National Institute for Health and Clinical Excellence

SOCIAL VALUE JUDGEMENTS

Principles for the development of NICE guidance

Second edition

(Draft for public consultation)
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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. The first edition was prepared using the published literature, reports on clinical need and age by NICE’s Citizens Council, and the results of a survey conducted on behalf of NICE. (See section 1.5 for information about the Citizens Council.)

This second edition has been prepared using:

- further reports from NICE’s Citizens Council:
  - Mandatory public health measures (July 2005)
  - Rule of rescue (January 2006)
  - Inequalities in health (June 2006)
  - Only in research (January 2007)
  - Patient safety (June 2007)
- publications commenting on the first edition
- the results of a survey of members of NICE’s advisory bodies on how the principles set out in the first edition 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.
All NICE guidance, and the procedures NICE uses to develop its guidance, should be in line with NICE’s legal obligations and the social value principles set out in this document. If any parts of NICE’s guidance do not follow these social value principles, NICE should identify them and explain the reasons why.
1 Introduction

1.1 Background

The National Institute for Health and Clinical Excellence (NICE) is the independent organisation responsible for providing national advice (‘guidance’) on promoting good health and preventing and treating ill health. It was established 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 health promotion and disease prevention.

NICE has four programmes that produce guidance, including clinical guidelines and recommendations on ‘health technologies’ (such as surgical interventions and pharmaceuticals) and public health. Some guidance takes into account both effectiveness (how well it works) and cost effectiveness (how well it works in relation to how much it costs). Some guidance just looks at efficacy (how well it works under ideally controlled conditions). See Table 1 for more information about the different types of NICE guidance.
<table>
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<th>NICE programme</th>
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<td>Technology appraisals</td>
<td>The use of health technologies, which include:</td>
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<td>Clinical guidelines</td>
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<td>Interventional procedures</td>
<td>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.</td>
<td>Clinical efficacy and safety of the intervention. It does not take cost effectiveness into account.</td>
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<tr>
<td>Public health guidance</td>
<td>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).</td>
<td>Effectiveness and cost effectiveness of public health activities.</td>
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</table>

**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.

**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.

**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.

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 and social value judgements. Scientific value judgements are about interpreting the quality and significance of the evidence available. Social value judgements relate to society rather than science.

1.2 Aim of this document

This document describes the principles NICE should follow when applying the second type of these judgements, social value judgements, both in the processes it uses to develop guidance and during the development of individual pieces of guidance. It is mainly about the social value judgements that NICE should apply when making decisions about effectiveness and cost effectiveness.

1.3 Areas not covered by the principles

There are two areas that are not considered in this document.

First, the principles do not describe the social value judgements that should be applied when developing guidance on the use of drugs (medicines) used to treat very rare conditions or diseases (that is, conditions or diseases that occur in fewer than 1 in 50,000 people in the UK population). These are known as ‘ultra-orphan’ drugs.

Second, the principles apply differently to NICE interventional procedures guidance. They do not cover the social value judgements required in making decisions about the relative risks and benefits of interventional procedures, and they do not cover decisions about the cost of interventional procedures. NICE plans to include risk/benefit considerations in a future edition of this document.

1.4 Intended audiences for these principles

The principles are intended for three audiences:

- people who are involved in designing or revising the processes for developing NICE guidance
- NICE’s advisory bodies, which are independent groups responsible for developing individual items of NICE guidance (see page 18)
• the Institute’s stakeholders\(^1\) and the wider public, to enable them to understand the social values that underpin NICE guidance.

1.5 **Who has developed these principles?**

These principles are unusual in being the direct responsibility of the board of NICE. (Although the board is ultimately responsible for all NICE guidance, the content of individual pieces of guidance is usually approved by senior members of staff, on behalf of the board.)

The first edition of this document was prepared using the published literature, reports on clinical need and age by NICE’s Citizens Council, and the results of a survey conducted on behalf of NICE.

**Literature review**

The aim of the literature review was to identify published material that might help the board in 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.

**Citizens Council**

NICE’s advisory bodies can make 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.

NICE therefore established the Citizens Council 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, but bring their own personal attitudes,

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\(^1\) The Institute’s stakeholders include relevant professional bodies, patients and patient–carer organisations, health-related industries and the wider public health community.
preferences, beliefs and prejudices. 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 NICE 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. The Council presents its conclusions in a report to the NICE board.

ICM survey

In March 2004, ICM carried out a telephone survey on behalf of NICE among a sample of 1010 people in the UK. The questions related to:

- awareness of the existence and functions of NICE
- attitudes about priority setting, particularly in relation to patients’ age.

NICE recognised that polling, like all methods of seeking ‘public opinion’, has two major limitations: (1) the results are very sensitive to the way questions are written, and (2) responses are immediate replies without the benefit of learning about the underlying issues. NICE therefore combined the survey results with the reports of the Citizens Council and the relevant literature. (For more information about the ICM poll see www.nice.org.uk/page.aspx?o=268902.)

