

House of Commons

Health Committee

**NATIONAL INSTITUTE
FOR CLINICAL
EXCELLENCE**

Second Report of Session 2001–02

Volume I

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Footnotes

In the footnotes of this Report, references to oral evidence are indicated by 'Q' followed by the question number. References to written evidence are indicated by the page number as in 'Ev 12'. The oral and written evidence is published separately in Volume II (HC515-II).

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SECOND REPORT

The Health Committee has agreed to the following Report:

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTRODUCTION

1. Speaking at the first national conference of the National Institute for Clinical Excellence (NICE) in December 1999, the Secretary of State commented that:

“the NHS, just like every other healthcare system in the world – public or private – has to set priorities and make choices. The issue is not whether there are choices to be made, but how those choices are made. There is not a service in the world, defence, education or health, where this is not the case.”¹

2. Just as the issue of prioritisation is not confined to the UK or to the health sector, neither is it particularly new. In 1986, the Government introduced the Selected List Scheme, a national system that excluded the provision on the NHS of licensed drugs which were deemed to be obsolete or of marginal therapeutic value. In 1994, one of our predecessor committees recommended the extension of the Selected List Scheme beyond the “arbitrary” categories of drugs previously chosen for assessment, such that there would be a comprehensive formulary of recommended medicines with the aim of encouraging better prescribing as well as reducing costs.²

3. Towards the end of the 1990s ‘postcode prescribing’ had become a key issue for the NHS. Examples where access to certain treatments and services differed between health authorities were frequent, and controversies had emerged over access to a wide range of treatments, including beta interferon for multiple sclerosis, and taxanes for ovarian cancer.³ In April 1999, the National Institute for Clinical Excellence was established, with the task of tackling what had become known as the NHS ‘postcode lottery’.

4. Just prior to NICE’s launch, the Secretary of State asserted that “NICE guidance will produce a common currency of effectiveness for the NHS, to inform and assist decision-making about treatment and health care at all levels”.⁴ NICE would do this through conducting appraisals of the clinical and cost-effectiveness of new and existing ‘technologies’ such as drugs, devices or surgical interventions, and issuing recommendations to the NHS on their use; and through developing more broadly-based clinical guidelines covering a wider range of treatment for different conditions. In addition to this, NICE was also given a role in assisting the NHS with clinical audit. Although the work carried out by the Medicines Control Agency (MCA) and Medical Devices Agency (MDA) in assessing the safety and efficacy of new drugs and devices may have some relevance to NICE’s assessments of clinical effectiveness, NICE does not play any part in the licensing of new drugs or approval of medical devices. A full description of NICE’s processes and structures can be found in the Annex.

¹ Rt Hon Alan Milburn MP, Speech to Clinical Excellence 1999, 8 December 1999, <http://www.nice.org.uk>.

² See Second Report of the Health Committee, Session 1993–94, *Priority Setting in the NHS: the NHS Drugs Budget*, (HC80), para 132.

³ Women caught in cancer lottery, BBC online, 29 October 1998, http://news.bbc.co.uk/1/hi/english/health/newsid_203000/203494.stm.

⁴ Rt Hon Frank Dobson MP, 31 March 1999, <http://www.nice.org.uk>.

5. Our terms of reference were to consider the progress NICE has made towards achieving the key goals envisaged in *A First Class Service*,⁵ the consultation document that set out NICE's remit in detail – namely, whether NICE:

- *is producing clear, credible guidance*
- *has ended confusion by providing a single national focus*
- *is providing guidance that is locally owned and acted on in the right way*
- *is actively promoting interventions with good evidence of clinical and cost-effectiveness so that patients have faster access to treatments known to work.*

We also decided specifically to examine the independence of NICE.

6. According to the National Collaborating Centre for Mental Health, the aims set out for NICE in *A First Class Service* “amount to nothing less than a revolution within the health service”, and as such “may take rather longer to achieve than the two-and-a-half years that NICE has existed to date”.⁶ **It is clear that expectations of NICE have been high, and in addition to the challenges of its remit, NICE has also faced the same logistical and operational challenges as all nascent organisations. In this context, we welcome the support we have seen for the establishment of NICE, and we recognise that this represents an improvement on the previous situation.**

7. We have also seen evidence of the considerable scale and complexity of NICE's undertaking, conducted in the face of articulate and often vociferous scrutiny from the clinical professions, the NHS, patient organisations, national and international pharmaceutical companies, and the media. Indeed, the evidence we have received attests to the breadth of stakeholders on whom NICE's work impacts, and its pivotal and influential position in the debate on quality, funding and priorities in the NHS. We received over 120 memoranda from a wide variety of stakeholders, including individual patients and clinicians, Royal Colleges and professional clinical bodies, academics from the fields of health policy, health economics and health law, research organisations, NHS acute trusts, primary care trusts and health authorities, statutory Non-Departmental Public Bodies (including the Health Technology Board for Scotland and the Commission for Health Improvement), pharmaceutical companies and associations, and prescribing publications.

8. Between January and March 2002 we took oral evidence from health authorities, from clinicians and academics with a particular interest in and knowledge of clinical guidelines, from several patient organisations, from the Consumers' Association, the Drug and Therapeutics Bulletin, the British National Formulary and Bandolier, from representatives of the pharmaceutical industry, from the National Institute for Clinical Excellence, from Lord Hunt of Kings Heath OBE, Parliamentary Under Secretary of State, and from the lead Department of Health official. We are extremely grateful to all those who submitted oral or written evidence.

9. We are also indebted to our specialist advisers, Professor Joe Collier, Professor of Medicines Policy, St George's Hospital Medical School, and Dr Hilary Pickles, Director of Public Health Policy at the Public Health Laboratory Service, for lending their expertise. Their assistance in a technically complex inquiry has been invaluable.

10. Our terms of reference are not discrete areas for which there are clear criteria by which ‘success’ and ‘failure’ can be easily judged, and in many cases they overlap and inform one another. The clarity and credibility of NICE's guidance is obviously crucial to its success in ending confusion by providing a single national focus. The credibility of NICE's guidance is inextricably linked to local ownership, to its success in presenting evidence-based recommendations, and to NICE's independence. Whether or not NICE is facilitating faster patient access is largely dependent on whether or not its guidance is acted on in the right way. In interpreting our terms of reference, we have not attempted to assess

⁵ *A First Class Service: Quality in the New NHS – a Consultation Paper*, Department of Health, 1998, Section 2.

⁶ Ev 217.

the technical merits of individual NICE appraisals, nor to challenge the scientific robustness of NICE's methods and processes. Where we have received evidence that touches on these areas, we have used this as a basis for exploring NICE's performance in a broader sense, and the overarching issues that may impact on it.

11. The report examines our five terms of reference, devoting a section to each in turn. This then leads into a broader consideration, in the final section, of the three key areas where we have made recommendations: the quality and credibility of NICE's work; its focus, organisation and implementation; and NICE in its wider context. In examining NICE's progress, we have focused primarily on its work in producing technology appraisals, although we have considered the other areas of its work programme, including clinical guidelines, where we have received relevant evidence. Our use of the term 'guidance' should be read as referring to both technology appraisals and clinical guidelines.

I. IS NICE PROVIDING CLEAR AND CREDIBLE GUIDANCE?

12. *A First Class Service* set out one of NICE’s key objectives as the provision of clear, credible guidance:

“NICE will produce clear guidance for clinicians about which treatments work best for which patients”

“The National Institute for Clinical Excellence will ensure authoritative national guidance is available for all health professionals on the latest drugs and technologies”

“Clear credible guidance and the production of robust audit methodologies are essential”

[*A First Class Service*, Department of Health, 1998, 1.15.]

Clarity

13. Clarity is crucial to the success of NICE’s guidance, particularly given the complex and broad subject matter falling within its portfolio and the proliferation of guidance of various quality now available to clinicians and patients. Although we received evidence giving examples where NICE guidance could have been worded more clearly, many written memoranda praised the presentational quality of NICE’s work.⁷ However clarity extends beyond presentation, encompassing consistency of message, lack of ambiguity, and the provision of relevant context. Our evidence suggests that for NICE stakeholders the degree of clarity with which NICE is able to link its evidence to its recommendations is very important, and is also closely linked to its intended function of “ending confusion by providing a single national focus”.

Credibility

14. Lord Hunt emphasised the importance of credibility in implementing NICE guidance successfully: “my expectation is that NICE guidance will be credible, that the profession will see it as credible, and will see the merit in following the advice that they give”.⁸ Establishing credibility with its sponsors, within the policy arena in which it operates, and with its stakeholders is vital for any new organisation. When giving evidence to our predecessor Committee in February 1999, shortly before taking up his position as Chair of NICE, Professor Sir Michael Rawlins highlighted this as his highest priority:

“... the most important thing is for us to gain the confidence of the professions, of the public, of Parliament, of ministers, of the Department as a whole. If we can do that, and do that early on, then I think that is the most important thing to do. We will do that by the quality of the technical scientific work we do, by being transparent in so far as is humanly possible, and in making sure that we can consult and disseminate the output as widely as possible.”⁹

15. Credibility is clearly a subjective issue. NICE’s credibility can only be properly judged by its users, who will inevitably reach their own conclusions about the value and trust they are able to attach to NICE’s guidance. Within the evidence we have received about the credibility of NICE’s guidance from its stakeholders, the three contributory factors identified by Professor Rawlins have emerged as recurrent themes:

- Clinical credibility is largely determined by the technical *quality* of the guidance produced. Does it ask and answer the right questions? Is it factually accurate and

⁷ Ev 102 (GlaxoSmithKline); Ev 77 (North Tyneside Health Authority); Ev 234 (Hammersmith Hospitals NHS Trust).

