

# National Institute for Health and Clinical Excellence

## Memorandum of Evidence to the Health Select Committee March 2007

### Introduction

- 1 NICE is responsible for providing national guidance on the promotion of good health and the prevention and treatment of ill health, in three areas:
  - Health technologies – guidance on the use of new and existing medicines, treatments and procedures, including interventional procedures used in the NHS.
  - Clinical practice – guidance on the appropriate treatment and care of people with specific diseases and conditions within the NHS.
  - Public health – guidance on the promotion of good health and the prevention of ill health for those working in the NHS, local authorities and the wider public and voluntary sector.
- 2 The Institute and its remit have grown rapidly since its establishment in 1999 and it is now the primary source of clinical standards, based on clinical and cost effectiveness, in England, Wales and Northern Ireland. The applicability of NICE guidance in the UK, as a whole, is summarised in Table 1.

**Table 1: Applicability of NICE guidance in the UK**

Country	Technology appraisals	Clinical guidelines	Interventional procedures	Public health guidance
England	Yes	Yes	Yes	Yes
Wales	Yes	Yes	Yes	No
Scotland	Yes <sup>a</sup>	No	Yes	No
N Ireland	Yes <sup>b</sup>	Yes <sup>b</sup>	Yes	No

<sup>a</sup> With advice on implementation in Scotland from NHS Quality Improvement Scotland and <sup>b</sup> in Northern Ireland, from the DHSSPNI.

- 3 Established in April 1999 to set clinical standards as part of a comprehensive quality framework for the NHS, our role has since been extended. The public health white paper *Choosing Health*, published in November 2004, confirmed the Institute's new role in providing the NHS and the wider community with guidance on effective public health practice. NICE merged with the Health Development Agency in April 2005 (producing a saving of £3 million) and by the end of 2006 systems to deliver public health interventions and programme guidance were fully established and beginning to provide guidance in a wide range of areas, including physical activity, smoking cessation, sexually transmitted infection and drug misuse.
- 4 The implementation of NICE guidance is, for obvious reasons, of fundamental importance. In 2004, the Institute launched a series of initiatives, described in more detail later in this submission, designed to support the NHS and the wider public health community to make better, more rapid and more consistent use of our recommendations.
- 5 In December 2006, the Department of Health published *Safety First*, the review of patient safety arrangements commissioned by the Chief Medical Officer. The review made a number of recommendations about the future of patient safety, including the establishment of a Patient Safety Forum, which includes NICE in its membership. The report also recommended that NICE pilot the development of technical patient safety solutions commissioned by the National Patient Safety Agency (NPSA). This is now being taken forward and will be completed in the Autumn of 2007. In February 2007, the Institute co-signed the Patient Safety Charter alongside the NPSA, the Healthcare Commission and other national bodies to emphasise organisational commitment to improving patient safety.
- 6 In addition to its current responsibilities, the Institute believes that the responsibilities of the National Screening Committee and the Joint Committee on Vaccination and Immunisation should fall within the scope of NICE, for the following reasons. First, both screening and immunization are bulwarks of public health. Since NICE is developing other forms of public health guidance it makes sense for the Institute to become involved. Second, the distinction between immunization to prevent disease, and immunization as a treatment, has become increasingly blurred with the emergence of 'therapeutic vaccines'. Third, aspects relating to screening have become an increasing part of NICE guidelines, based on the remits given to us by the Department of Health. Our ability to take on this and any other new work which it may be appropriate for us to carry out will require additional resources. Of course, before any organisation can ask for more money, it needs to be able to demonstrate that it has made the best use of what it already has. The Institute has made more than £5.5 million in efficiency savings over the last 2 years. It has a budget, for

2006/7, of £31 million and employs around 240 staff.

- 7 The House of Commons Health Select Committee undertook an Inquiry into NICE in 2002. Annex 1 describes the actions taken by the Institute in response to the Committee's recommendations. Additional background information about the Institute is set out in Annex 2.
  
- 8 The Institute believes that it has established a reputation, both in the United Kingdom and throughout the world, for a thorough, fair, transparent and inclusive process which leads to credible and robust guidance. It is in the nature of the work that NICE does that its advice will sometimes be controversial. After all, our purpose is to help the country to decide on the best use of the resources it devotes to the health service; resources which are, although increasing, invariably limited. Such judgements will inevitably and rightly be subject to scrutiny from those who have a direct interest in them and from the media. It is why we welcome this Select Committee inquiry and the opportunity that it provides for us to explain the way we work and to record what we have achieved.

## Health Select Committee Inquiry

### Why NICE's decisions are increasingly being challenged

9 We do not believe that there is any objective evidence that indicates that NICE's decisions are *increasingly* being challenged, although we are conscious that there has been, in recent times, an increase in the reporting of the Institute's decisions.

9.1 The frequency of appeals against the Appraisal Committee's draft guidance has shown no significant change over the years (Table 4).

**Table 4: Appeals in the technology appraisals programme**

<b>Year</b>	<b>Published appraisals (total)</b>	<b>Appeals submitted (total)</b>
2000	17	7
2001	14	7
2002	24	8
2003	19	3
2004	13	4
2005	6	5
2006	20	5
2007	6	1
<b>Total</b>	<b>119</b>	<b>40</b>

Note: This Table does not include appeals against final draft guidance which have been upheld on appeal but have yet to be published.

9.2 With few exceptions, the Institute's published clinical guidelines have been well received by both health professionals and patient organisations.

- 9.3 The Institute established a 'review' process in its interventional procedures programme in 2005. Since then, 24 out of 72 pieces of guidance have been the subject of requests for reviews of decisions. Ten were upheld but all required only minor changes to the wording. None was referred back to the Interventional Procedures Advisory Committee.

**Whether public confidence in the Institute is waning, and if so why**

- 10 NICE guidance, especially when it advises against the use of interventions on grounds of cost ineffectiveness, is sometimes uncomfortable and on occasions, controversial. Much of NICE's guidance, however, is positive and promotes the use of effective treatments which improve the quality of care that patients can expect to receive from the NHS.
- 11 Polling data since 2002 (Table 5) indicates that although the proportion of respondents aware of NICE has risen, those who are neutral or positive about its guidance have remained constant at between 67 and 72%. This is broadly consistent with the results of an independent media audit (covering the period April 2005 to April 2006) carried out on behalf of NICE, showing that 63% of the 'overall tone' of NICE's media coverage was either neutral or positive.

**Table 5: Awareness and Image of NICE<sup>1</sup>**

<b>Year</b>	<b>Awareness of NICE</b>	<b>Rating of NICE's image (neutral or positive)</b>
2002	25%	67%
2004	27%	72%
2006	36%	71%
2007	34%	71%

1 Data from ICM Omnibus Poll with sample sizes of 1005 (2002), 1010 (2004), 1002 (2006) and 1002 (2007)

- 12 The extensive, and increasing, traffic on the Institute's website provides a further indication of the value placed on NICE guidance by both national and international audiences (Table 6).

**Table 6: Annual NICE website traffic (2001 to 2006)**

Year	Hits	Visitor sessions
2001	3,888,936	597,636
2002	6,595,428	745,404
2003	8,810,760	1,185,036
2004	30,845,064	2,723,568
2005	46,027,164	4,928,304
2006	74,051,952	9,041,448

- 13 The quality of NICE guidance has been commended in recent reports from the World Health Organization <sup>12</sup> the Audit Commission <sup>3</sup>, and the Office of Fair Trading <sup>4</sup>; and its relevance to the NHS is confirmed in the report of the Ministerial Industry Strategy Group <sup>5</sup>. An editorial in the *Lancet* (2005) described the Institute in the following terms: “...NICE's hard-won and well-deserved reputation for independence and scientific rigour....”; and the editor of the *British Medical Journal* (2004) stated: “NICE may prove to

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<sup>1</sup> World Health Organisation (2003) *The Technology Appraisal Programme of the National Institute for Clinical Excellence*. Copenhagen: World Health Organization.  
[www.nice.org.uk/pdf/boardmeeting/brdsep03itemtabled.pdf](http://www.nice.org.uk/pdf/boardmeeting/brdsep03itemtabled.pdf)

<sup>2</sup> World Health Organisation (2006) *The Clinical Guideline Programme of the National Institute for Health and Clinical Excellence*. Copenhagen: World Health Organisation.  
[www.nice.org.uk/page.aspx?o=399754](http://www.nice.org.uk/page.aspx?o=399754)