1.6 How have these principles been revised?

This second edition of ‘Social value judgements: principles for the development of NICE guidance’ has been prepared using:

- Further reports from the Citizens Council:
  - Mandatory public health measures (July 2005)
  - Rule of rescue (January 2006)
  - Inequalities in health (June 2006)
  - Only in research (January 2007)
  - Patient safety (June 2007).
- 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.

1.7 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 follows these principles.
2 Principles of bioethics

2.1 Moral principles

There are four widely accepted principles that apply when moral issues arise during decisions about healthcare:

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

**Respect for autonomy** recognises the rights of individuals to make informed choices about healthcare, health promotion and health protection. From this arises the idea of ‘patient choice’. It 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).
There are tensions between these four principles. For example, allowing a few individuals to choose a very expensive treatment through respect for their autonomy may deprive many others of the benefit of a more cost-effective treatment, which would be against the principle of justice.

NICE’s social value judgements have been developed to find a way of addressing such tensions when NICE is developing its guidance.

### 2.2 Distributive justice

The mismatch between demands and resources in healthcare leads to problems of ‘distributive justice’: how to allocate limited healthcare resources fairly within society. Two different ethical approaches that societies can take to such problems are the utilitarian and the egalitarian.

The **utilitarian approach** involves allocating healthcare resources to maximise the health of the community as a whole. It allows an efficient distribution of resources, but possibly at the expense of fairness. It can allow the interests of minorities to be overridden by the majority, and 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, and raises questions as to what is ‘fair’.

There is no consensus as to which approach provides the more ethical basis for allocating resources fairly. Each has strengths and weaknesses, and therefore a compromise has to be found. One compromise is so-called ‘procedural justice’. 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 the 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: 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-makers. There must be mechanisms for resolving disputes and transparent systems available for revising decisions when 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 NICE produces its recommendations. NICE should always adhere to these.

3.1 Legal obligations

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

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<th>NICE’s Establishment Order</th>
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<td><strong>(See <a href="http://www.opsi.gov.uk/si/si2005/20050497.htm%5D">www.opsi.gov.uk/si/si2005/20050497.htm</a></strong></td>
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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
(See www.nice.org.uk/page.aspx?o=347219)

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.

‘NICE’s equality scheme and action plan 2007–2010’ describes in detail how it meets these commitments and fulfils its obligations to:

- promote race and disability equality and equality of opportunity between men and women, and
- eliminate unlawful discrimination on grounds of race, disability, age, sex and gender, sexual orientation, and religion or belief in the way it carries out its functions and in its employment policies and practices.
It also sets out the action NICE intends to take in this area over the next 3 years.

(See [http://www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp](http://www.nice.org.uk/aboutnice/howwework/NICEEqualityScheme.jsp))

Assessing the impact of its guidance on equality is now an integral part of NICE’s guidance development process. NICE uses an equality impact assessment tool at key stages of the process, including selection of guidance topics and developing recommendations. 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 types of guidance.
Scientific rigour
NICE’s guidance development processes should be scientifically rigorous. For example, wherever possible, guidance should be based on a systematic review of the relevant published and selected unpublished literature.

Inclusiveness
The development of NICE guidance includes all parties with an interest in the guidance. This includes relevant professional bodies, patients and patient–carer organisations, health-related industries and the wider public health community. They are involved in determining the scope of the guidance at the start of the process, and can comment on drafts of the guidance.

Transparency
NICE publishes descriptions of all its guidance development processes on its website 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 on the website 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 independent advisory bodies. The members of these bodies are drawn from the NHS, academia, 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 UK (and EU) courts.

Review
Most NICE guidance is reviewed 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 conflicts with the need for guidance to be based on robust evidence and subject to appropriate consultation. Appropriate arrangements are needed for guidance to be developed swiftly 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 to decide whether the available evidence is sufficient to provide a basis for deciding whether or not to recommend the use of an intervention. NICE recognises that there is a difference between ‘evidence of lack of effectiveness’ and ‘lack of evidence of effectiveness’. But in general, NICE should avoid recommending interventions where evidence of their effectiveness is absent or too weak for reasonable conclusions to be drawn.

NICE’s advisory bodies can sometimes recommend that an intervention is used only within a data collection or 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 may recommend the use of the intervention within a data collection or research programme if this will provide more information about the effectiveness, safety or cost of the intervention.
4.2 Cost effectiveness

Except in the case of interventional procedures, NICE has to consider whether interventions are cost effective before recommending their use.

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: cost–utility analysis**

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 for short). 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. For example, one additional QALY might equal 1 year of ‘perfect’ health for one person, or 2 years of life with 0.5 quality of life for one person, or 1 year of life with 0.5 quality of life for two people.

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. This reflects the value judgement that mere survival is an insufficient measure of success 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.
Another reason for using the QALY is that it acts as a ‘common currency’ which allows different interventions to be compared in different circumstances. This allows NICE to make its decisions consistently and transparently.