⁸ Q501.

⁹ Health Committee, Minutes of Evidence, 4 February 1999, Session 1998–99 (HC222–i), Q52.

is it evidence-based? Does its methodology ensure that the evidence it receives is assessed fairly and rigorously?

- Closely linked to quality and rigour is the issue of *inclusiveness*. Do NICE's processes ensure that the right people, whether they are clinical or academic experts, patient groups or pharmaceutical companies, are appropriately involved in its work? As far as possible, is NICE's guidance sensitive to local concerns and priorities?
- Finally, *transparency* is needed to enable stakeholders to assess for themselves the rigour and inclusiveness of NICE's decision-making processes.

16. Independence is central to credibility and is linked to each of these areas. Rigorous and well-reported analysis is necessary to reassure stakeholders that decisions are evidence-based and not influenced by outside factors; including the right groups in its processes ensures that NICE's relationships with stakeholders are, and appear to be, measured and proportionate; full transparency about NICE's processes and relationships will add confidence to this. This section gives a brief overview of NICE's performance in these three areas in turn, before exploring the issue of technical quality in greater depth in section IV, and that of independence in section V.

Clinical credibility

17. NICE's work on zanamivir (also known by the brand name Relenza) provides a useful example of how doubts over independence and technical quality can adversely effect credibility. NICE's initial 'rapid' appraisal of Relenza, a drug marketed for the treatment of influenza, was published in October 1999. NICE recommended the treatment should not be used in the NHS, citing evidence showing that to be effective treatment had to be started within a very stringent timeframe, and even when started early in patients with confirmed influenza it was only likely to reduce the duration of symptoms by one day. NICE also felt that there was insufficient evidence about the drug's effects in 'at risk' groups. The decision was generally supported by clinicians and the NHS, but was opposed by Relenza's manufacturer, Glaxo Wellcome, and by other pharmaceutical companies.¹⁰

18. In November 2000, NICE issued new guidance on Relenza, this time recommending the treatment for use in 'at risk' individuals on the basis of new evidence prepared by manufacturers. In February 2001, the Drug and Therapeutics Bulletin, an independent prescribing journal published by the Consumers' Association, published an article offering advice contrary to NICE's guidance. It highlighted what it claimed were weaknesses in NICE's evidence base and analysis, and argued that NICE's recommendation for Relenza to be used in 'at risk' patients seemed at odds with the patient information leaflet supplied with the drug, which in fact offers particular cautions to 'at risk' patients who might take the drug.¹¹ This dispute was well-publicised.¹²

19. Many witnesses attested to the impact of the new Relenza guidance on NICE's credibility – Dr Martin Duerden, a general practitioner with specialist interest and experience in prescribing and therapeutics, argued that “The real problem that has challenged the credibility of NICE with GPs has been the change in guidance for use of zanamivir (Relenza, the flu drug) without an obvious change in the evidence base to support this approach”.¹³ Dr Duerden told us that the reversal had “created a perception that maybe NICE had been got at, that it had made a change in response to major political

¹⁰

For example, *Too little action, too much uncertainty says GPs' leader*, BMA press notice 8 October 1999; *Relenza: Drug companies join flu protest*, BBC online 6 October 1999, http://news.bbc.co.uk/1/hi/english/business/newsid_466000/466563.stm; note: Glaxo Wellcome is now part of GlaxoSmithKline.

¹¹ *Why not zanamivir?* DTB 2001; 39: 9–10.

¹² *Guidance over anti-flu drug 'wrong'*, BBC online 15 February 2001 http://news.bbc.co.uk/1/hi/english/health/newsid_1170000/1170376.stm.

¹³ Ev 18.

pressure, pressure from the media and the drug industry”.¹⁴ Helen Marlow, Pharmaceutical Advisor to Croydon Health Authority, described “incredulity within the NHS when NICE reversed its decision not to recommend zanamivir for the treatment of influenza” and agreed with Dr Duerden that the perception that “external pressure” accounted for this change had “seriously damaged NICE’s credibility”.¹⁵

20. As well the relevance of NICE’s independence, this emphasises the importance for NHS professionals of what Professor Rawlins termed the “quality of the technical scientific work”, about which several witnesses raised concerns. Although we are not qualified to judge the quality and robustness of individual appraisals, and nor is it within the remit of this inquiry to do so, when criticisms are voiced by other respected and established authorities in the field, the potential for damage to NICE’s credibility is evident. The North Liverpool Primary Care Trust told us that:

“Unlike the MeReC Bulletin, the Drug and Therapeutics Bulletin and Clinical Evidence [prescribing publications], NICE is widely viewed as pursuing a political agenda at the expense of clinical credibility. This perception became apparent amongst prescribers and advisers after the rapid reversal of guidance on the use of zanamivir.”¹⁶

21. NICE clearly operates in an environment populated by information providers who are already established and respected by clinicians. This means that if NICE is not able to produce guidance which clinicians find credible, then it is likely and reasonable that clinicians will use these other sources of information. Professor David Barnett, Chairman of NICE’s Appraisals Committee, implied that NICE’s relationships with other information providers should be collaborative rather than competitive, telling us that it was not an “either/or” situation, and that NICE guidance “should be read in conjunction with the BNF [British National Formulary], not instead of or in any other way”.¹⁷ However, when NICE and other organisations offer conflicting guidance, as has been the case with Relenza and, for example, guidance on glitazones (drugs used to treat diabetes), clinicians and commissioners of care have to make a choice, or at the very least attempt to grapple with these differences themselves: as Ms Marlow told us, “other authoritative and respected sources, for example the Drug and Therapeutics Bulletin, have drawn conclusions about treatments which are different to NICE and one has to ask why there is that conflict”.¹⁸

22. Evidence from GlaxoSmithKline suggested that NICE has been willing to accept constructive criticism from pharmaceutical companies.¹⁹ However, we are concerned by the reports we have received showing an apparent failure on the part of NICE to engage, either proactively or even reactively, in dialogue with respected prescribing organisations such as the Drug and Therapeutics Bulletin (DTB) and the British National Formulary (BNF) about the content of their work. The DTB told us:

“We compiled a fairly detailed report listing all of our concerns and sent that to NICE. That was in February last year, 11 months ago. To date, we have not received an official response to that report. We have not received a rebuttal. NICE has not formally accepted our invitation to debate the issues we raised.”²⁰

23. The BNF experienced a similar lack of engagement:

¹⁴ Q33.

¹⁵ Ev 68.

¹⁶ Ev 240.

¹⁷ Q378.

¹⁸ Ev 5 (Consumers’ Association); Q165.

¹⁹ Q261: “An example would be in a diabetes treatment where the original assessment included commentary about use of the product on its own with patients, not in combination with any other products. That is actually outside of the licence indication. We were able to point that out and it was changed” (GlaxoSmithKline).

²⁰ Q9.

“We have offered to read the NICE guidelines before they come out and come up with these little points before they go public, and so far they have not taken up the offer although it still stands.”²¹

24. Professor Rawlins told us that “one of our problems in a sense, which will always remain with us, is that we will only please some of the people some of the time. We will never please everybody all the time”.²² We agree that it will not be possible for NICE always to achieve consensus between all of its stakeholders. Indeed, if NICE’s work attracted no criticism at all, it would be failing in its task. However, we believe that there is a core group of relevant organisations, including the Scottish Intercollegiate Guidelines Network (SIGN), DTB, the BNF, and the Royal Colleges, that it is essential for NICE to engage with constructively and collaboratively in order to maintain its clinical credibility. This view was endorsed by Lord Hunt, who told us that he was “very anxious to ensure that it [NICE] learns as it goes along and that it does engage in dialogue and that even when organisations disagree fundamentally with a decision none the less there should be constructive dialogue”.²³ He went on to agree that “in relation to BNF or the Drug and Therapeutics Bulletin I would certainly want to encourage NICE to sit down with the people who produce these two services to discuss where there may be differences, why there may be differences, and whether that might lead to any modification of NICE’s process”.²⁴

25. This view was also echoed by Professor Rawlins, who, prior to NICE’s establishment, expressed a hope that eventually “doctors will go to work with the *British National Formulary* in one pocket and a copy of NICE guidelines in the other”.²⁵ During our evidence session he seemed surprised to learn that the BNF was not given the opportunity to comment on NICE’s draft guidance:

“(Professor Sir Michael Rawlins) The British National Formulary have received many of our forms of guidance in draft form, have they, Mr Dillon?
(Mr Dillon) No. The BNF is not a formal consultee. The definition of ‘consultees’ is representative patient and professional organisations that have a direct interest in the work that we do, and manufacturers.”²⁶

26. Since the completion of our evidence sessions, it has been announced that NICE and SIGN will formally collaborate on the production of clinical guidelines, a move we commend. We also note that Royal Colleges are well represented on NICE’s six National Collaborating Centres.²⁷ **To neglect the input of respected bodies such as the DTB and the BNF 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.**

Inclusiveness

27. Ensuring that its processes are as inclusive as possible is critical if NICE is to achieve and maintain credibility. If a process is insufficiently inclusive, not only does NICE risk losing valuable input which could improve the quality of its products, as we have seen above, but without representative input from relevant groups there is the potential for bias against those who have not been included.