<sup>3</sup> Audit Commission (2005) *Managing the Financial Implications of NICE Guidance*. London: Audit Commission.  
[www.audit-commission.gov.uk/reports/NATIONAL-REPORT.asp?CategoryID=&ProdID=CC53DDFE-42C8-49c7-BB53-9F6485262718](http://www.audit-commission.gov.uk/reports/NATIONAL-REPORT.asp?CategoryID=&ProdID=CC53DDFE-42C8-49c7-BB53-9F6485262718)

<sup>4</sup> Office of Fair Trading (2007) *The Pharmaceutical Price Regulation Scheme – an OFT market study*. London: Office of Fair Trading.  
[www.offt.gov.uk/shared\\_offt/reports/comp\\_policy/oft885.pdf](http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft885.pdf)

<sup>5</sup> Ministerial Industry Strategy Group (2007) *Long-Term Leadership Strategy* London: Department of Health; ABPI.  
[www.dh.gov.uk/assetRoot/04/14/28/49/04142849.pdf](http://www.dh.gov.uk/assetRoot/04/14/28/49/04142849.pdf)

*be one of Britain's greatest cultural exports, along with Shakespeare, Newtonian physics, the Beatles, Harry Potter, and the Teletubbies”.*

### **NICE’s evaluation process and whether any particular groups are disadvantaged by the process**

- 14 When developing advice for the NHS and wider public health community, the Institute bases its conclusions on the best available evidence. The best available evidence is rarely (if ever) complete. It may be of poor quality, lack critical elements, or both. Those responsible for formulating the Institute’s advice about efficacy, effectiveness, cost effectiveness and safety are therefore required to make two categories of judgments. These are scientific value judgments, which are concerned with interpreting the significance of the available scientific, technical and clinical data and social value judgements, which take account of the ethical principles, preferences, culture and aspirations that should underpin the nature and extent of the care provided by the NHS.

#### ***Scientific value judgments***

- 15 In the development of its guidance, the Institute is required to take account of both clinical/public health effectiveness as well as cost effectiveness. The Institute’s approach to assessing clinical/public health *effectiveness* has rarely caused significant adverse comment or controversy. The basis of the Institute’s approach to economic evaluation, however, has sometimes been misunderstood or misinterpreted.
- 16 Cost utility analysis is the Institute’s preferred approach to evaluating cost effectiveness. This allows both the improvement in health outcome (referred to as ‘health gain’), and the increased costs associated with it, to be compared to current standard practice. The principle measure of value for money is the incremental cost effectiveness ratio (ICER), expressed as the cost per quality adjusted life year (cost/QALY). This approach allows the cost effectiveness of one technology for one particular condition, to be compared with the cost effectiveness of another technology in a different condition.
- 17 NICE is required under the terms of its Directions (Directions and Consolidating Direction to the National Institute for Health and Clinical Excellence, March 2005. Section 2) to have regard to the “effective use of resources available in the health service and other available public funds” The Institute’s Framework Document, issued by the Department of Health in 2000, indicates (Annex C, paragraph 10) that NICE, in its appraisal of health technologies, should assess whether they can be recommended as “a cost-effective use of NHS and PSS resources”. Finally, the Institute is required to evaluate cost effectiveness (that is, value-for-money) rather than affordability or budgetary impact.

- 18 Health gain is assessed by linking the increased health-related quality of life, attributable to the new treatment (compared to current standard practice), with the time for which it is enjoyed. This enables the quality adjusted life year (QALY) to be calculated. The main assumption embodied in QALYs is that health-related quality of life can be captured in terms of:
- physical mobility,
  - ability to self care,
  - ability to carry out the activities of daily living,
  - absence of pain and discomfort, and
  - absence of anxiety and depression.
- 19 Having established the most plausible cost per QALY the Institute's advisory bodies must then assess whether this represents value-for-money for the NHS. There is no empirical research to indicate the cost per QALY threshold that should be applied and NICE has not adopted one. Instead, it provides its advisory bodies with a framework for decision-making as follows<sup>6</sup>:
- *Below a most plausible ICER of £20,000/QALY, judgements about the acceptability of a technology as an effective use of NHS resources are based primarily on considerations on the cost effectiveness estimate.*
  - *Above a most plausible ICER of £20,000/QALY, judgments about the acceptability of the technology as an effective use of NHS resources are more likely to make more explicit reference to factors including the degree of uncertainty of the ICER, the innovative nature of the technology, the particular features of the condition and population receiving the technology, and (where appropriate) the wider societal costs and benefits."*
  - *Above an ICER of £30,000/QALY the case for supporting the technology on these factors has to be increasingly strong.*
- 20 In making these judgments NICE recognizes that its advisory bodies need to take social, as well as scientific, factors into account. The Institute has therefore developed guidance – *Social Value Judgments: Principles for the Development of NICE Guidance* – for its advisory bodies to use as a point of reference (see 23 -25 below). The Institute acknowledges that the cost per QALY can only inform, and not determine, NICE guidance.
- 21 The Institute's approach to assessing cost effectiveness has been criticized, in particular, for three reasons.

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<sup>6</sup> From *Guide to the Methods of Technology Appraisal*. National Institute for Clinical Excellence (April 2004)

- 21.1 It has been suggested that the economic perspective, used by NICE, should encompass the broader economic implications of its recommendations. Irrespective of the merits of such an approach, the Institute's Directions currently preclude it.
- 21.2 It has been postulated that the measurement of health-related quality of life is either unreliable or fails to capture some essential components. This is not supported by the evidence. Health-related quality of life instruments such as the EQ-5D have been validated amongst many thousands of people across Europe and North America. They have been shown to capture the major components of health gain (either directly or indirectly). And they are widely used by health technology assessment centres across Europe, Australasia and North America.
- 21.3 It has also been alleged that QALYs disadvantage the elderly. This is incorrect in both theory and in practice. In practice, we have found that estimates of the cost per QALY can be advantageous to older people. For example, the Institute recommends that drug treatments for flu should be made available for people over-65 as they are a vulnerable group and likely to be more seriously affected by flu than younger people. Older people would only be potentially disadvantaged by QALYs in the event of a hugely expensive, curative procedure whose benefits were lifelong. A child aged three would then be likely to enjoy more than 70 years of benefit compared to the additional five years or so that an 80-year old. To date, NICE has not been asked to look at a single procedure of this type. Importantly, the Institute has emphasized in its *Social Value Judgments* document that the 'value' of a QALY should not be age-related.
- 22 The scientific basis for economic evaluation in healthcare is moving rapidly and there are inevitably aspects of NICE's methodology that should be reviewed. A review of the Institute's methodology for technology appraisals is starting in March 2007 with a view to taking a paper to the Institute's Board in November 2007. This review will focus on areas where methods have evolved over the last three years or where NICE's methodological approach is being questioned. These areas include: evidence synthesis; exploring uncertainty; identifying subgroups and exploring heterogeneity; health related utility measurement; equity and social value judgements; and estimation of costs.

## **Social value judgments**

23 The Institute's *Social Value Judgments*<sup>7</sup> document has been produced to help NICE and its advisory bodies in developing guidance. They describe the social value judgements that should, generally, be incorporated into the methods used to develop NICE guidance. The principles are set out in summary form below.

- *Principle 1* – The fundamental principles that underpin the processes by which NICE guidance is developed should be maintained for current, and applied to future, forms of guidance.
- *Principle 2* – For both legal and bioethical reasons those undertaking technology appraisals and developing clinical guidelines must take account of economic considerations.
- *Principle 3* – NICE guidance should not support the use of interventions<sup>8</sup> for which evidence of clinical effectiveness is either absent or too weak for reasonable conclusions to be reached.
- *Principle 4* – In the economic evaluation of particular interventions, cost–utility analysis is necessary but should not be the sole basis for decisions on cost effectiveness.
- *Principle 5* – NICE guidance should explain, explicitly, reasons for recommending – as cost effective – those interventions with an incremental cost-effectiveness ratio in excess of £20,000 to £30,000 per QALY.
- *Principle 6* – NICE clinical guidance should only recommend the use of a therapeutic or preventive intervention for a particular age group when there is clear evidence of differences in the clinical effectiveness of the measure in different age groups that cannot be identified by any other means.
- *Principle 7* – In setting priorities there is no case for the Institute or its advisory bodies to distinguish between individuals on the basis of gender or sexual orientation unless these are indicators for the benefits or risks of preventative or therapeutic interventions.
- *Principle 8* – In developing clinical guidance for the NHS, no priority should be given based on individuals' income, social class or position in life and individuals' social roles, at different ages, when considering cost effectiveness. Nevertheless, in developing its approach to public

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<sup>7</sup> National Institute for Health and Clinical Excellence. Social Value Judgements. [www.nice.org.uk/page.aspx?o=283494](http://www.nice.org.uk/page.aspx?o=283494)

<sup>8</sup> The term “intervention” is used in these guidelines to encompass health technologies and any other measure used to influence the course of a particular condition.

health guidance, NICE wishes its advisory bodies to promote preventative measures likely to reduce those health inequalities that are associated with socioeconomic status.

