct substantial benefits that may not have been adequately captured in the measurement of health gain.

As the ICER of an intervention increases in the £20,000 to £30,000 range, an advisory body's judgement about its acceptability as an effective use of NHS resources should make explicit reference to the relevant factors considered above. Above a most plausible ICER of £30,000 per QALY gained, advisory bodies will need to make an increasingly stronger case for supporting the intervention as an effective use of NHS resources with respect to the factors considered above.

#### **Principle 4**

NICE usually expresses the cost effectiveness of an intervention as the 'cost (in £) per quality-adjusted life year (QALY) gained.' This is based on an assessment of how much the intervention costs and how much health benefit it produces compared to an alternative. NICE should explain its reasons when it decides that an intervention with an ICER below £20,000 per QALY gained is not cost effective; and when an intervention with an ICER of more than £20,000 to £30,000 per QALY gained is cost effective.

### **4.3 Individual choice**

The Citizens Council emphasised the importance of individual choice and of respecting individuals' values, cultural attitudes and religious views. However, it recognised that it might sometimes be necessary to limit individual choice in the interests of the population as a whole.

Although NICE agrees that respect for autonomy and individual choice are important for the NHS and its users, this should not mean that NHS users as a whole are disadvantaged by guidance recommending interventions that are not clinically and/or cost effective.

#### **Principle 5**

Although NICE accepts that individual NHS users will expect to receive treatments to which their condition will respond, this should not impose a requirement on NICE's advisory bodies to recommend interventions that are not effective, or are not cost effective enough to provide the best value to users of the NHS as a whole.

#### **4.4 Rare conditions**

NICE considers that it should evaluate drugs to treat rare conditions, known as 'orphan drugs', in the same way as any other treatment (see Glossary).

NICE does not expect to receive referrals from the Secretary of State for Health to evaluate 'ultra-orphan drugs' (drugs used to treat very rare diseases or conditions). This is because the Department of Health currently has other mechanisms to assess the availability of ultra-orphan drugs in the NHS.

#### **4.5 'Rule of rescue'**

There is a powerful human impulse, known as the 'rule of rescue', to attempt to help an identifiable person whose life is in danger, no matter how much it costs. When there are limited resources for healthcare, applying the 'rule of rescue' may mean that other people will not be able to have the care or treatment they need.

NICE recognises that when it is making its decisions it should consider the needs of present and future patients of the NHS who are anonymous and who do not necessarily have people to argue their case on their behalf. NICE considers that the principles provided in this document are appropriate to resolve the tension between the needs of an individual patient and the needs

of present and future users of the NHS. The Institute has not therefore adopted an additional 'rule of rescue'.

## 5 Responding to comments and criticism

NICE's processes encourage the active involvement of consultees and stakeholders. It is the duty of NICE and its advisory bodies to consider and respond objectively to the comments of consultees and stakeholders and, where appropriate, to amend its guidance.

Sometimes attempts are made, directly or indirectly, to influence NICE's decisions in ways that are not in the broad public interest. While NICE must consider all relevant comments, it is for the Institute alone to make the decisions entrusted to it. NICE and its advisory bodies must not respond to 'special pleading' but must be consistent in using its own judgement to make sure that what it recommends is cost effective and takes account of the need to distribute health resources in the fairest way within society as a whole.

### **Principle 6**

NICE should consider and respond to comments it receives about its draft guidance, and make changes where appropriate. But NICE and its advisory bodies must use their own judgement to ensure that what it recommends is cost effective and takes account of the need to distribute health resources in the fairest way within society as a whole.

## **6 Avoiding discrimination and promoting equality**

The NHS aims to provide free, necessary and appropriate treatment to the whole UK population. Legislation on human rights, discrimination and equality requires that patients are not denied access, or have different or restricted access, to NHS care because of their race, disability, age, sex/gender, sexual orientation, religion, beliefs, or socioeconomic or other status. The board of NICE expects everyone working for or with NICE to be particularly vigilant in avoiding discrimination and promoting equality. NICE's general approach to equality was discussed in section 3.1 above. This section deals with the specific question as to the circumstances in which NICE should recommend that the use of an intervention be restricted to particular group of people within the population.