²¹ Q72.

²² Q431.

²³ Q451.

²⁴ Q489.

²⁵ Coulson J. *NICE work*. (Interview with Sir Michael Rawlins.) *BMA News Review* 1999, 13 Mar, pp. 20–23.

²⁶ Q376.

²⁷ <http://www.nice.org>.

28. Yet the Health Technology Board for Scotland commended NICE's inclusiveness, and pointed out that "NICE was the first appraisal organisation to take evidence from all stakeholders (few involve manufacturers or patient groups)", suggesting that "such broad consultation" was helpful in creating "credible guidance".²⁸ However, much of our evidence highlighted perceived shortcomings in the ways in which NICE decides which stakeholders to involve in its work.

29. Dr Andrew Bamji, a consultant rheumatologist, claimed that the involvement of the British Society for Rheumatology in the production of GP referral guidelines occurred "by chance" despite the clear relevance of specialist rheumatology input.²⁹ The Cancer Research Campaign suggested that in NICE's appraisals of cancer drugs "there are issues in relation to credibility where a lack of expertise in oncology has led to a perception that the appraisals lack specialist 'clinical common sense'".³⁰ The Alzheimer's Society and the Campaign for Effective and Rational Treatment (CERT), an organisation sponsored by the pharmaceutical industry which campaigns for better treatment in a number of different clinical areas, gave examples of seemingly insufficient stakeholder consultation. The Alzheimer's Society argued that during its appraisal of drugs for Alzheimer's disease, NICE, in error, included the Chartered Society for Physiotherapists but not the Royal College of Psychiatrists.³¹ Similarly, CERT maintained that NICE did not contact the two specialist colorectal cancer patient advocacy groups during its appraisal of drugs for colorectal cancer,³² and suggested that in some cases timing may be an issue:

"We have heard of occasions when NICE has telephoned experts to ask whether they would be available to advise the Appraisals Committee on a particular date in two or three weeks time. When the experts have said that they were not available on a particular date, NICE have simply advised that they would find someone else ... Medical consultants have said that they find it 'staggering' that treatments are being appraised by clinicians who have no working understanding of the clinical area they are investigating."³³

30. Similar concerns have been raised about NICE's processes for identifying which patient groups to include as formal consultees: "we welcome the commitment that NICE has given from the start to the user and carer perspective, but perceive that NICE has had difficulty in discovering for itself what the patient perspective is and which organisations properly represent it".³⁴

31. 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.

32. Some patient organisations raised wider concerns which went beyond NICE's stakeholder identification processes, and questioned its commitment to patient involvement, as illustrated by the MS Society: "The institute has shown itself consistently unwilling to engage with people who are expert in MS by virtue of having it. Our view is that the Society has a valuable organisational perspective on the appraisal of MS drugs, but that it is complementary to – and not a replacement for – the perspective of people who

²⁸ Ev 208.

²⁹ Ev 194.

³⁰ Ev 255.

³¹ Ev 55.

³² Ev 105.

³³ Ev 106.

³⁴ Ev 54 (Consumers' Association).

have MS”.³⁵ We examine the issue of patient evidence alongside our broader consideration of NICE’s methodology in section IV.

33. Despite these concerns, the large number of memoranda we received from patient organisations who have been involved in NICE’s processes over the past two years clearly demonstrates that NICE has attempted to consider the patient perspective. In marked contrast to this, our evidence from NHS staff suggested that NICE made comparatively little attempt to involve them: Helen Marlow told us that “frontline NHS staff and policy makers are not consulted in the drafting of NICE Technology Appraisals ... there is no opportunity for the NHS to provide practical feedback to NICE about how its guidance is received and implemented in practice”.³⁶ NHS Trusts and Strategic Health Authorities also have no right of appeal against NICE guidance which “does not really help in terms of ownership of the guidance”.

34. We were told by the Royal College of General Practitioners that “although NICE has built into its processes a wide stakeholder involvement, including patients, and has introduced a requirement to look at cost effectiveness, NICE does not seem to have processes for considering the impact of guidelines on patterns of service delivery”.³⁷ Following NICE’s revised guidance on Relenza, some clinicians voiced concern and disappointment that NICE had not taken into account the practical impact its recommendations could have on general practitioners, who might be inundated with people asking for the drug.³⁸ Nicola John, Prescribing Adviser to Iechyd Morgannwg Health, argued that “it would be helpful if the guidelines also assessed the service implications of their introduction. For some drugs, the effect on service provision is minimal, but for others, major investment is required in staff recruitment and training”.³⁹ North Derbyshire Health Authority argued that NICE “does not appear to make recommendations that are sensitive to current resourcing problems”, and gave the example of NICE’s guidance on anti-obesity drugs, claiming that at present “there is simply not the dietetic and nurse time available to provide the level of support likely to make the drugs beneficial, and indeed without such support it might be questionable if they were being prescribed within their Product Licence”.⁴⁰

35. NHS representatives also have a further crucial contribution to make, as within NICE’s processes they are currently the only advocate for the wider patient population served by the NHS, whose lives may not be directly impacted by NICE’s decision on a particular treatment, but may be indirectly impacted if resources, both financial and staffing, are diverted from other NHS services in order to implement NICE recommendations.⁴¹

36. NICE has changed its processes so that now two health authority representatives sit on the Appraisal Committee. However, our evidence suggested that these measures have not been entirely successful in fostering within the NHS a sense of inclusion in NICE’s processes. Clearly this is vital to securing the local ownership needed to facilitate the implementation of NICE guidance. **We recommend that NICE takes steps to improve current methods of involving the NHS in the development of technology 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**

³⁵ Ev 44.

³⁶ Ev 69.

³⁷ Ev 231.

³⁸ *Flu Drug available on NHS*, BBC News Online, 21 November 2000 (http://news.bbc.co.uk/1/hi/english/health/newsid_1026000/1026481.stm).

³⁹ Ev 255.

⁴⁰ Ev 228.

⁴¹ The issues of mandatory funding and diversion of resources are explored more fully in section V.

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.

37. We hope that the recommendations we have made will help NICE to improve the inclusiveness of its processes. However, as well as ensuring that it gets the 'theoretical' aspects of inclusiveness and stakeholder relations right through well-designed processes, an organisation with as high a public profile as NICE must also ensure that well-intentioned theory is translated into practice through other perhaps less tangible means, such as maintaining a sufficiently outward facing focus and fostering a general organisational culture of inclusiveness. We note the fact that almost a fifth of the memoranda we received came from people with some financial or professional interest in NICE (including even its publisher). NICE issued a very prompt press release following their evidence to us, and this energetically proactive media relations strategy appears to be emerging as characteristic of NICE, with an equally swift rebuttal issued after criticisms of NICE were raised in evidence to the Science and Technology Committee.⁴² We recognise that if this is not done in what will often be a difficult field – particularly with the interests of pharmaceutical companies – other interpretations of events and evidence can get established as the only interpretation available to patients, the public and professionals. However, NICE has to be sure that this strong media presence does not stop the organisation from always listening to and responding to counter claims and criticisms of its work.

38. We welcome NICE's attempts to achieve better relationships and open channels of communication with stakeholders – particularly the NHS and patient groups. The future credibility of NICE rests on it being responsive to criticisms, and to it 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.

Transparency

39. As shown by the example of Relenza, clarity and transparency about the basis on which decisions have been made is key to NICE maintaining its credibility with clinicians, with the wider NHS, and with patient groups. It is also vital that NICE is able to establish and publish a consistent and robust framework setting out methodology and evidence weighting, an issue which is discussed more fully in section IV.

40. Sir Iain Chalmers, Director of the UK Cochrane Centre, along with several other witnesses,⁴³ raised the point that much of the information on which NICE appraisals are based is unpublished, as it is supplied to NICE by manufacturers in confidence. Sir Iain argued that "while this state of affairs persists NICE cannot be expected to achieve the credibility that is essential for it to earn the trust of the public".⁴⁴ **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.** If pharmaceutical companies insist that unpublished data relating to the indication in question remain confidential, this may mean NICE will be forced to withdraw that treatment from the appraisal process. This carries the risk that guidance on a treatment will be delayed until published information is available. However, we believe that pharmaceutical companies are unlikely to use this as an 'opt-out' clause because their refusal to submit their evidence to public scrutiny would be likely to have a negative impact on commissioners' and clinicians' confidence in their product.

41. Besides transparency about the evidence base for NICE's recommendations, it is also crucial for stakeholders that transparency is maintained during the appraisal process. The

⁴² NICE press notice 2002/002, *NICE responds to comments made by Director of the Cancer Research Campaign* (<http://www.nice.org.uk/article.asp?a=26605>).

⁴³ See, for example, Ev 213 (Mid Devon Doctors' Group).

⁴⁴ Ev 199; The UK Cochrane Centre forms part of the Cochrane Collaboration, an international organisation which prepares, maintains and makes accessible systematic reviews of evidence on the effects of health care interventions.