- *Principle 9* – NICE clinical guidance should only recommend the use of an intervention for a particular racial (ethnic) group if there is clear evidence of differences between racial (ethnic) groups in the clinical effectiveness of the intervention that cannot be identified by any other means.
- *Principle 10* – NICE and its advisory bodies should avoid denying care to patients with conditions that are, or may be, self-inflicted (in part or in whole). If, however, self-inflicted cause(s) of the condition influence the clinical or cost effectiveness of the use of an intervention, it may be appropriate to take this into account.
- *Principle 11* – Although respect for autonomy, and individual choice, are important for the NHS and its users, they should not have the consequence of promoting the use of interventions that are not clinically and/or cost effective.
- *Principle 12* – It is incumbent on the Institute and its advisory bodies to respond appropriately to the comments of stakeholders and consultees and, where necessary, to amend the guidance. The board is aware, however, that there may be occasions when attempts are made (directly or indirectly) to influence the decisions of its advisory bodies that are not in the broad public interest. The board requires the Institute, and members of its advisory bodies, to resist such pressures.
- *Principle 13* – Priority for patients with conditions associated with social stigma should only be considered if the additional psychological burdens have not been adequately taken into account in the cost–utility analyses.

The Institute recognises, however, that there will be circumstances when, for valid reasons, departures from these general principles are appropriate. When departures from these principles are made, the reasons should be explained.

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

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

25 *Social Value Judgments* will be formally reviewed in 2007.

### **The speed of publishing guidance**

26 NICE guidance has not always appeared as quickly as patients or the NHS would have wished. This has sometimes been because we have not been asked to evaluate a new treatment early enough or because we have not had enough capacity to do so immediately, or as a result of a combination of both. In addition, because we offer the opportunity for an appeal, guidance can be delayed in order for such challenges to be heard and for the consequential action to be taken. It is also the case that because NICE regards its job as finding out precisely where a treatment works best, sometimes time-consuming investigation needs to be undertaken. This is, however, much better than defaulting to the easier option of simply saying no, in the face of uncertainty.

27 When presenting evidence to the Health Select Committee inquiry into NICE in 2002, the Institute put forward the view that it should be routinely commissioned to undertake reviews of technologies at an early stage in their development to enable guidance to be issued to the NHS at or shortly after they became available for use in the NHS. To increase the speed of the development and publication of its technology appraisal guidance the Institute has put in train the following measures:

27.1 In 2006 the Institute took over, from the Department of Health, the preparatory work associated with selecting topics for NICE to develop guidance. Topic selection is now centred on Consideration Panels most of which are chaired by the relevant National Clinical Director. Decisions about which topics should be formally referred still remain the responsibility of ministers. For technology appraisals, ministers consult before confirming their decision to refer to NICE.

27.2 In November 2005, the Institute established a new process for technology appraisals – the Single Technology Appraisal (STA) process, for new pharmaceuticals (or devices), or for new major indications. In this process the assessment report (including the associated economic model) is prepared by the manufacturer rather than an academic Health Technology Assessment centre. Moreover, provided the Advisory Committee recommends use in

the NHS that is broadly comparable to the licensed indications, the general consultation period is omitted (although the opportunity for an appeal is retained).

- 27.3 Provided this process starts around the time the manufacturer requests marketing authorization from the relevant drug regulatory authority and, subject to appeal, NICE expects to be able to advise on use in the NHS within 3 months of licensing. In the case of Herceptin, where all these conditions were met, the Appraisal Committee issued its final draft guidance within 3 weeks of the granting of a marketing authorization by the European Commission. The STA process has been facilitated by the withdrawal of the pharmaceutical industry's longstanding opposition to early appraisals of new products.
- 27.4 Timelines for the Institute's clinical guidelines have been reduced by eliminating one of the three consultation steps. Most stakeholders have agreed to this because of the consequent 3 month reduction in development time. The Institute has also instituted a short guideline programme for those instances where the NHS seeks advice on a relatively narrow area of practice. This should not take more than 12 months to complete including two periods for consultation with stakeholders.

### **The appeal system**

- 28 Appeals against the Appraisal Committee's final draft guidance are an integral part of the technology appraisal process. The details of the procedures are shown in Table 6 on p.15. Appeals provide registered consultees (sponsors of the technology, relevant professional and patient organisations, and two representatives of Primary Care Trusts) with an opportunity to make representations against the proposed guidance.
- 29 The appeal process is based on the principles of English administrative law. It is not intended, or designed, to provide an opportunity for technologies to be re-appraised, or for an appraisal to be challenged on its merits, save on limited grounds. Rather, it requires the Appraisal Committee:
  - 29.1 To demonstrate that the appraisal has been undertaken fairly and in accordance with the Institute's published processes. (This is treated as two separate requirements so that an appraisal must both be fair and also in accordance with the Institute's published procedures);
  - 29.2 To show that it has not acted perversely in reaching its conclusions;

29.3 To indicate that its recommendations do not exceed the legal powers of the Institute.

These grounds of appeal mirror the administrative court’s jurisdiction on a judicial review.

30 Appeals are heard, in public, by a panel comprising three non-executive directors of the Institute (or two non-executive directors together with a clinician actively working in the National Health Service); an individual with experience in the relevant industry following consultation with the relevant trade associations; and a lay representative.

31 Over the period of NICE’s existence the Appraisal Committee’s final draft recommendations have been subject to 43 appeals. Details are shown in Table 6. All panels’ decisions have, to date, been unanimous.

**Table 6: appeals in the technology appraisal programme and their outcomes**

<b>Year</b>	<b>Published appraisals (total)</b>	<b>Appeals submitted (total)</b>	<b>Appeals allowed (withdrawn or dismissed without a hearing)</b>	<b>Appeals upheld after a hearing</b>	<b>Appeals dismissed after a hearing</b>
2000	17	8	8 (0)	2	6
2001	14	5	4 (1)	1	3
2002	24	11	10 (1)	7	3
2003	19	4	4 (0)	1	3
2004	13	5	2 (3)	1	1
2005	6	3	3 (0)	0	3
2006	20	6	6 (0)	3	3
2007	6	1	1 (0)	1	0
<b>Total</b>	<b>119</b>	<b>43</b>	<b>38 (5)</b>	<b>16</b>	<b>22</b>

- 32 Two particular criticisms of the Institute’s appeal system have been made: that the grounds for appeal are drawn too narrowly; and that the membership of appeal panels should be confined to individuals with no formal connection with NICE.
- 32.1 The grounds for appeals are provided in the Institute’s Directions and are fully compatible with English administrative law. The Board does not seek to enlarge their scope and, in particular, considers it would be inappropriate for an appeal panel to attempt to re-appraise the clinical and cost effectiveness technologies under consideration.
- 32.2 The membership of appeal panels appropriately includes non-executive directors of the Institute. It is important to emphasise that appeals in the technology appraisals programme relate to the Appraisal Committee’s, not the Institute’s, final draft guidance. This distinction is important: the Appraisal Committee’s final draft guidance only becomes formal “NICE Guidance” once it has been accepted by the Institute’s Guidance Executive (acting, with delegated powers, on behalf of the Board). As members of appeal panels, non-executive directors are fulfilling their role as custodians of the quality and probity of NICE guidance.
- 32.3 The data in Table 6 shows that half of all allowed appeals have been upheld on one or more grounds. The notion that appeal panels might be inherently prejudiced in favour of the Appraisal Committee is not born out by the evidence.