### **6.1 Race (*ethnicity*)**

NICE should recommend the use of an intervention for a particular racial (ethnic) group only where there is clear evidence of differences in its clinical effectiveness within racial groups that cannot be identified in any other way.

### **6.2 Disability**

NICE should take special account of the needs of disabled people, which includes considering whether there are obstacles that might prevent them from benefiting from NICE guidance. Where necessary and appropriate it should take positive steps to take account of these needs.

### **6.3 Age**

There is much debate over whether, or how, age should be taken into account when allocating healthcare resources. The Citizens Council considered that health should not be valued more highly in some age groups than in others; and that social roles at different ages should not affect decisions about cost effectiveness. They said, though, that where age is an indicator of benefit or risk, it can be taken into account.

NICE's general principle is that patients should not be denied, or have restricted access to, NHS treatment simply because of their age. The

Institute's guidance should refer to age only when one or more of the following apply.

- There is evidence that age is a good indicator for some aspect of patients' health status and/or the likelihood of adverse effects of the treatment.
- There is no practical way of identifying patients other than by their age (for example, there is no test available to measure their state of health in another way).
- There is good evidence, or good grounds for believing, that because of their age patients will respond differently to the treatment in question.

Where NICE and its advisory bodies refers to age in its guidance, it should explain the reasons within the guidance.

#### **6.4 *Sex/gender and sexual orientation***

In making recommendations, NICE and its advisory bodies should avoid distinguishing between individuals on the basis of their gender or sexual orientation unless these are indicators for the benefits or risks of interventions.

#### **6.5 *Conditions associated with stigma***

Some conditions, for example, sexually transmitted diseases and drug dependency, are associated with stigma. NICE does not consider that stigma itself is a reason for altering its normal approach to assessing cost effectiveness. However, NICE is aware that stigma may affect people's behaviour in a way that changes the effectiveness of an intervention and that the relief of stigma may not always be captured by routine quality of life assessments. Therefore, NICE expects its advisory bodies to take these considerations into account.

#### **6.6 *Behaviour-dependent conditions***

The Citizens Council advised that NICE should not take into consideration whether or not a particular condition was self-induced. It was often impossible, in an individual, to decide whether the condition was dependent on their own behaviour or not; and receiving NHS care should not depend on whether people 'deserved' it or not.

NICE should not produce guidance that results in care being denied to patients with conditions that are, or may have been, dependent on their behaviour. However, if the behaviour is likely to continue and can make a treatment less clinically effective or cost effective, then it may be appropriate to take this into account.

### **6.7 Socioeconomic status**

NICE should not recommend interventions on the basis of individuals' income, social class or position in life. Nor should individuals' social roles at different ages affect decisions about cost effectiveness.

#### **Principle 7**

NICE can recommend that use of an intervention is restricted to a particular group of people within the population (for example, people under or over a certain age, or women only), but only in certain circumstances. There must be clear evidence about the increased effectiveness of the intervention in this subgroup, or other reasons relating to fairness for society as a whole, or a legal requirement to act in this way.

## **7 Particular issues for NICE guidance on public health**

Public health initiatives make major contributions to promoting good health and preventing ill health. The broad moral principles set out in this document apply equally to the development of both NICE's public health guidance and its clinical guidance. The requirements of 'accountability for reasonableness' described in chapter 3 also apply to public health guidance.

However, 'public health' refers to the efforts of society as a whole to improve health. Interventions are aimed at prevention rather than treatment; and at populations rather than patients. This raises additional ethical problems [19]. Traditional bioethics emphasise the freedom of the individual, but to be successful a public health approach may, as in the case of seat belt legislation, limit individual autonomy.

NICE asked the Citizens Council to consider when it is legitimate for authorities to intervene in a 'mandatory' way to address a public health problem. (Mandatory means that an intervention would be legally enforced – for example, legislation to ban smoking in public places.) The Council considered that non-mandatory public health measures, such as providing education and information, were preferable to mandatory ones, provided they were effective. Non-mandatory measures were less controversial and easier to introduce. Nor did they breach the principle of individual autonomy. In many cases, non-mandatory measures are the only practicable way of improving public health (for example, safe sex, taking exercise and attending smoking cessation clinics).

However, although the Citizens Council thought that where possible people should have freedom of choice and be responsible for their own health, they also considered that, when necessary NICE, should recommend that interventions should be mandatory.