MS Society felt that “people affected by the Institute’s decisions should be able to follow an audit trail of decision-making. It is currently impossible for consultees – let alone members of the general public – to do this”.⁴⁵ Specific barriers identified by the MS Society included the fact that patient organisations are unable to attend the final deliberations of the Appraisal Committee, and the fact that minutes of these meetings are often published late and “include little flavour of how conclusions have been reached”.⁴⁶

42. Alongside clarity about decision-making, several witnesses felt that confidence in NICE and credibility in its guidance could be improved by publishing members’ declarations of interest more explicitly. Ms Marlow told us that:

“When the NICE guidance comes out about a particular technology a number of parties have been involved in developing that and advising NICE. Some parties have relationships with other organisations, for example, the pharmaceutical industry. It would help the openness and robustness of the process if things were openly declared in the final guidance which comes out because it is not made public in the guidance.”⁴⁷

43. While we accept NICE’s position that members’ declarations of interests are available on its website, they are not particularly obvious or easy to locate. **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.**

Appeals

44. We were concerned to hear from the MS Society that during the course of an appraisal “straightforward questions ... were turned aside by the Institute and we were told that the only way of finding out how that information had been used was through NICE’s formal appeals process, which we did, but we could not actually make any critique of how that information had been used because no explanation was given of how it had been used”.⁴⁸ Some support for this view can also be drawn from Professor Rawlins’ description of an appeal which had proved a useful mediation exercise:

“This was an opportunity to allow the particular organisation, which in one case was actually a patient organisation, to explain what their problem was and we could explain what our problem was and I think they were reasonably satisfied. Although the specific appeal was rejected I think they were satisfied that their point of view had been put and we had explained why we could not meet their demands.”⁴⁹

45. Although we welcome this example of constructive dialogue between NICE and its stakeholders, we feel that NICE needs to be able to engage in this type of dialogue within its routine processes, rather than in the costly and potentially adversarial setting of a formal appeal. **Improvements 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.**

46. Many memoranda also expressed wider concern that the Chairman of NICE has sole

⁴⁵ Ev 43.

⁴⁶ Ev 43.

⁴⁷ Q136.

⁴⁸ Q106.

⁴⁹ Q409.

responsibility for deciding whether or not an appeal is heard, and that he is also Chair of the Appeals Committee.⁵⁰ The MS Society argued that “the NICE Appeals Panel has neither the qualities of independence or impartiality that are required of a public body exercising an appeals function”, without which it will be unable to maintain the confidence of the public.⁵¹ The Association of the British Pharmaceutical Industry (ABPI) agreed with this: “As much as we fully respect Sir Michael Rawlins’s independence, he is the Chairman of the Appeals Commission as well as the Chairman of NICE. That seems to be, for his benefit and the benefit of NICE, something which probably ought to change”.⁵²

47. NICE gave us assurances that the Chairman maintained full independence by having no involvement at all in the technology appraisal process, and told us that they felt this was an appropriate arrangement.⁵³ However, a perverse consequence of this is that the Chairman may not be able to keep his finger on the pulse of NICE, and may be prevented from giving it vital strategic direction. Indeed, there were occasions during oral evidence when, in response to questioning, Professor Rawlins excused his lack of knowledge about NICE’s processes as being the result of his need to stay out of the deliberations of NICE so that he could remain independent for appeals.⁵⁴

48. In an ideal situation, there should be only very limited recourse to an appeals panel. Professor Rawlins told us that around 40% of NICE decisions on technology appraisals are appealed against, and he said that this rate was comparable to that of the Committee on Safety of Medicines.⁵⁵ However, figures published by the Medicines Control Agency indicate that between 1995 and 1999, the proportion of decisions that were the subject of an appeal hearing in fact ranged between 4.6 and 9%, with the proportion subject to independent appeals even smaller.⁵⁶ We recognise that NICE was created to take difficult decisions about which there will inevitably be disagreement. However, appeals are meant to resolve any genuine concerns that NICE has not followed its own processes properly, rather than to act as a means for stakeholders to question the validity of those processes, or to enter into dialogue with NICE. There should be the opportunity for this to take place within normal procedures, so that by the time NICE reaches a final determination, stakeholders have sufficient confidence in the technical quality and accuracy of the appraisal work, and are satisfied that their own evidence and views have been taken on board and used properly.

49. NICE is currently undertaking a public consultation into its appeals process, the key proposals of which are that all hearings will be held in public, and that NHS organisations who are formal consultees will be given the right to appeal. However, **the current role of the Chair in the appeals system seems to 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 that this creates between the Chair and the everyday business of NICE may be to the detriment of the organisation as a whole.**

⁵⁰ For a full description of the Appeals process see Annex

⁵¹ Ev 43–44.

⁵² Q287.

⁵³ Q309; Q363; Q426.

⁵⁴ Q309; Q363.

⁵⁵ Q411.

⁵⁶ *Official Report*, 19 March 2002, col. 289w. Additional information supplied by Medicines Control Agency.

II. HAS NICE ENDED CONFUSION BY PROVIDING A SINGLE NATIONAL FOCUS?

“There is currently no coherent approach to the appraisal of research evidence and the subsequent production of guidance for clinical practice. Guidance is issued by numerous bodies at national, regional and local levels, each of which have different ways of appraising the evidence and developing recommendations. The status and implications of the products are not always clear, nor what actions are expected to follow as a result of them. This is confusing for clinicians wanting to know what care they should be expected to give, and for patients knowing what care to expect. NICE will reduce duplication of this activity”. “It will provide a single national focus for appraisal of significant new and existing interventions, with subsequent guidance”

[*A First Class Service*, Department of Health, 1998, 2.11.]

Confusion between NICE guidance and guidance issued by other bodies

50. Our evidence revealed widespread support for NICE’s aim of providing a single focus for guidance.⁵⁷ However, as noted by the Royal College of Paediatrics, “other groups such as SIGN and the Drug and Therapeutics Bulletin have continued to provide alternative guidance which does not always agree with NICE guidance”,⁵⁸ with the potential to cause confusion and to damage NICE’s credibility. The NHS Centre for Reviews and Dissemination argued that despite NICE’s aim to provide a single national focus, decision-makers in the NHS would still “need to sift and weigh evidence, from a range of sources, to provide best practice”, and that in this context collaborative working with “independent and well-respected sources, such as the Drug and Therapeutics Bulletin, the Effective Health Care publications, and the Cochrane Library” remained essential for NICE.⁵⁹

Confusion about NICE’s own guidance

51. As well as the confusion that can be generated by conflicting guidance from different organisations, some memoranda complained of a lack of co-ordination between different types of guidance issued by NICE. *A First Class Service* gives an example of the sort of ‘Conflicting clinical advice’ NICE was aiming to clarify:

“Current guidelines from the British Hypertensive Society are ambivalent about the role of ACE inhibitors as a first line treatment for uncomplicated hypertension. Some clinicians hold that there is now sufficient evidence to justify using these medicines as the preferred treatment ... However, there is still no unequivocal guidance available for clinicians. In such cases, NICE will look at the evidence and make a clear recommendation, issue appropriate guidance and advise on what further research is needed.”⁶⁰

52. In its written submission, the British Cardiac Patients’ Association used the same example to argue that such confusion still persists, claiming that hypertension has “to date been covered in four separate NICE clinical guidelines and one technology appraisal, in addition to other guidelines and recommendations that remain relevant from other professional and advisory bodies”.⁶¹ The Association pointed out that as well as creating confusion this placed a significant burden on clinicians in terms of duplication in reading and implementation.

⁵⁷ For example, Ev 77 (Newcastle and North Tyneside Health Authority); Ev 71 (Croydon Health Authority); Ev 73 (Lambeth, Southwark and Lewisham Health Authority).

⁵⁸ Ev 232.

⁵⁹ Ev 223.

⁶⁰ *A First Class Service*, Ch2.

⁶¹ Ev 242.