### **Comparison with the work of the Scottish Intercollegiate Guidelines Network**

- 33 Scotland has two organisations with responsibilities that are similar to some of those of NICE. The Scottish Intercollegiate Guideline Network (SIGN) develops clinical guidelines; and the Scottish Medicines Consortium (SMC) appraises pharmaceuticals for their clinical and cost effectiveness.
- 34 SIGN, now part of NHS Quality Improvement Scotland, has published 96 clinical guidelines since its formation by the late Professor James Petrie in 1993. Like NICE, its guidelines are developed by multi-disciplinary groups including both health professionals and representative service users after a review of the relevant literature. Its guideline development time development time is normally between 24 and 30 months.
- 35 There are several differences between the status and methodological development of SIGN and NICE guidelines.

- NICE clinical guidelines form part of the performance management process of the English NHS and are developmental standards. SIGN guidelines do not have such status within the Scottish NHS.
- NICE guidelines are based on considerations of both clinical and cost effectiveness. SIGN guidelines have historically focused solely on clinical effectiveness.
- NICE's guideline development groups include (or have ready access to the skills of) guideline methodologists, statisticians, meta-analysts and health economists.

36 The SMC provides Scottish Health Boards solely with advice on the clinical and cost effectiveness of new pharmaceutical products. There are, however, important differences between NICE's technology appraisals programme and that of the SMC. Many of these relate to the Institute's core principles for developing robust guidance.

- NICE technology appraisals evaluate all categories of health technologies as directed by the Secretary of State for Health. The SMC only considers pharmaceutical products.
- NICE's technology appraisals follow published processes and methods that have been subject to public consultation. There are no equivalent documents governing the work of the SMC.
- NICE includes a comprehensive scoping phase designed to identify the basis, and appropriate boundaries, for each appraisal and is the subject of early consultation. This is pivotal as it ensures an appropriate focus for a robust appraisal. SMC has no equivalent process.
- Stakeholders (relevant patients and professional organisations, as well as healthcare industries) interact with every stage of the NICE appraisal process and have several opportunities to make their case. By contrast, the SMC's engagement and consultation processes are limited in both scope and breadth.
- All NICE's technology appraisals are subject to public consultation where preliminary recommendations are restrictive or at variance with the product's marketing authorisation. The SMC does not engage in public consultation for any of its recommendations and recommendations emerging from its New Drugs Sub-Committee are only sent to the sponsor of the technology for comment.
- NICE has a formal appeal, held in public, as part of its technology appraisal process. The SMC has no formal appeal process although it

does have a mechanism for reviewing its decisions when these are challenged.

**The implementation of NICE guidance, both technology appraisals and clinical guidelines (which guidance is acted on, which is not, and the reasons for this)**

- 37 NICE guidance is developed for the NHS in England. Some forms are also applicable in the other UK countries through Service Level Agreements (see Table 1).
- 38 When the Institute was first established NICE was not expected (as indicated in *A First Class Service*) to play any part in the implementation of its guidance. In 2003, however, the board agreed to commit some of the Institute's resources to the establishment of an Implementation Directorate which was launched in 2004.
- 39 NICE's implementation strategy has three main elements: encouraging change by working through other organisations/mechanisms to generate 'leverage'; providing practical support; and monitoring the uptake of recommendations.
- 39.1 Other organizations or programmes with whom the Institute is actively working, to secure the implementation of its guidance include the Healthcare Commission; the Quality and Outcomes Framework; the National Tariff; Connecting for Health and the National Knowledge Service; the Royal Medical, Nursing and Midwifery Colleges; the Litigation Authority; the National Institute for Improvement and Innovation; and the Audit Commission.
- 39.2 Providing practical support includes the provision of a guide entitled *How to Implement NICE Guidance*; a forward planner on the NICE website; cost impact tools to help local NHS organisations estimate likely costs and savings; other practical tools (for example, audit criteria, slide sets and practical implementation advice); commissioning guides in an interactive web-based format; a small team of implementation consultants to provide practical support and advice to NHS trusts; and a shared learning database on the NICE website (ERNIE).
- 39.3 To monitor the uptake of its guidance NICE collects, analyses and collates published and unpublished reports to build up a comprehensive overview. This is available on the NICE website in a dedicated database (Evaluation of Reviews of NICE Implementation Effectiveness, ERNIE). Examples of the information held on ERNIE are set out in Annex 2.

- 40 The most comprehensive assessment of the uptake of NICE guidance, by the NHS as a whole, is provided in the Healthcare Commission's 2005-6 annual health check. This was confined to an assessment of institutions' compliance with "core" standards in the Department of Health's *Standards for Better Health*. NICE's technology appraisals and interventional procedures were included in this and the results are shown in Table 7.

**Table 7**

**Self-assessment of Compliance with NICE Interventional Procedure (IP) and Technology Appraisal (TA) Guidance**

<b>Core Standard</b>	<b>Total</b>	<b>Compliant (%)</b>	<b>Insufficient assurance</b>	<b>Not met (%)</b>
<b>CO3 (IPs)</b>				
- Acute trusts	171	153 (89)	13 (8)	5 (3)
- Mental Health Trusts	61	61 (100)	0 (100)	0 (100)
- PCTs	302	266 (88)	27 (9)	9 (3)
<b>CO5 (TAs)</b>				
- Acute trusts	171	142 (83)	17 (10)	12 (7)
- Mental Health Trusts	61	57 (93)	2 (3)	2 (3)
- PCTs	302	248 (82)	43 (14)	11 (4)

Note: It should be emphasized that these returns represent Institutions' own evaluation of their compliance and the results of a deeper inquiry, on a sample of trusts, has yet to be published. The Healthcare Commission plans to include an assessment of compliance with NICE clinical guidelines in its next annual health check (2006-7).

- 41 The main barriers to implementing NICE guidance identified by the Institute are: lack of resources; disagreement with the recommendations; and lack of a clear organisational process.

- 41.1 The issue of lack of resources can, to a considerable extent, be mitigated by careful financial planning as described in the Audit Commission's report *Financial Planning for NICE Guidance*.
- 41.2 To avoid clinical disagreement with its recommendations NICE engages with clinicians at all stages of the guidance development process. As NICE's national and international reputation has increased, however, such disagreements appear to have considerably reduced.
- 41.3 The lack of organisational support for the implementation of NICE guidance (including board support) has improved since the publication of the *How to Implement NICE Guidance* but recent financial pressures mean that some trusts lack the capacity to manage change, particularly in areas such as clinical audit.

## Annex 1

### Responses to the Health Committee's 2002 Report

1. In its 2002 report, the Committee directed a number of recommendations to both NICE and the government. Those recommendations relevant to the Institute (in bold italics below) are reproduced together with NICE's subsequent actions.
2. ***To neglect the input of respected bodies such as the Drug and Therapeutics Bulletin and the British National formulary is to miss a key opportunity for quality assuring NICE's work, and risks serious damage to the credibility of its guidance. We recommend that NICE puts in place robust mechanisms to ensure closer and more constructive collaborative working with BNF, DTB, and other similar bodies. Although we recognise that such bodies may not have the capacity to contribute to every piece of guidance that NICE issues, they should be allowed a formal opportunity to contribute to work where they have relevant expertise, and there should be an established mechanism for discussing and resolving technical differences (paragraph 26).***

The Institute recognised the potential contributions from collaboration with bodies undertaking comparable work and entered into formal arrangements with the editors of the British National Formulary, the Drug and Therapeutics Bulletin, and the MeReC Bulletin to seek comments on draft appraisals of pharmaceutical technologies.

3. ***Involving such a broad sweep of stakeholders is a complex and time-consuming task, and we welcome NICE's efforts in this area to date. We recommend that NICE should take steps to improve its stakeholder identification methods, to ensure that relevant bodies and individuals are systematically identified for inclusion. If NICE is to gain the full respect of the medical profession, it is essential that it involves clinicians with relevant clinical experience, alongside those capable of taking a broad overview. NICE should consider the possibility of inviting stakeholders in the technology appraisal process to 'self nominate' in the same way as they are permitted to in the clinical guidelines process.***

From the outset, the Institute had in place arrangements for relevant professional organisations to act as full consultees in appraisals. Arrangements were also in place for stakeholders to self nominate at any point in the appraisal process up to the ACD stage. However, following the Committee's Report, the Institute extended the remit of its Public and Patient Involvement Unit (PPIU) to include appraisals as well as guidelines (and, now, interventional procedures and public health). The Unit has well-developed developed strategies for ensuring that appropriate patient

and carer organisations are invited to act as stakeholders/consultees in all NICE's guidance programmes.

The Institute now has a database of over 2,000 clinical, patient and industrial organisations. No request to act as a stakeholder is refused provided the body falls within the Institute's definition of a national body with a relevant interest.