However, cost–utility analysis should not be the only basis for NICE’s decisions. NICE expects its advisory bodies to use their judgement when considering the results of cost effectiveness analyses.

**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, NICE must decide whether the increase in cost associated with the increase in effectiveness represents reasonable ‘value for money’ for the NHS.

NICE generally compares interventions by calculating the incremental cost-effectiveness ratio (ICER). An 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 outcomes. ICERs are expressed as cost (£) per QALY gained.

NICE has never identified an ICER above which interventions should not be recommended and below which they should. However, NICE presumes that interventions with an ICER of less than £20,000 per QALY gained are cost effective. There must be increasingly strong reasons for recommending interventions with an ICER of more than £20,000 per QALY gained, and even stronger reasons where the ICER is more than £30,000 per QALY gained.

Reasons for NICE decisions about cost effectiveness may refer to the adequacy of the assessment of health benefit or the degree of certainty around the ICER.
Principle 4

NICE sometimes expresses the cost effectiveness of an intervention as the ‘cost (£) 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. If NICE decides not to recommend use of an intervention with a cost per QALY gained within or below the range £20,000 to £30,000 per QALY gained, or decides it will recommend use of an intervention within or above this range, it must explain the reasons why.

4.3 Patient 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.

NICE agrees that although 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 upholds the right of individuals to make their own decisions about their care, this should not lead NICE to recommend interventions that are not effective and cost effective enough to provide the best value to users of the NHS as a whole.

4.4 Rare and very rare conditions

NICE considers that it should assess drugs to treat rare conditions or diseases in the same way as any other treatment.
diseases are considered to be those that occur in fewer than 1 in 2000 people in the population.) These are known as ‘orphan’ drugs.

NICE has not yet been asked to assess drugs for very rare conditions or diseases (which occur in fewer than 1 in 50,000 people in the population). If NICE was asked to do so, it would have to consider its approach.

4.5 ‘Rule of rescue’

There is a powerful human impulse to attempt to rescue a single identifiable person whose life is in danger, no matter how much it costs. This is called the ‘rule of rescue.’ 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 have people to argue their case. 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 other users of the NHS, present and future. Therefore, the Institute has not adopted an additional ‘rule of rescue’.
5 Responding to comments and criticism

NICE’s processes encourage the 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 NICE alone to make the decisions entrusted to it: NICE 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 change it where appropriate. But NICE must always use its 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 between 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 benefitting from NICE guidance. Where necessary 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 decided 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. NICE 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, it is likely that, because of their age, patients will respond differently to the treatment in question.

Where NICE needs to refer to age in its guidance, it should explain the reasons why within the guidance.

### 6.4 Sex/gender and sexual orientation

In making recommendations, NICE should not distinguish 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 Self-inflicted conditions

The Citizens Council decided that NICE should not take into consideration whether or not a particular condition was self-induced. It was impossible to
decide whether an individual’s condition was ‘self-inflicted’ 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, self-inflicted, for this reason alone. However, if the self-inflicted condition is likely to continue and can make a treatment less clinically 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.

<table>
<thead>
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<th>Principle 7</th>
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<td>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 for 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.</td>
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7 Particular issues for public health guidance

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 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, and this raises additional ethical problems. Traditional bioethics emphasises the freedom of the individual, but to be successful a public health approach may, as in the case of seat belt legislation, have to limit individual autonomy.

Members of the Citizens Council were invited to consider two issues facing NICE in issuing public health guidance: choosing between mandatory and non-mandatory measures, and trying to reduce inequalities in health status between different groups in the population. The Citizens Council’s views on the first of these issues are explained below. The issue of reducing health inequalities is deal with in the next chapter.

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 thought that non-mandatory public health measures, such as providing education and information, are preferable to mandatory ones, provided they are effective. Non-mandatory measures are less controversial and easier to introduce, and do not 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 thought 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 discontinued as required to avoid harmful consequences.
- The importance of implementing measures in consultation with the broader community and after explaining the reasons for their introduction.²

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² In November 2007, just before the start of NICE’s public consultation on this document, the Nuffield Council on Bioethics published ‘Public Health: ethical issues.’ It is available at http://www.nuffieldbioethics.org/go/ourwork/publichealth/introduction. This important contribution to the literature on the ethics of public health emphasises two concepts (‘stewardship’ and ‘the intervention ladder’) that may well be useful to NICE in developing its approach to deciding between mandatory and non-mandatory approaches. NICE intends to explore this further.
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 NICE’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 NICE 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 supporting people who are putting NICE guidance into practice.

Principle 8

When choosing guidance topics, when developing guidance and when supporting people who are putting the guidance into practice, NICE should actively target health inequalities, such as those associated with sex, age, race, disability and socioeconomic status.
9 Following the principles

The work of NICE must follow the principles in 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 and also 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 and ensure compliance to these principles, particularly with respect to legislation on human rights, discrimination and equality.