53. NICE and National Service Frameworks (NSFs) were conceived as a dual initiative to set quality standards in the NHS, and it was assumed that the two initiatives would work in close concert. However, uncertainty about the relationship between government-issued NSFs and NICE guidance was a common theme in the evidence we received from both clinicians⁶² and from patient organisations such as the British Cardiac Patients' Association, who argued that "Poor integration between technology appraisals, clinical guidelines and other initiatives such as National Service Frameworks has in some ways neglected an opportunity to end confusion".⁶³

54. The ABPI felt that there remained "room for improvement in coordination between the creation of NICE clinical guidelines and the broader issues considered by such policy areas as NSFs. For example, Standard 6 of the NSF for Older People covers both falls and fractures as priority areas of clinical need to reduce visits to A&E Departments. The scope of the NICE guideline for falls excludes any consideration of fractures".⁶⁴ **We recommend that NICE should strive to improve clarity and co-ordination within and between its own workstreams, and should work closely with the Government to ensure clarity about the relationship between its own work, NSFs and other policy initiatives in the NHS.**

Confusion between technology appraisals and clinical guidelines

55. The ABPI argued that in separating its programmes of technology appraisal and clinical guidelines, NICE was suffering from "double vision": "Completely different experts are used for each process, and guidelines groups are not allowed to comment on draft guidance issued for technology appraisals. Quoting specific examples, the scope of the clinical guideline for multiple sclerosis, which is under development, does not include reference to any disease-modifying therapies and is focused only on palliative care".⁶⁵ This concern was echoed by the NHS Alliance: "NICE have not connected their production of technology assessments (both drugs and non-drug interventions) with the issue of treatment guidelines and referral guidance. Such a disjointed approach runs the risk of, at best, damaging the credibility of NICE, and at worst, producing confusion".⁶⁶

56. Several witnesses felt that the development of technology appraisals outside the context of a disease management framework made them less useful and potentially confusing. Dr Duerden used the example of technology appraisals issued by NICE on two anti-obesity drugs, orlistat and sibutramine: "These clearly should be used within a carefully constructed and agreed obesity management guideline. Taken in isolation it is difficult to know how best to use these; for example, which should be used in preference, and in what circumstances".⁶⁷ This was supported by oral evidence from Professor Tom Walley, a clinical pharmacologist with recognised expertise in guideline issues: "We have two appraisals on two separate technologies rather than the consideration of how we should manage obesity in the whole of the NHS. It is being driven by the existence of the technology, not the priority of the NHS in managing the condition".⁶⁸

57. Guidelines produced by SIGN were frequently cited as an example of good practice⁶⁹ and we also received suggestions that NICE might improve its usefulness by following SIGN's example and devoting a significantly larger proportion (or even all) of its resources to guideline development.⁷⁰ GlaxoSmithKline added that the subsequent reduction in distinct pieces of work could ease NICE's workload, although clearly producing

⁶² For example Ev 213 (Mid Devon Doctors' Group).

⁶³ Ev 242.

⁶⁴ Ev 93.

⁶⁵ Ev 93.

⁶⁶ Ev 252.

⁶⁷ Ev 18.

⁶⁸ Q79.

⁶⁹ Ev 70.

⁷⁰ For example, Ev 209 (Health Technology Board for Scotland); Ev 90 (ABPI).

comprehensive clinical guidelines takes significantly longer than completing a technology appraisal.⁷¹

58. The report of the public inquiry into children’s heart surgery at the Bristol Royal Infirmary chaired by Professor Sir Ian Kennedy (The Kennedy Report), proposed that NICE’s programme of clinical guidelines should be extended to cover the treatment and management of all major areas of morbidity and mortality in the UK, a task which NICE told us it would welcome.⁷² In evidence to us, Lord Hunt was also supportive of this idea: “we do not want to ... just target drugs in isolation from the clinical priorities of the NHS or the guidelines. That would not be sensible ... I think we have learned through experience that you can move away from very narrow remits in terms of asking to appraise one drug to get a more balanced view by making comparisons with a class of drugs”.⁷³

59. We recommend that the Government should fundamentally shift the emphasis of NICE’s work away from appraisals of specific treatments or interventions in isolation from the wider condition-management framework, towards producing guidance relating to classes of drugs or relevant groups of drugs, and/or on the treatment of particular conditions. In addition, we endorse the recommendation of the Kennedy Report that NICE’s guideline development programme should be extended to cover all major causes of mortality and morbidity. This may necessitate an increase in NICE’s capacity and/or a change in its organisational structure.

The timing of NICE guidance, ‘NICE blight’, and confusion and duplication within local health economies

60. One of the reasons for NICE’s establishment was to reduce the need for duplication of effort within local health economies.⁷⁴ Our evidence suggested that this aim was welcomed by the NHS, in that, as Croydon Health Authority argued, “the centralised sifting through the evidence offers the NHS as a whole an economy of scale”.⁷⁵ However, Hammersmith Hospitals NHS Trust commented that within its local health economy there were still a number of other bodies who independently reviewed the use of new drugs, including the New Drugs Panel within the hospital, the Health Authority Priority Setting Sub-Committee, and the relevant sub-committee of the Regional Specialist Commissioning Group. The consequence of this was that “there appears still to be considerable confusion as to the roles of these different bodies in the light of NICE guidance”.⁷⁶

61. Several memoranda suggested that NICE’s aim of ending confusion was hampered by the lengthy duration of the technology appraisal process, which could give rise to the phenomenon of ‘NICE blight’, whereby some health authorities issued blanket bans on the use of all treatments while they were going through the NICE process. CancerBACUP, a national charity providing information and support to people affected by cancer, said that this had occurred with the drugs trastuzumab for breast cancer and irinotecan for colorectal cancer, and argued that “In the case of cancer, this means that patients are being denied treatments that their doctors want to prescribe and that may offer them extra survival time and improved quality of life”.⁷⁷ The ABPI argued that ‘NICE blight’ operated at two different levels: firstly, health authorities and primary care organizations withhold funding of a product on the NICE work programme pending the NICE verdict; secondly, the same organizations also withhold funding in areas *not* listed when they assume that NICE is likely to look at them in the future.⁷⁸ A graph of prescribing data for the obesity drug orlistat, submitted to us by the Department of Health, shows a surge in prescriptions

⁷¹ Q277.

⁷² *Learning from Bristol: The Report of the Public Inquiry into children’s heart surgery at the Bristol Royal Infirmary, 1984–1995*, Recommendation 127, p.453; Ev 126.

⁷³ Q488; Q524.

⁷⁴ *A First Class Service*, 2.11.

⁷⁵ Ev 71; see also Ev 73 (Lambeth, Southwark and Lewisham Health Authority).

⁷⁶ Ev 234.

⁷⁷ Ev 52.

⁷⁸ Ev 90.

following the issue of NICE guidance, perhaps suggesting that ‘NICE blight’ had limited the use of the treatment prior to guidance being issued.⁷⁹

62. The Department of Health has now issued guidance prohibiting health authorities from issuing blanket bans on treatments awaiting NICE appraisal. While we welcome this, the persisting time lapse between launch of new treatments and publication of NICE guidance means that health authorities and primary care trusts must continue to conduct their own interim appraisals of treatments or interventions in the same way as they did prior to NICE’s formation. As Ealing, Hammersmith and Hounslow Health Authority put it, “Despite the creation of NICE ... a need to assess technologies and set priorities locally has remained because of the inherent delays in the NICE appraisal process”.⁸⁰ This leads to duplication of effort and variation of outcome, the potential scale of which will be substantially increased when health authority budgets are fully subdelegated to primary care trusts (PCTs). Problems may also arise when a local decision is contradicted by subsequent NICE guidance.

63. NICE accepted that the issue of timing was causing considerable problems:

“We have been playing a lot of catch-up at NICE. We have been looking at anti-cancer drugs that were first launched in 1994. This is not a tolerable situation. What we do need to do ... is to be proactive. We need to be starting the appraisal process a year before a drug is licensed. It is perfectly feasible to do it.”⁸¹

64. Mr Dillon cited the technology appraisal of glitazones for the treatment of diabetes as an example of guidance which had been issued shortly after launch and had worked well as a result. In its submission to us, NICE specifically suggested that it should be 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 become available for use in the NHS”.⁸²

65. We agree with Dr Duerden that “the expectations on NICE have been tremendous”.⁸³ Over the past two years the sheer scale of work has become apparent, and with this has come an increased recognition of the cost of such processes. With the benefit of hindsight, it could be argued more consideration should have been given to this prior to NICE’s establishment. Dr Duerden also suggested that “it might have been better to clearly separate the *catch up* role, where central guidance was required for drugs already on the market, being used subject to local vagaries (for example beta interferon for multiple sclerosis) from the need to horizon-scan and have guidance available for drugs at point of licence”.⁸⁴

66. Lord Hunt told us that over the next five to ten years it was his expectation that “any significant new technology where there was likely to be any doubt or controversy over cost-effectiveness and clinical effectiveness would be reviewed by NICE after launch or within a short period of time after launch”.⁸⁵ We welcome this aim, but remain concerned that without further investment in capacity and detailed consideration of the process it may not be possible for NICE to deliver this. We also feel that the five to ten year timescale proposed by Lord Hunt is too long given the significant problems this is causing the NHS.

67. 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.

⁷⁹ Ev 174.

⁸⁰ Ev 204 (Ealing, Hammersmith and Hounslow Health Authority).

⁸¹ Q274.

⁸² Ev 129.

⁸³ Ev 17.

⁸⁴ Ev 17.

⁸⁵ Q542.

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 expanded 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.

Status of NICE guidance

68. Our evidence revealed persisting confusion regarding the status and authority of NICE guidance. This came both from clinicians and from academics in the medico-legal field, who found it difficult to reconcile the conflicting messages given by the legal Directions made on 11 December 2001 and the duties of healthcare commissioners to respond to the needs of the local communities they serve.⁸⁶ In addition to this, clinicians have a legal duty of care to their patients, and PCTs have a duty to remain within their budgets. As pointed out by Dr Crayford: “It is very expensive seeking medico-legal advice and usually the same firms of lawyers are giving the same advice to all of our different authorities”.⁸⁷ **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.**

⁸⁶ “Before the Directions were published, it was understood that PCTs would be duty-bound to implement all NICE guidance. The press release which announced the policy said health authorities and PCTs would be expected to manage their budgets ‘so that patients can be guaranteed that if a treatment recommended by NICE is ... the appropriate treatment for them, they will receive it’. But the wording of the Direction itself is much less clear. The Direction says:

A Health Authority shall ... apply such amounts paid to it ... as may be required so as to ensure that a [treatment] recommended by the Institute ... is normally available ...