NICE should take the following issues into account when deciding whether to recommend that a measure is mandatory.

- The balance of benefits and costs. In the case of a national emergency, the evidence needed to justify a public health intervention might be of lower quality.
- The importance of respecting individual choice but within limits.
- The proportionality of the measures relevant to the risk.
- The requirement to reduce health inequalities.
- Potential adverse effects on vulnerable members of society.
- The need to ensure mandatory measures are monitored, evaluated and (as required) discontinued so as to avoid harmful consequences.
- The importance of implementing measures in consultation with the broader community and after explaining the reasons for their introduction.

This approach is compatible with the stewardship model described in the Nuffield Council on Bioethics report [19]. However, implementing mandatory public health measures is the responsibility of the Government and not that of NICE.

## 8 Reducing health inequalities

While the overall health of the population continues to improve, the differences in health between the rich and poor have increased despite many attempts to change this. NICE asked the Citizens Council to consider the Institute's approach to health inequalities.

The Citizens Council concluded that, where feasible, NICE should support strategies that improve the health of the population while offering particular benefit to the most disadvantaged so as to reduce health inequalities, particularly in the context of public health.

The board considers that the Institute has a duty to take into account the impact of its guidance on health inequalities; and that its advisory bodies should try to ensure that implementing NICE guidance will not widen existing inequalities. Furthermore, in promoting measures to reduce health inequalities, NICE's board places particular emphasis on the importance of selecting the right topics on which to develop guidance; and in supporting those with responsibility for putting NICE guidance into practice.

### **Principle 8**

When choosing guidance topics, developing guidance and supporting those who put its guidance into practice, the Institute should actively consider reducing health inequalities including those associated with sex, age, race, disability and socioeconomic status.

## **9 Following the principles**

The work of the Institute must follow the principles of this document if NICE guidance is to meet NICE's legal and moral obligations to the people it serves. Together the principles fulfil the requirements of 'accountability for reasonableness'.

The board of NICE considers that a statement of broad compliance with the principles should be included in all NICE guidance as well as in its process and methods manuals. In situations where guidance appears to depart from these principles, this should be stated and there should be a clear explanation. NICE has a responsibility to monitor adherence to and ensure compliance with these principles, particularly those relating to legislation on human rights, discrimination and equality.

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## Glossary of terms

**Advisory bodies** NICE's advisory bodies develop NICE guidance. The advisory bodies (June 2008) are: the three technology appraisal committees, the Interventional Procedures Advisory Committee, the subject-specific guideline development groups and their guideline review panels, the Public Health Interventions Advisory Committee and the subject-specific public health programme development groups.

**Beneficence** Beneficence refers to the obligation to benefit individuals.

**Bioethics** The ethics of medical and biological research and practice.

**Carer** Someone, who, without payment, provides help and support to a partner, child, relative, friend or neighbour, who could not manage without their help. This could be due to age, physical or mental illness, addiction or disability.

**Citizens Council** The Citizens Council brings the views of the public to NICE decision-making about guidance on the promotion of good health and the prevention and treatment of ill health. A group of 30 people drawn from all walks of life, the Citizens Council tackles challenging questions about values - such as fairness and need.

**Clinical effectiveness** The extent to which a specific treatment or intervention, **when used under usual or everyday conditions**, has a beneficial effect on the course or outcome of disease compared to no treatment or other routine care.

**Clinical efficacy** The extent to which a specific treatment or intervention, **under ideally controlled conditions**, has a beneficial effect on the course or outcome of disease compared with no treatment or other routine care.

**Clinical guideline** NICE guidance on the treatment and care of people with a specific disease or condition in the NHS.

**Clinician** A healthcare professional providing patient care, for example, a doctor, nurse, or physiotherapist.

**Consultees** An organisation invited to take part in a technology appraisal.. Consultee organisations include: national groups representing patients and carers; bodies representing healthcare professionals; manufacturers of the health technology being appraised.

**Cost-effectiveness analysis** A type of economic evaluation comparing the costs and the effects on health of different treatments. Health effects are measured in 'health-related units', for example, the cost of preventing one additional heart attack.

**Cost-utility analysis** A form of cost effectiveness analysis where a treatment is assessed in terms of its ability to both extend life and to improve the quality of life. The unit of measurement is called a quality adjusted life year (QALY).