- 4. We recommend that NICE takes steps to improve current methods of involving the NHS in the development of technical appraisals and clinical guidelines, including arrangements for the NHS to be involved in a timely appeal process. Measures to achieve this might include the extension of membership of the Appraisal Committee to more than two NHS representatives; and the establishment of a network of designated individuals within NHS Trusts and strategic health authorities, through whom NICE can maintain open dialogue with working clinicians and commissioners of care throughout the guidance development process. These individuals would be able to act as intermediary facilitators between NICE and the wider NHS, acting as a local source of reference about NICE's processes and promoting the implementation of its guidance, as well as ensuring the systematic inclusion of NHS representatives in NICE decision-making.***

NHS staff have, since the Institute's inception, formed a majority of the membership of the Appraisal Committee. Since 2002 two PCTs (different for each topic) have also been designated as appellate consultees in the appraisal process to allow additional NHS input. One PCT has used this position to appeal against the Appraisal Committee's final draft guidance (in the case of Herceptin for early stage breast cancer). The Institute welcomed the suggestion to creating a network of NICE clinicians and commissioners to act as a conduit for information and to assist in the implementation of its guidance. It continues to pursue the development of such networks.

- 5. We welcome NICE's attempts to achieve better relationships and open channels of communication with stakeholders – particularly the professional and patient groups. The future credibility of NICE rests on its being responsible to criticisms, and to its being willing to study them, and if necessary, learn from them. Wherever possible any resulting press statements about the resolution of disagreements should be agreed with the other parties involved before release.***

We agreed that it was in the interests of patients that disagreements between the Institute and its stakeholders be resolved cordially and we always work to achieve a satisfactory resolution. It is important when doing so, however, to ensure that accurate information about our guidance

is placed in the public domain. Moreover, where the Institute is subject to unwarranted criticism by stakeholders NICE must reserve the right to respond in the interests of patients and the wider public.

6. ***We recommend that all information which NICE uses in its decision-making process is made available for public scrutiny. If industry or others have previously unpublished data which they want to use to support their case then this should no longer be presented to NICE subject to confidentiality.***

NICE endorsed this proposal and the position has generally improved. It has not, however, been possible to implement the proposal in practice. NICE and the Association of the British Pharmaceutical Industry agreed an approach to the release of unpublished data but some restrictions remain. Nevertheless, where the sponsors of manufactured technologies have claimed data to be “commercial-in-confidence” or “academic-in-confidence” we have been able to obtain their agreement to allow reproduction of critical elements.

7. ***We recommend that NICE should improve the transparency of its processes by striving to make information on how and why its decisions are taken, and on members’ declarations of interests as readily and clearly available to lay stakeholders as possible. For the sake of clarity, members should declare all interests at the beginning of each appraisal. The decision-making audit trail could be improved if the NICE website supplemented its sections on individual technology appraisals with links to the minutes of all relevant meetings. It would also be helpful if, instead of listing the full membership of the Appraisal Committee, each guidance document listed those specific members who had taken part in decision-making on that particular treatment, and those who had withdrawn due to competing interests.***

The Institute has always been fully committed to the full disclosure of potential conflicting interests of the members of its advisory bodies. Members of the appraisal committee have always been required to disclose any interests at the start of each agenda item; and those with clearly conflicting interests play no part. The Institute instituted three further measures to improve the transparency and clarity with which decision-making audit trails could be made. First, it has ensured that its website facilitates searches between its technology appraisal guidance and the relevant appraisal committee minutes. Second, the unconfirmed minutes of the appraisal committee meetings are posted on the NICE website as soon as they have been agreed by its chair. These are replaced by the confirmed minutes, when they are available. Third, technology appraisal guidance documents record only those members of

the appraisal committee actually involved (rather than the full membership).

8. ***Improvement in the inclusiveness and transparency of NICE's processes are needed to ensure that the appeals process is not the only means for stakeholders to enter into constructive dialogue with NICE (Paragraph 45).***

The appeal process has never been the sole means through which stakeholders can engage with us. Consultees in the technology appraisal process attend "scoping meetings" at the start of an appraisal, and they have opportunities to comment on the evidence used as well as the initial and final draft recommendations. Comparable opportunities are provided to stakeholders in the Institute's other programmes.

9. ***The current role of the Chair in the appeals system seems to be us to be flawed. We recommend that the government gives careful consideration to reforming the appeals system as it has at least the appearance of lacking impartiality. We are also concerned that the distance this creates between the chair and the everyday business of NICE may be to the detriment of the organisation as a whole.***

Although the board disagreed with the implication that its appeal system lacked impartiality it nevertheless agreed, in 2002, that the chair of the Appeals Committee should be occupied by one of the non executive directors; and that decisions about the validity of appeals should be taken (with legal advice) by the chair of this committee. The Institute did not, however, accept that the chair of the Institute should be disqualified from either chairing, or sitting as a member of, an appeal panel.

In this context it is important to emphasise that appeals in the technology appraisals programme relate to the Appraisal Committee's, not the Institute's, final draft guidance. This distinction is important: the Appraisal Committee's final draft guidance only becomes "NICE Guidance" once it has been formally accepted by the Institute's Guidance Executive or the Board.

10. ***We recommend that for all new technologies, NICE's work programme is arranged to facilitate publication of guidance at the time of launch. When this is not possible, NICE should conduct rapid 'interim' appraisals of clinical and cost-effectiveness to be published at the time of a treatment's launch, as was the case with zanamivir. The funding of these interim appraisals should not be mandatory. Although the amount and type of information available at time of launch may be less than ideal, an 'interim' appraisal will provide useful guidance until a more detailed appraisal of the treatment is conducted as part of NICE's expanding main function of developing clinical guidelines. While issuing revised guidance does have the***

***potential to cause confusion, we trust that NICE will learn from the experience of its zanamivir appraisal and be very explicit about the reasons for any changes in the new guidance. Appraisals on existing treatments or interventions should also be conducted as part of NICE's clinical guidelines programme (paragraph 67).***

NICE also strongly endorsed (and continues to endorse) the proposal that all new relevant technologies should have completed their appraisal around the time of their launch. The Institute's new single technology appraisal process, as discussed elsewhere in its evidence to the present Inquiry, is intended to facilitate this. Updates (reviews) of guidance are essential in maintaining the value and credibility of our guidance and are always triggered by material new evidence.

11. ***We recommend that the Government and NICE should clarify the legal status of NICE guidance in relation to the other legal duties incumbent upon clinicians and commissioners of health care (paragraph 68).***

The status of our guidance (as advice that should be fully taken into account by clinicians and NHS organisations) is clearly set out in all our documents. However, we recognise the importance of absolute clarity on this to NHS organisations (and to patients) and the status of all NICE guidance is now codified in *Standards for Better Health*. The status of NICE guidance in the devolved administrations is described, further, in our Evidence to this Inquiry.

12. ***We recommend that the Government ensures the systematic monitoring of the implementation of NICE guidance. The Government should ensure that CHI (and later, CHAI) is encouraged to undertake specific national reviews of NICE guidance in priority areas, and that strategic health authorities include the implementation of NICE guidance as part of their regular monitoring of PCTs and acute trusts. Monitoring data should then be used to review and improve systems for dissemination and the implementation.***

NICE strongly endorsed this proposal. The Healthcare Commission has, since 2005-6, included compliance with NICE guidance as part of its annual health check. This too is discussed further in the Institute's Evidence to the present Inquiry.

13. ***We recommend that the Government should consider what practical systems and structures could be put in place to improve the NHS's capacity to implement NICE guidance, including the possibility of designated individuals within NHS trusts and strategic health authorities liaising with NICE to facilitate implementation.***

Following the publication of the Committee's 2002 Report the Institute established an Implementation Systems Directorate headed by an executive director. The work of this Directorate is discussed elsewhere in the Institute's evidence to the present Inquiry.

14. ***Improved regulation of submission of information to NICE should be supplemented by closer working relationships between the MCA and NICE, including the sharing of appropriate summary information prepared for the CSM, in order to prevent duplication and strengthen the quality of NICE's output.***

Whilst sharing summary information, prepared for the CHM, may be of some assistance to NICE and its Appraisal Committee the increasing use of the centralised EU procedure for granting marketing authorisations means that the scope will be limited. Nevertheless, NICE and the MHRA work closely together in both the appraisals and guidelines programmes particularly in relation to safety.