What does this mean? A ‘guarantee’ of access to care would direct that treatment recommended by NICE is always available. Why use the phrase ‘normally available’? Crucially, in what abnormal circumstances can PCTs decide not to implement NICE guidance? Would scarce resources be a good reason? If so, how different is the duty of PCTs now by comparison to the position before 2002?” [Christopher Newdick] (Ev. 19; see also Q197).

⁸⁷ Q197.

III. IS NICE PROVIDING GUIDANCE THAT IS LOCALLY OWNED AND ACTED ON IN THE RIGHT WAY?

“Clear credible guidance and robust audit methodologies are essential. But in themselves, these will not achieve change. Information needs to reach the right people – health professionals, patients, carers and those commissioning services – and be locally owned and acted on in the right way”

[*A First Class Service*, Department of Health, 1998, 2.21.]

Securing local ownership

69. Many witnesses suggested that there was an inherent contradiction in the aspiration for centrally produced national guidance to be locally owned, as national priorities might not always coincide with local needs.⁸⁸ However, most organisations who submitted evidence to us agreed that some level of national priority setting was appropriate. Inclusive processes that involve and engage appropriate stakeholders may go some way towards improving local ownership of national guidance, but as discussed in section I, there is some doubt as to whether NICE has succeeded in achieving ownership within the NHS.

Has NICE guidance been acted on in the right way and been implemented fully?

70. While it is not within NICE’s remit to ensure that the guidance it issues is fully implemented by the NHS, NICE clearly has an active interest in its impact, and it cited a survey of health authorities carried out by CancerBACUP to argue that “The majority of health authorities (80%) have a written policy for assessing the clinical and financial implications of implementing NICE guidance. Sixty-five per cent have a written policy for disseminating NICE guidance locally”.⁸⁹ The research suggests that NICE guidance on the use of taxanes in treating breast and ovarian cancer is well implemented, with over 90% of suitable breast cancer patients being offered taxanes and nearly 90% of suitable ovarian cancer patients.

71. However, CancerBACUP used this research to claim that NICE guidance was not being implemented uniformly throughout the NHS: “While some health authorities have set aside funds to ensure that NICE guidance is fully implemented, the majority have not. Fewer than half the health authorities in England and Wales have a policy for monitoring local compliance with NICE guidance, and most do not know whether all suitable patients are being offered treatments recommended by NICE”.⁹⁰ Using their own analysis of prescribing data, the ABPI claimed that there had been wide variations in uptake of medicines that have been appraised by NICE, with actual increases in prescribing of NICE-approved drugs only totalling at most a third of NICE’s projected estimates.⁹¹

72. In addition to claims of ‘under-implementation’, we also received evidence of inappropriate ‘over-implementation’. Alan Maynard, Professor of Health Economics at the University of York, suggested that following the issue of a NICE recommendation, pressure from patient groups sponsored by industry led to “excessive and inefficient use of the new technology beyond the recommendations of NICE”, and cited the example of rosiglitazone in the treatment of diabetes, where actual NHS expenditure has far outstripped NICE’s

⁸⁸ Ev 213 (Mid Devon Doctors’ Group); Ev 74 (Lambeth, Southwark and Lewisham Health Authority).

⁸⁹ Ev 127.

⁹⁰ Ev 52.

⁹¹ Ev 94–97.

estimates.⁹² Professor Walley gave the example of the now widespread use of Cox II inhibitors, which, he claimed, clinicians justified on the basis of the NICE guidance, but “which is in reality contrary to the detail of this advice”.⁹³

73. Professor Rawlins did not give us a definitive answer on whether he thought NICE guidance had been properly implemented, citing amongst other factors a lack of reliable data about secondary care prescribing. Lord Hunt also told us it was “hard to come up with precise figures” for the implementation of NICE guidance due to methodological difficulties. Rather than giving blanket approval or rejection, NICE guidance often recommends drugs in very specific circumstances, making it hard to gauge implementation by looking at overall prescribing changes; another problem is that it is hard to separate the impact of NICE guidance from other factors which may influence prescribing behaviour, including the fact that a treatment or intervention has been referred to NICE.⁹⁴ The Department of Health’s evidence includes primary care prescribing data showing increases in prescribing of certain drugs following a NICE recommendation, but given the difficulties outlined by Lord Hunt, it is probably inappropriate to infer the impact of NICE guidance from these figures.⁹⁵ Despite these difficulties in obtaining precise data, Lord Hunt told us that “the general feeling we have is that NICE guidance is taken very seriously by the NHS”.⁹⁶ To ensure uniformity over implementation, in December 2001 the Government issued directions making it mandatory for health authorities to act on NICE recommendations.

74. There also seemed to be a lack of clarity surrounding the role of the Commission for Health Improvement (CHI) in monitoring the implementation of NICE guidance. CHI suggested that would be part of their “future work” and Lord Hunt told us the same thing.⁹⁷ However, Professor Aidan Halligan, Director of the Clinical Governance Support Team within the Department of Health, suggested that NICE guidance had already been subject to some monitoring by CHI, arguing that: “One of the most common findings by the Commission for Health Improvement in their clinical governance reviews is that guidance from NICE and elsewhere is only partially, or sometimes not at all, implemented”.⁹⁸

75. There is a clear and urgent need for a systematic and co-ordinated approach to monitoring the implementation of NICE guidance. Given the difficulties associated with monitoring implementation using relatively crude indicators such as change in prescribing rates, we feel it is important that where possible, monitoring should focus on the use of particular treatments as part of holistic patient management. The Commission for Health Improvement, and in future the Commission for Healthcare Audit and Inspection (CHAI), seems to us the appropriate body to lead monitoring of NICE guidance. However, we are concerned that under its current organisation and power CHI may not be able to conduct detailed national audits of individual pieces of NICE guidance. Under current CHI arrangements NHS organisations are reviewed every four years, and the implementation of NICE guidance constitutes only a small part of a more broadly focused review, so may not be able to provide enough detail.⁹⁹ CHI plans for its national studies to include a review of implementation of NICE guidance, but national studies are currently only being carried out in National Service Framework areas. While in the long term the NSF programme may expand to be in concert with all NICE guidelines, there remains a question about the monitoring of the implementation of guidance on individual technologies that fall outside the areas for which there are currently National Service Frameworks, including, for example, Relenza.

⁹² Ev 237.

⁹³ Ev 25.

⁹⁴ Q523.

⁹⁵ Ev 174.

⁹⁶ Q523.

⁹⁷ Ev 200; Q523.

⁹⁸ Ev 226–27.

⁹⁹ *How Successful has NICE been?* T Dent, M Sadler, *BMJ* 2002; 324: 842–45.

76. 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 implementation.

Mandatory implementation of NICE's recommendations

77. The Government's recent directive announcing that implementation of NICE's recommendations on technology appraisals will be mandatory within three months of their issue can be seen as a positive step towards ensuring that NICE's guidance is acted on in the right way. Although the implementation of NICE's recommendations will not be 'mandatory' in the sense that NICE recommendations will override individual clinical judgement, health authorities and PCTs will have to ensure that the funding is available and the infrastructure in place to enable clinicians to act on NICE's recommendations. However, clinicians and commissioners of care are concerned that without specific 'extra' funding this will lead to inequities in the funding and provision of treatments and services which are not subject to NICE appraisal. The NHS Alliance argued that, because of mandatory funding, "In the pursuit of national equity ... there is a real danger of producing an even more sinister form of rationing than postcode prescribing – based on whether or not a patient has a 'politically correct' disease".¹⁰⁰

78. As well as treatments that are not initially investigated by NICE, other fields that may be disadvantaged include less visible but equally important parts of the care package such as nursing services. Dr Crayford told us that:

"four implantable cardiac defibrillators cost £120,000 and for that same amount of money you could have funded four extra nurses ... the nurses we could put into accident and emergency very directly stack up against some of the things which NICE have funded. When NICE says yes and it is mandatory, it deprives our local residents of the chance of getting core and basic services."¹⁰¹

79. Several of our witnesses maintained that mandatory funding of NICE recommendations meant that inequities would appear not only between different conditions and areas of service provision, but even within different aspects of service provision within one treatment area. Thus, the NHS Confederation suggested:

"A very disturbing example of perverse and unintended consequences of mandated funding is beginning to be apparent in the case of atypical anti-psychotics (which is currently at final appraisal stage). To fund the implications of the NICE decisions, reductions will need to be made in the already stretched staffing of mental health trusts, which will mean poorer overall care for patients."¹⁰²

80. Health authorities argued that a remedy to this problem would be for the implementation of NICE guidance to be given additional ring-fenced funding. Lord Hunt, however, told us he believed the additional funding currently being directed into the health service was sufficient to fund the impact of NICE guidance as well as funding and developing other service areas.¹⁰³ **Our inquiry has not probed the budgetary and financial impact of NICE guidance in detail, and so we are not able to make an informed assessment of whether or not PCTs will be able to afford to implement all NICE guidance. However, it is clear that in making the implementation of NICE**

¹⁰⁰ Ev 252.

¹⁰¹ Q182.

¹⁰² Ev 225; see also Q175.

¹⁰³ Q508.