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

**Distributive justice** The fair and consistent allocation of goods or services (including healthcare) to society.

**Effectiveness** See 'Clinical effectiveness'.

**Efficacy** See 'Clinical efficacy'.

**Efficiency** In healthcare, efficiency involves using the available resources in a manner that maximises the health of the population as a whole.

**Establishment orders (NICE's)** The legal instruments establishing NICE, 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 and expert opinion (of clinical professionals and/or patients).

**Generalisability** The extent to which the results of a study conducted in a particular patient population and/or a specific context will apply for another population and/or in a different context.

**Guideline development group** A group of healthcare professionals, patients, carers and technical staff who develop the recommendations for a NICE clinical guideline.

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

**Health technologies** New and existing drugs, devices, treatments, surgical procedures and therapies designed to prevent and treat disease and/or improve rehabilitation and long-term care.

**Incremental cost-effectiveness ratio (ICER)** The ratio of the difference in the mean costs of a technology compared with the next best alternative to the differences in the mean outcomes.

**Interventional Procedures Advisory Committee** The independent committee that advises NICE on whether an interventional procedure is safe enough and works well enough to be used in the NHS. An interventional procedure is a procedure used for diagnosis or treatment that involves making a cut or hole in the patient's body, entry into a body cavity or using electromagnetic radiation (including X-rays or lasers).

**NICE guidance** NICE produces guidance in three main areas: **health technologies**, focusing on the use of new and existing drugs, devices, therapies and surgical procedures; **clinical practice**, relating to appropriate treatment for specific diseases and conditions; and **public health**, involving the promoting good health and preventing of ill health.

**Non-maleficence** An obligation not to inflict either physical or psychological harm (section 2.1).

**Orphan drugs** Drugs indicated for rare conditions or diseases (those that occur in fewer than 1 in 2000 of the population). (See also ‘Ultra-orphan drugs’.)

**Outcome measure** A measure of the degree of success obtained from the treatment or care of a disease or condition.

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

**Public Health Interventions Advisory Committee** An independent advisory body that produces recommendations for NICE on the use of discrete activities (interventions) that help to reduce people’s risk of developing a disease or condition or help to promote or maintain a healthy lifestyle. Examples of interventions include giving advice, providing services or providing support on specific topics: for example, giving advice in GP practices to encourage exercise, providing a needle exchange scheme for injecting drug users, providing support on breastfeeding for new mothers.

**Public Health Programme Development Group** An independent advisory body that produces recommendations for NICE on broad actions for the promotion of good health and the prevention of ill-health. This guidance may focus on a topic, such as smoking, or on a particular population, such as young people, or on a particular setting, for example, the workplace..

**Quality-adjusted life year (QALY)** A measure of health outcome which looks at both length of life and quality of life. QALYS are calculated by estimating the years of life remaining for a patient following a particular care pathway and weighting each year with a quality of life score (on a zero to one scale). One QALY is equal to one year of life in perfect health, or two years at 50% health, and so on.

**Quality of life** See ‘Health-related quality of life’.

**Stakeholder** An organisation with an interest in a topic on which NICE is developing a clinical guideline or piece of public health guidance.

Stakeholders may be: manufacturers of drugs or equipment; national patient and carer organisations; NHS organisations; organisations representing healthcare professionals.

**Systematic review** Research that identifies and analyses the full range of good quality scientific studies that have been carried out to answer the same question.

**Technology** See 'Health technology'.

**Technology appraisal committee** An independent advisory body that reviews evidence to produce recommendations for NICE on the use of technologies (new and existing drugs, devices, treatments, surgical procedures and therapies) in the NHS.

**Technology appraisal guidance** NICE recommendations on the use of new and existing drugs, devices, treatments, surgical procedures and therapies within the NHS in England and Wales.

**Ultra-orphan drug** A term used by NICE to describe interventions for very rare conditions or diseases that occur in fewer than 1 in 50,000 of the population; it also covers interventions for which there are no other known or possible uses.

**Utility** A measure of the strength of a person's preference for a specific health state in relation to alternative health states. The utility scale assigns numerical values on a scale from 0 (death) to 1 (optimal or 'perfect' health). Health states can be considered worse than death and thus have a negative value.