15. ***We accept that there are limitations on the information that can be gained prior to the launch of a treatment, and that there is a tension between the difficulties in assessing clinical effectiveness at an early stage, and the NHS's evident need for guidance at the time of launch to help it manage the introduction (or restriction) of new treatments in the NHS. The system of appraisals at the time of launch that we have recommended does not preclude the possibility of conducting fuller appraisals of treatment's effectiveness when more information has been collected. Indeed, we recommend this should take place, but within the broader context of NICE's main work on clinical guidelines (paragraph 91).***

The Institute's continues its commitment to review its guidance as new information becomes. Of the 119 published appraisals 12 have been reviews of previous guidance. Our clinical guidelines are now also starting to be reviewed. In some instances, technology appraisal updates have been transferred to the clinical guidelines programme where this is clearly the most appropriate way of developing and presenting guidance to patients and the NHS.

16. ***We recommend that the Government institutes independent detailed peer review of a random selection of guidance prepared by NICE. This could be carried out by CHI/CHAI on a three-yearly basis (paragraph 99).***

NICE welcomed this proposal for an independent review of a selection of its guidance. In 2003 we invited the European Regional Office of the World Health Organisation to review the appraisals programme; and in 2006 the Regional Office undertook a review of the clinical guidelines programme. Both reports, whilst making many helpful suggestions to

improving our processes, strongly endorsed the overall quality of both programmes' guidance.

17. ***Whether or not Quality Adjusted Life Years are used, we recommend that NICE should consider the wider societal costs and advantages of particular treatments and in particular the wider costs and benefits to the public purse of reduced benefit dependency and improved ability to work both for patients and their carers (paragraph 102).***

The economic perspective the Institute is required to adopt is mandated in its Statutory Instruments and is limited to that of the National Health Service. The issue is discussed further in the Institute's evidence to the Committee's present Inquiry.

18. ***We note NICE's plans to establish a Citizens Council composed of "ordinary men and women around the country" to advise on these value judgements. We agree with the many witnesses who argued for a review of NICE's appraisal methodology, and the publication of clear criteria. We therefore recommend that NICE, aided by the Department of health, should conduct a review of its methodologies for assessing clinical and cost-effectiveness, which should result in the publication of a set of clear and consistent criteria for the assessment of both aspects. This should include a description of the weighting given to different types of evidence, a detailed argument for its use of Quality Adjusted Life Years, and the impact of both cost and clinical effectiveness on the final determination, including any cost-effectiveness 'thresholds'. In tandem with this, NICE should work to strengthen its cost-effectiveness evidence based by encouraging pharmaceutical companies to collect this type of data routinely..***

At the time of the publication of the Committee's report, in 2002, the Institute had already embarked on a full review of its technology appraisal processes and methods. A revised manual was published in 2004, which contains a full explanation of our approach to assessing and interpreting evidence, including the use of quality adjusted life years. A further revision, with full public consultation, is now being undertaken (see our evidence to the current Inquiry).

The work of the Citizens Council has been embodied in *Social Value Judgments: Principles for the Development of NICE Guidance* that provides our advisory bodies with advice on the social values that should normally underpin their work. This, too, will undergo revision, with full public consultation, during 2007.

19. ***We welcome in principle the idea of a web-based topic proposal system suggested in the Government's consultation, but this needs to be supported by a clear and transparent selection process for the***

***assessment of proposed topics. We feel that current government proposals for widening the membership of the Technology Advisory Group (TAG) still leaves the NHS, and in particular patients, under-represented. We therefore recommend that the skills mix of the TAG is further weighted towards these groups, and that the deliberations and decisions of TAG meetings are put into the public domain.***

There have been considerable changes to the topic selection process since the Committee's 2002 Inquiry. Although topics are still formally referred to the Institute by ministers, their development is now undertaken with NICE and centres around 7 subject-specific "Consideration Panels" which are mainly chaired by the relevant National Clinical Director. The web-based topic proposal system is one of the streams of suggestions feeding into these panels.

## Annex 2

### Additional background information on NICE

- 1 In July 2004, the Department of Health published *Standards for Better Health*. These standards (which were updated in 2006) provide a common set of requirements applying across all health care organisations and a framework for continuous improvement in the quality of care people receive. Health care organisations are expected to comply with the core standards identified in the document, and to make progress in achieving its developmental standards. Compliance with NICE technology appraisals and interventional procedures guidance are core standards; and implementation of clinical guidelines and public health guidance is a developmental standard.
- 2 In December 2005, the Department of Health published *Health Reform in England*, which describes the framework for reform of the NHS in England. The Institute can play an important role in supporting many aspects of these reforms to secure better care, better patient experience and better value for money. The new field-force team of NICE Implementation Consultants is developing active relationships with the new Primary Care Trusts and Strategic Health Authorities; and the Institute will continue to develop tailored approaches for implementation, working with the Department of Health to incorporate the costs of compliance with all NICE guidance into the payment by results system. The NICE Patient and Public Involvement Programme (PPIP) is fostering relationships with patient groups, voluntary organisations and statutory patient and public involvement structures to harness their support in publicising and disseminating NICE guidance to patients and the public at local levels.
- 3 The 2006 white paper on community health services, *Our health, our care, our say*, shifts the focus of the NHS away from the acute sector and towards primary care and community services, and gives a higher priority to self-management of care, disease prevention and the public health goal of tackling health inequalities. These changes will have a significant impact on the environment within which NICE operates. Like the programme of change arising from *Every Child Matters*, they reinforce the importance of joint commissioning by PCTs and local authorities for health and well-being. This should support implementation of NICE guidance that cuts across services or sectors including not only public health guidance, but also guidance relating to long-term conditions and to groups such as children and older people.
- 4 The creation of a single outcomes framework covering health, adult social care, and children's services, along with the alignment or integration of planning and budgetary cycles, and performance management and inspection regimes, should enable NICE better to link guidance to local

- priorities, particularly those of local authorities. The 2006 local government white paper, *Strong and prosperous communities*, reinforces these changes, for example, by promising a new framework for strategic leadership in local communities, with local area agreements becoming a statutory requirement as the focus of joint local planning and delivery.
- 5 NICE must meet a variety of legal requirements to promote equality and eliminate discrimination in the way it carries out its functions and in its employment policies and practices; this includes the way guidance is developed and the contractual arrangements established by the Institute. From 2007, we will take account of new requirements arising from the Equality Act 2006 to promote equality between men and women, as well as continuing to implement commitments in our equality scheme in relation to race equality, disability equality, tackling age discrimination, and discrimination on other grounds.
  - 8 The Institute's work programme is determined by Department of Health ministers. Once it has been agreed, the development of the guidance is entirely the responsibility of NICE and the Institute issues its guidance directly to the NHS and patients.
  - 9 The Institute's guidance is developed by independent advisory groups composed of relevant experts (including those who speak on behalf of patients). These groups scrutinize the evidence with the utmost care to formulate guidance that is in the best interests of patients. Although the Institute seeks the views of the relevant professions, patient/carer organisations, manufacturers and government, the work of its advisory groups is independent of any vested interests.
  - 10 Individual clinicians, NHS and patient bodies, professional organisations, manufacturers and public health bodies contribute to the development of each piece of guidance through a process that is transparent, objective, inclusive and offers appropriate opportunity for consultation. This includes the submission of evidence from all stakeholder groups and the publication of preliminary versions of guidance on the Institute's public website.
  - 11 To date, the Institute has issued the following guidance to the NHS and wider public health audiences as set out in Table 1:

**Table 1: Published NICE guidance**

<b>Year</b>	<b>Technology Appraisals</b>	<b>Clinical guidelines</b>	<b>Interventional procedures</b>	<b>Public Health Interventions</b>
2000	17	0	n/a**	n/a
2001	14	4	n/a	n/a
2002	24	5	n/a	n/a
2003	19	7	29	n/a
2004	13	13	70	n/a
2005	6	8	46	0
2006	20	12	47	2
2007*	6	2	9	1

\* As of end of February 2007

\*\* No NICE programmes

### ***Technology appraisals***

- 12 Technology appraisals offer guidance on the use of new and existing medicines and treatments within the NHS. When developing this guidance, NICE is required by its Statutory Instruments to take into account both clinical and cost effectiveness. NICE has issued 119 technology appraisals to date, including guidance on statins for cardiovascular disease and computerized cognitive behavioural therapy for depression. The Institute currently has 57 technology appraisals in development.

- 13 In the technology appraisals programme it has been very unusual for NICE to recommend “no use” in the NHS for a technology (Table 2).