Health Technology Appraisals mandatory in a healthcare system which operates within fixed budgets, there is the potential to give the provision of certain, NICE-approved treatments priority over other, perhaps equally important treatments and services not considered by NICE. This is a broader issue warranting consideration by the Department of Health rather than by NICE, and is discussed in greater detail in section V.

81. Much of our evidence indicated that there may be other barriers to the successful implementation of NICE guidance. The RCGP argued that given NICE's ambitious work programme, "there is a danger of overloading clinicians, particularly generalists, with information", and recommended that "the considerable level of investment by NICE should be paralleled by local resources directed at supporting clinicians in implementing the guidance."¹⁰⁴ In his written submission Andrew Moore, editor of *Bandolier*, an evidence-based medicine journal, put forward the concept of each NHS trust and primary care trust nominating a 'NICE ambassador' to improve the level of NHS input into NICE processes, and to facilitate greater implementation of NICE guidance at a local level. **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.**

¹⁰⁴ Ev 230.

IV. IS NICE ACTIVELY PROMOTING INTERVENTIONS WITH GOOD EVIDENCE OF CLINICAL AND COST-EFFECTIVENESS SO THAT PATIENTS HAVE FASTER ACCESS TO TREATMENTS KNOWN TO WORK?

“national guidance will mean that interventions with good evidence of clinical and cost-effectiveness will be actively promoted, so that patients have faster access to treatments known to work.”

[*A First Class Service*, Department of Health, 1998, 2.17.]

Faster access for patients?

82. NICE pointed out to us that it could not, on its own, “provide faster access to treatments”, and that guidance clearly needs to be properly implemented before patients would feel its benefit. According to NICE, “it has been independently argued that, generally, where NICE recommends the use of a technology it will lead to faster and more uniform access to these technologies”.¹⁰⁵ However, some witnesses contended that because of ‘NICE blight’ the existence of NICE has in fact considerably slowed access, with drugs that might previously have been available being vetoed pending a recommendation from NICE. It is to be hoped that the recent government directives will put an end to this practice, and that our recommendation that NICE move towards assessing new treatments at the time of launch will enable NICE to secure faster access for patients in future.

The issue of evidence and technical quality

83. For NICE’s stakeholders the importance of ensuring that its work is carried out to the highest possible standard is clear: “For the final guidance (HTA [health technology appraisal] or [clinical] guidelines) to be credible, whether with the public, patients, or the NHS, the process of assessment or development needs to be highly robust, transparent, and if at all possible, above criticism”.¹⁰⁶ This view was endorsed by Professor Maynard, who asserted that “it is essential that the science supporting NICE and other regulatory bodies be of the highest quality. Poor science and bad management can discredit the whole process”.¹⁰⁷ While we are not expert in the methodology for assessing either clinical or cost-effectiveness, there are some generic issues relating to NICE’s processes which have become clear during the course of our inquiry. Whether or not the treatments or interventions NICE promotes can be said to be supported by “good evidence of clinical and cost-effectiveness” is essentially dependent on three key factors: the quality of the evidence on which the assessment is based; the quality of the actual analysis and assessment; and the clarity with which NICE links its recommendations to its analysis and evidence.

Quality of evidence

84. The Alzheimer’s Society pointed out that “the decisions that NICE makes can only be as good as the evidence it receives”.¹⁰⁸ The Consumers’ Association, which publishes the Drug and Therapeutics Bulletin, argued that it was “worrying that the group commissioned by NICE to prepare the Health Technology Assessment report on zanamivir indicated they did not have access to all the information needed to fulfill this brief”.¹⁰⁹ A lack of information from manufacturers was also mentioned by Dr Sheila Bird, a member

¹⁰⁵ Ev 128, citing Raftery, J, *Analysis of guidance on health technologies*, *BMJ* 2001; 323:1300–1303.

¹⁰⁶ Ev 47 (National Cancer Alliance).

¹⁰⁷ Ev 236.

¹⁰⁸ Ev 54.

¹⁰⁹ Ev 5.

of NICE's Appraisal Committee, who noted that "NICE-commissioned research into cost-effectiveness of disease-modifying treatments of multiple sclerosis was not accorded full access [to individual patient data] by all pharmaceutical companies".¹¹⁰

85. As discussed in paragraph 40, the UK Cochrane Centre and the MRC Clinical Trials Unit both made the point that, unlike the situation which applies in respect of the medicines licensing system, there is no legal requirement for manufacturers to provide NICE with all the relevant information about a treatment or intervention under assessment, and they claimed that this left open the possibility of NICE decisions being based on a biased subset of data.¹¹¹ In their oral evidence, both NICE and the pharmaceutical industry strongly contested that this had ever happened in practice.¹¹² However, NICE felt that being able to back up requests for information with the force of statute would be helpful. **We recommend that the Government should take steps to ensure the submission of all relevant clinical information to NICE. The definition of what types of information are deemed 'relevant' to NICE will obviously require careful consideration, and to this end we suggest that NICE should work with the ABPI to establish guidelines on which types of information must be routinely supplied to NICE, and which types must be made available on request. If the ABPI is prepared to require companies' compliance with these guidelines as a condition of continued membership, it may be possible to avoid the alternative of legislation in order to ensure that no important information is withheld from NICE.** As we have recommended that all data submitted to NICE should be made public, it would clearly be necessary to put in place mechanisms to ensure that no information identifying individual patients is submitted to NICE, and neither would companies be required to submit efficacy data on the use of a particular drug or intervention in indications other than those under consideration by NICE, as these may be legitimately commercially confidential.

86. The Medicines Control Agency (MCA), working with the Committee on Safety of Medicines (CSM), conducts detailed assessments of the quality, safety and efficacy of new medicines as part of the licensing process, and the preliminary summary and committee judgements produced are likely to prove a valuable analytical resource for NICE. **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 outputs.**

87. At present, the information submitted to the CSM as part of the drug licensing process remains confidential, as do the CSM's preliminary summary and committee judgements. If this information were to be shared with NICE in confidence, this would run counter to the principle of transparency that NICE should publish all the evidence on which its decisions are made. Under the system we have proposed in section II, if pharmaceutical companies insist that their unpublished data remain confidential then they will be forced to withdraw from the NICE interim appraisal process. Although this carries the risk of the NHS being denied interim guidance on a treatment, we believe that pharmaceutical companies are unlikely to use this as an 'opt-out' clause, as their refusal to submit their evidence to public scrutiny would surely have a negative impact on commissioners' and clinicians' perception of the usefulness of their product.

88. There are, however, further issues relating to the strength of NICE's evidence base which relate to the availability rather than the accessibility of information. Much of the evidence NICE uses in its assessments comes from research conducted by drug manufacturers prior to the drug licensing process. Professor David Barnett, Chair of NICE's Appraisal Committee, described the shortcomings of this information: "Frequently the evidence base available for the appraisal is limited to little more than that which is used

¹¹⁰ Ev 196.

¹¹¹ Ev 199; Ev 244.

¹¹² QQ290-93; QQ348-55.

for licensing purposes and the important issues of clinical and cost-effectiveness in real life practice have not been investigated sufficiently”.¹¹³ Aventis explained the distinction between the types of appraisal:

“Clinical effectiveness differs from clinical efficacy as it incorporates the notion of how a drug works in real life, rather than the constrained observational environment of a clinical trial being run according to a strict protocol. It also includes the expanded notion of tolerability, which includes not only the classical side effect profile but also the broader, specific and general impact on a patient’s quality of life.”¹¹⁴

89. While the clinical effectiveness of treatments for short-duration illnesses such as influenza may be relatively easy to assess, for chronic relapsing conditions such as multiple sclerosis, it can take decades before the final value of the treatment is known. Equally, for cancer treatments a determinant of clinical effectiveness such as five-year survival rates will obviously not be available until five years after patients are first treated. This means that in assessing the clinical effectiveness of a drug before or at the time of licensing, NICE often has to rely on evidence gained via a range of modelling techniques where other more quickly measurable endpoints (for example, time to disease progression) are used as surrogate endpoints for clinical outcomes such as survival. This type of modelling is at best an imperfect science, and several of our memoranda questioned the appropriateness of approximations used by NICE in different appraisals.¹¹⁵

90. The ABPI raised concerns that “recommendations made by NICE in some circumstances are being made too early, on the basis of immature evidence”, and went on to argue that “issuing definitive guidance on a medicine too early can have damaging consequences – it can deny opportunities for discovery of valuable therapeutic potential in the form of new uses”.¹¹⁶ A further problem with conducting technology appraisals solely on the basis of pre-licensing research is that, as most of this research is industry-sponsored, the full disadvantages of the use of the treatment in practice have rarely been revealed.

91. 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 a 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.

92. According to the definition given by Aventis, clinical effectiveness includes a treatment or intervention’s “general impact on a patient’s quality of life”. As such measures are frequently not included in the efficacy trials conducted by pharmaceutical companies, patient organisations are often the only source of information on the impact of a treatment on quality of life. Such organisations vary considerably in their size and in their capacity to contribute to NICE’s work, and less common conditions, acute conditions and those with short survival times may lack representative organisations. This means that the quality of evidence on quality of life and patient experience supplied to NICE may vary considerably between different appraisals and guidelines. This gap was identified by the Alzheimer’s Society: “NICE must have high quality evidence of what patients think. If NICE cannot get that from the patient groups in a particular appraisal then it should be

¹¹³ Ev 131.