**Table 2: Summary Conclusions of Technology Appraisals Guidance**

<b>Technology</b>	<b>Routine use</b>	<b>Selective use</b>	<b>Research only</b>	<b>Not recommended</b>
Pharmaceuticals	29	51*	2	4**
Devices	5	11	2	0
Diagnostics	1	1	1	0
Procedures	1	6	3	0
Health promotion	2	0	0	0
<b>Total</b>	<b>38</b>	<b>69</b>	<b>8</b>	<b>4</b>

\* Includes 2 multi-product appraisals one technology, in each, was not recommended for NHS use.

\*\* Single or multi-product appraisals where no technology was recommended for NHS use.

- 14 In November 2005 NICE launched the single technology appraisal process to produce faster guidance on life-saving drugs that have already been licensed and guidance on new medicines close to when they first become available. NICE consulted with organisations representing patients, healthcare professionals and healthcare industries on its details.

### ***Clinical guidelines***

- 15 Clinical guidelines provide advice on the appropriate care of people with specific diseases or conditions. When developing these guidelines, NICE is again required by its Statutory Instruments to take into account both clinical and cost effectiveness. NICE has issued 45 clinical guidelines, to date, including prevention of malnutrition in the NHS, the care of pressure ulcers and the use of long-acting reversible contraception. The Institute currently has 41 clinical guidelines in development (including 6 reviews) and a full list can be found at <http://guidance.nice.org.uk/type>.

- 16 NICE continues to endorse the proposal set out in the *Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984-1995* (Kennedy Report) that NICE should give given the task of extending its programmes to cover the major areas of morbidity and mortality. A comprehensive suite of clinical guidelines will secure the quality of care that NHS patients deserve.

### ***Interventional procedures***

- 17 Since 2003 NICE has offered advice to the NHS on whether interventional procedures are safe enough and whether they work well enough for routine use in the diagnosis and treatment of NHS patients or whether special arrangements are needed for patient consent. When developing this guidance NICE considers evidence on efficacy and safety. To date NICE has issued advice on 211 interventional procedures, including laser eye surgery and managing the risk of transmitting spongiform encephalopathies (CJD, vCJD) during invasive procedures.
- 18 Topics are notified to NICE directly – usually by clinicians working in the NHS – rather than referred by a health minister. Guidance on interventional procedures protects patients' safety and supports people in the NHS during the introduction of new ones. Many of the procedures that NICE investigates are new, but we also look at more established procedures if there is uncertainty about their safety or how well they work.

### ***Public health interventions and programmes***

- 19 In April 2005 the functions of the Health Development Agency were absorbed into NICE. The Institute now develops guidance for the NHS and the wider public health community, on the effectiveness and cost effectiveness, of measures that sustain good health and prevent ill-health at both an individual and a population level. To date, NICE has issued guidance on 4 public health topics including physical activity, smoking cessation, underage conception and sexually transmitted infections, and drug misuse. The Institute currently has 9 public health interventions and 8 public health programmes in development.

### ***Advice on optimal practice***

- 20 In September 2006 the Department of Health asked NICE to develop a new set of products to help the NHS make better use of its resources by reducing spending on treatments being used in a way which does not improve patient care or does not represent good value for money. NICE will work in partnership with healthcare professionals working in the NHS to identify topics about which that it would be useful to develop guidance. NICE is developing three new forms of advice in this area:

- Technology appraisals and clinical guidelines aimed at identifying optimal practice where there is longstanding uncertainty about the best approach to care. For example, in January 2007 NICE issued guidance on the diagnosis, treatment and management of heavy menstrual bleeding that makes recommendations on a range of effective treatments that should be discussed with women prior to considering surgical options such as hysterectomy.
- Commissioning guides offering practical web-based advice for NHS commissioners on how to commission routine services in line with NICE recommendations. The first commissioning guide on upper gastrointestinal endoscopy services was published in October 2006, underpinned by NICE guidelines on dyspepsia and referral for suspected cancer. Four further guides have been published on anticoagulation therapy services, pulmonary rehabilitation for chronic obstructive pulmonary disease (COPD), assisted-discharge scheme for COPD, and diabetes foot care services.
- Reminders highlighting recommendations from existing NICE guidance that advise the NHS to re-position or stop the use of treatments, based on the evidence of their clinical and cost effectiveness. NICE has, to date, issued online reminders about drugs for eczema, long-acting reversible contraception, and treatments for post-traumatic stress disorder to date.

## Annex 3

### Evaluation and Review of NICE Implementation Evidence (ERNIE)

- 1 The ERNIE database is a source of information on the implementation and uptake of NICE guidance. One of its main purposes is to ensure implementers can see national reports and other data that help to set the context of implementation. ERNIE provides:
  - a data-base of in house reports on the implementation of specific forms of NICE guidance
  - references to external studies on the implementation of NICE guidance
- 2 The external references include studies published in journals and any further reports published by any organizations which come to the attention of NICE. These studies vary greatly and range from local audits with small samples to national investigations undertaken by, for example, the Department of Health and Healthcare Commission. To complement this external data, NICE has worked in partnership with the NHS Information Centre to secure access to national data to enable the production of NICE implementation uptake reports.

### ERNIE: Technology Appraisals

- 3 An overview of the number of studies relating to technology appraisals is presented below.

Number of external references entered in the databases	<b>71</b>
Number of in-house implementation uptake reports entered in the database (as at 1 March 2007)	<b>6</b>
Number and % of 'current' technology appraisals covered by at least one external or in-house study	<b>66 (67%)</b>

NB some external reports have assessed the uptake of several technology appraisals within one study. The 71 references therefore contain 171 assessments of uptake.

- 4 Examples of the information contained within the ERNIE database in relation to a number of technology appraisals is presented below. Examples have been selected as they represent those topics where national data is available rather than smaller local studies.

### Usage of cancer drugs

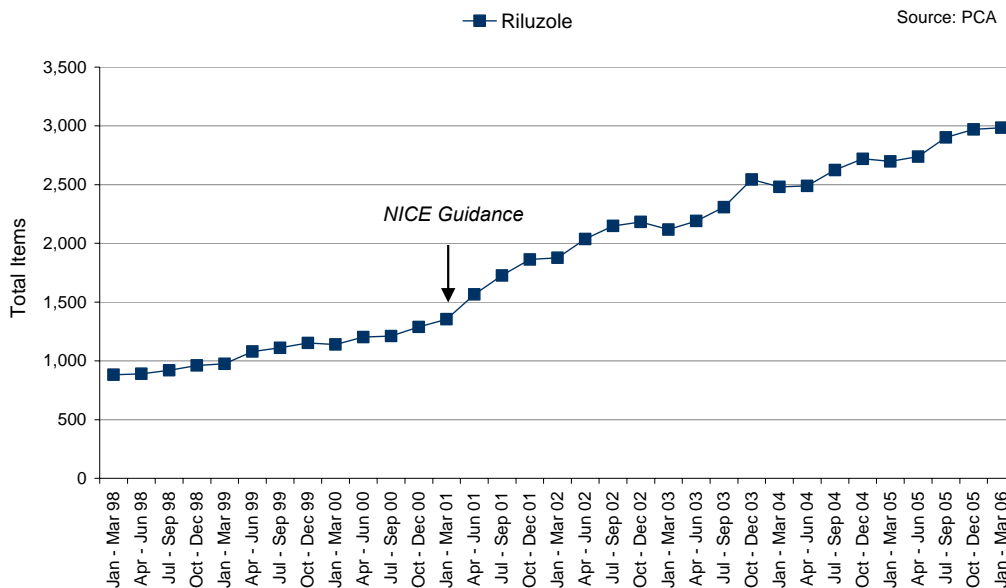
- 5 NICE has published a large number of pieces of guidance in relation to the use of cancer drugs. In 2004 the National Cancer Director conducted a

large investigation into the prescribing of these drugs. This study was repeated and published in September 2006 to provide a further overview of the usage of these drugs. The report found that following a positive appraisal by NICE the median increase in usage of 14 cancer drugs was 47%. The report also measured variation in the use of drugs between cancer networks which had been raised as a concern by the pharmaceutical industry. The report found that there had been a reduction in variation in the usage of all 15 NICE approved drugs.

### TA020 Motor neurone disease (MND) – riluzole

- 6 A NICE implementation uptake report showed a marked increase in uptake of riluzole around the time of publication of the guidance (graph 1). The guidance estimated that around 2,000 individuals are living with MND at any one time. This estimate is based on a range of assumptions and does not represent an absolute figure. The expenditure for riluzole in England for 2005 was £3.8 million. This is the equivalent of around 1400 12-month treatment courses based on 100mg/day (British National Formulary 51). The actual number of people receiving treatment during this period will be higher given the uncertainty about the proportion of patients who either take up or complete therapy.

**Graph 1 Riluzole dispensed in the community in primary care in England**

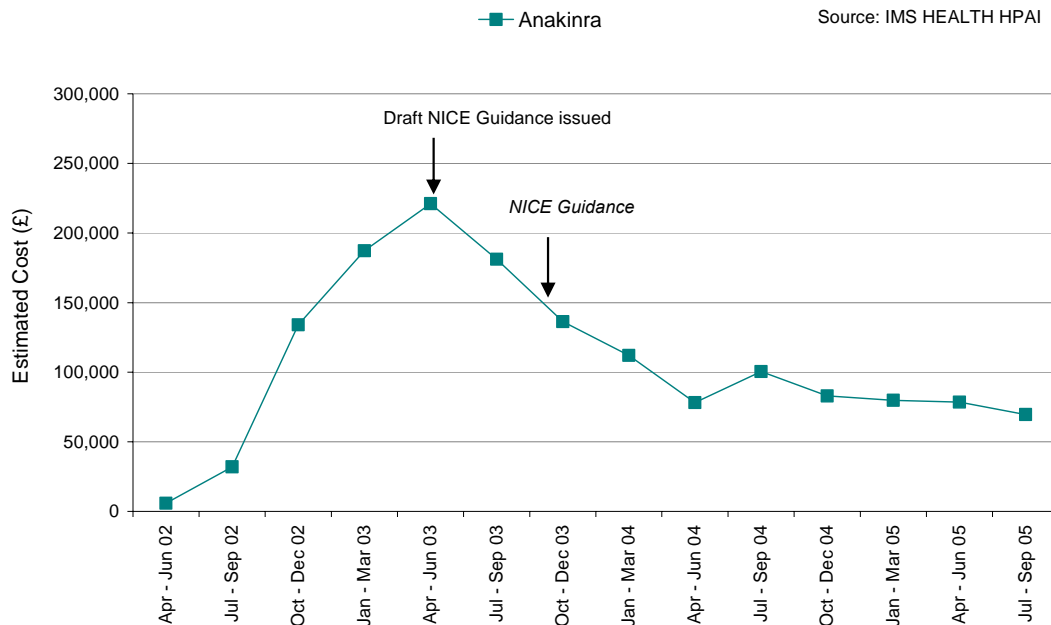


These findings mirror the results of a study completed by Abacus International in 2005. This study concluded that “NICE guidance has been fully implemented in secondary care and well implemented in primary care”.

## TA072 Rheumatoid arthritis – anakinra

- 7 NICE recommended that Anakinra should not normally be used as a treatment for rheumatoid arthritis. It should only be given to people who are taking part in a study on how well it works in the long term. A NICE implementation uptake report showed that there was a dramatic fall in the prescribing of anakinra in July 2003 (date of publication of the draft NICE guidance). The estimated cost for the latest available quarter (July – September 2005) was around £70,000 having been over £200,000 at the point of publication of the draft guidance (graph 3).

**Graph 3 – Anakinra issued in hospitals in England**

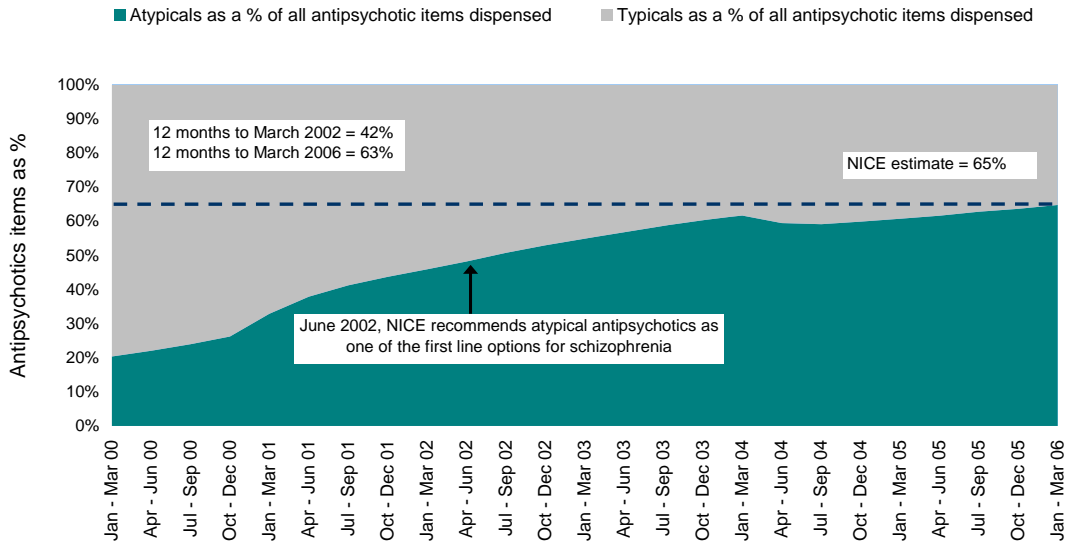


## TA043 Schizophrenia – atypical antipsychotics

- 8 NICE recommended the use of atypical (newer) oral antipsychotic drugs for a person who has been newly diagnosed with schizophrenia and for people who are currently taking typical (older) antipsychotic drugs that are controlling their symptoms of schizophrenia but are causing side effects. A NICE implementation uptake report showed that in the 12 months to March 2006, atypicals accounted for 63% of all antipsychotic items dispensed in primary care. This is consistent with the original NICE guidance that estimated around 65% antipsychotics prescribed ought to be atypicals (graph 4).

**Graph 4 - Atypical antipsychotics as a proportion of all antipsychotics dispensed in the community in England (total items)**

source: PCA



- 9 A study by Abacus International in 2004 found that a similar picture is seen in secondary care where atypical prescribing has grown from 40% of antipsychotic use in 1999 to 66% in 2003.

**ERNIE: Clinical Guidelines**

- 10 An overview of the number of studies relating to clinical guidelines is presented below.

Number of external report entered in the database	<b>31</b>
Number of in-house implementation uptake reports entered in the database (as at 1 March 2007)	<b>0</b>
Total number and % of 'current' clinical guidelines covered by at least one external or in-house study	<b>16 (40% excl. inherited guidelines)</b>

*NB the external references have not sought to assess the uptake of several clinical guidelines within one study. The 31 references therefore contain 31 assessments of uptake.*

- 11 The assessment of uptake and implementation of clinical guidelines is more challenging than for technology appraisals due to the lack of routinely collected data and the large number of recommendations in each guideline. Less than a third of the above studies have looked at practice at

a national level, and have instead a local focus. Furthermore, several of these have not looked specifically at the uptake of NICE guidance but may have included one or two NICE recommendations as part of a larger study.

- 12 In future we anticipate receiving data from studies by the Healthcare Commission regarding the implementation of NICE clinical guidelines. NICE is currently working with the HCC to identify indicators of uptake from their programmes of work and agree how this data may be published. The topics covered by Healthcare Commission work programmes are outlined in a joint statement that has been developed highlighting the different pieces of NICE guidance and how they fit into the HCC work streams [www.nice.org.uk/page.aspx?o=402286](http://www.nice.org.uk/page.aspx?o=402286) . The NICE guidance covered in this work includes lung cancer, head & neck cancer, bowel cancer, cardiac rhythm management, diabetes, stroke, violence in mental health, falls, chronic heart failure, type 1 diabetes, schizophrenia, violence, induction of labour, antenatal care, caesarean section, postnatal care, self-harm and COPD.

### **Shared learning database**

- 13 NICE has also developed an online shared learning database which contains examples of local implementation projects and aims to share learning across the NHS and beyond. The database, launched in December, already contains 32 examples of implementation initiatives. Examples range from the implementation of specific pieces of NICE guidance by specialist services to organisation-wide implementation systems that ensure all NICE guidance is assessed and appropriate implementation plans are put in place.

#### **Entries in the shared learning database (as at 1 March 2007)**

Type of example	Number
Generic systems/processes to ensure the implementation of NICE guidance	18
Case studies relating to clinical guidelines	13
Case studies relating to technology appraisals	1