¹¹⁴ Ev 247.

¹¹⁵ For example, Ev 4 (Consumers’ Association); Ev 248 (Aventis).

¹¹⁶ Ev 91.

commissioning that research”.¹¹⁷ Patients and carers themselves may be even less able to contribute. While the MS Society argued that NICE’s “attitude seems to be that ‘real’ people cannot be objective about their conditions and somehow pollute the Institute’s scientific approach”,¹¹⁸ Professor Barnett implied that the problem may be one of evidence quality, describing some patient and carer submissions as “rather disparate and poorly focused”. Professor Barnett did, however, agree that “often the patient perspective has not been, to date, given the credence it should and may seem disadvantaged relative to the weight of scientific, clinical and health economic data provided from other sources”.¹¹⁹

93. NICE now makes a payment of £400 to relevant patient organisations who submit evidence, to cover their costs in contributing to the assessment process. This may go some way towards alleviating the financial burden of the NICE appraisal process, but it does not address the underlying issue, which is the lack of a systematic means of securing reliable evidence of patient experience and quality of life to feed into the NICE appraisal process. Professor Barnett told of plans to develop a ‘Patient Impact Assessment Document’ which will draw together the patient and carer submissions received by NICE, and which will run alongside the academic Health Technology Appraisal report. While this may be an improvement on existing systems, we do not believe that continuing to rely on proactive submissions from patients and their representative organisations is a satisfactory alternative to systematically obtaining high-quality data on patient experience and quality of life.

94. We recommend that NICE should consider options for improving its evidence base in respect of patient experience and quality of life, including the possibility of working with governments, at national and EU level, and with the pharmaceutical industry to promote the routine inclusion of condition-specific quality of life measures into controlled clinical trials carried out prior to licensing by the pharmaceutical industry. NICE may find it profitable to draw on the expertise of the new Commission for Patient and Public Involvement in Health established by the NHS Reform and Healthcare Professions Act, when this body is established. The Government should consider extending the remit of this body to include explicitly the securing of appropriate patient input into NICE processes.

Quality of NICE’s analysis

95. How accurately and robustly NICE analyses the evidence it receives is also a key determinant of the overall quality of its appraisals. Many of our witnesses drew attention to problems in this area: Dr Duerden described “concerns about the technical integrity”¹²⁰ of some of NICE’s guidance, as well as “technical mistakes or omissions”. The Drug and Therapeutics Bulletin cited numerous examples of what they regarded as errors or discrepancies in individual pieces of NICE guidance, and told us that the scale and breadth of these made them feel that these were not isolated incidents, but “fairly fundamental problems”.¹²¹ Helen Marlow of Croydon Health Authority reported that “People who look at [NICE appraisals] in detail feel that the quality of some of them could be better”,¹²² and GlaxoSmithKline asserted that “Pretty much factual errors have occurred in all of the individual appraisals which we have been involved in”.¹²³

96. Crucial to the technology appraisal process is the Health Technology Assessment (HTA) report, the production of which NICE usually contracts out to one of six independent academic institutions. The Alzheimer’s Society levelled particular criticism at the HTA report on drugs in its area, arguing that “it contained many assertions unaccompanied by evidence and conclusions not justified by the evidence presented. It was

¹¹⁷ Q134.

¹¹⁸ Ev 44.

¹¹⁹ Ev 131.

¹²⁰ Ev 17.

¹²¹ Q9.

¹²² Q165.

¹²³ Q261.

inconsistent in its treatment of different types of evidence citing unpublished and unreferenced observational data as well as properly conducted trials. References in the report were incomplete, some were incorrect, relevant publications were omitted”.¹²⁴ GlaxoSmithKline also raised concerns about what they saw as “the great deal of variability in the assessment groups and the original assessments they provide for the Appraisal Committee to consider”.¹²⁵

97. The MRC Clinical Trials Unit and the NHS Centre for Reviews and Dissemination were concerned that the requirement for relative speed in making technology appraisals, might “seriously compromise [their] quality”.¹²⁶ In the estimation of the NHS Centre for Reviews and Dissemination, a high quality systematic review of scientific evidence can take an average of 12–18 months, while NICE aims for a six month turnaround. CERT argued that “some of the variability in the appraisals may reflect insufficient resources at NICE. The health technology groups commissioned to develop the evaluation reports are paid only around £14,000”.¹²⁷ NICE disputed this figure and asserted that the figure is approximately double this.¹²⁸ However, we would anticipate that a team of competent people (including four researchers and two administrators) working full time for six months with the necessary back up could cost as much as £150,000.

98. We recommend that NICE should ensure that the academic centres to which it contracts its assessment work are adequately resourced to enable them to conduct Health Technology Assessments to the highest possible standard. Increasing the resources NICE directs at this area of its activity may enable it to improve the quality of its work and recruit more scientists of the highest calibre and experience. In addition to this, we are concerned that with the considerable expansion in NICE’s coverage we have suggested, there may be workforce as well as funding issues. There are at present only a limited pool of skilled academics available within the UK, especially in the field of health economics, and the pharmaceutical industry is competing to recruit from the same pool. NICE and the Government must work together to address this problem.

99. Several of our submissions also pointed to a current lack of quality audit of NICE’s own appraisals.¹²⁹ Lord Hunt told us that in addition to workload and output targets, the annual accountability meeting held between NICE and its sponsor Minister considers the robustness of NICE’s processes in general terms, but this arrangement clearly does not offer the scope for detailed audit of NICE’s outputs.¹³⁰ **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.**

How does NICE arrive at its decisions?

100. A lack of understanding of NICE’s analytical methodology was a common theme in our evidence. North Tyneside Health Authority argued that the credibility of guidance has been undermined where it is unclear how the Institute reached its decision.¹³¹ Ealing Hammersmith and Hounslow Health Authority felt that “The 2001 Guide to the Technology Appraisal Process says very little about how the Appraisal Committee should come to its decision. Issues such as these could be given more prominence by making the process of weighting the strength of evidence, relative (cost) effectiveness and other factors

¹²⁴ Ev 54–55.

¹²⁵ Q259.

¹²⁶ Ev 222; Ev 243.

¹²⁷ Ev 107.

¹²⁸ Ev 166.

¹²⁹ For example, Ev 239 (Professor Maynard); Ev 54–55, Ev 56 (The Alzheimer’s Society).

¹³⁰ Q450.

¹³¹ Ev 77.

more explicit”.¹³² Confusion about evidence-weighting seemed widespread: Clara McKay, principal policy adviser to the Consumers’ Association, argued that a wide-ranging independent survey of patient organisations conducted by the Association revealed “a real concern across the board of patient organisations not having a sense of the impact they make on the outcome of the guidance”, and this uncertainty was not confined to patient organisations. The NHS Centre for Reviews and Dissemination asserted that:

“Research findings at times appear to receive less weight than submissions from other stakeholders. The lack of clarity and transparency in the decision making process may lend itself to accusations of bias in favour of certain aspects of the process (e.g. input by pharmaceutical companies). The independence of NICE is threatened by this lack of clarity.”¹³³

101. NICE told us quite categorically that “we regard the evidence submitted by all of our stakeholders as of equal value, and equal value also with the assessment report that we receive ... from the independent academic organisations”.¹³⁴ It had recognised a lack of clarity about how its decisions are reached, and its reports now included a “Consideration” section which sets out how the Appraisal Committee interpreted its evidence, and how different types of evidence influenced its conclusions.¹³⁵ However, we feel that this section is very brief, and has yet to offer the sort of information that will assure readers of the validity of NICE’s processes.

102. Many concerns were raised about cost-effectiveness, and in particular NICE’s use of cost per Quality Adjusted Life Years (QALYs), a method which attempts to provide a comparative measure of the benefits of a treatment against its cost, considering the extra years of life the treatment or intervention is likely to yield per person treated, adjusted to take account of quality of life. Dr Crayford of Croydon Health Authority was one of many who criticised NICE for its inconsistent approach to the use of Quality Adjusted Life Years, which he estimated NICE had employed in only about half of its assessments.¹³⁶ The ABPI argued that the true costs and benefits of treatments sometimes took years to establish, and several memoranda also made the point that NICE’s calculations of cost and benefit failed to take account of the wider societal costs and advantages of particular treatments, including, for example, reductions in benefit dependency and improved ability to work, both for patients and their carers.¹³⁷ The difficulties surrounding the new and imprecise science of cost-effectiveness were recognised by NICE, who told us that “QALYs are not the answer, definitely not. They are, however, the only thing we presently have which is internationally recognised and gives us a handle on comparisons across technologies, across disease states and across individuals and age groups”.¹³⁸ **Whether or not QALYs 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.**

103. Glyn McDonald of the MS Society raised concerns about NICE’s decision-making process, describing the “creeping establishment of a threshold for cost-effectiveness”.¹³⁹ Professor Barnett told us that “The Appraisal Committee does not consider the threshold [for cost per Quality Adjusted Life Year] and has not been given instructions about a

¹³² Ev 203.

¹³³ Q6; Ev 8; Ev 222.

¹³⁴ Q356.

¹³⁵ Q356.

¹³⁶ Ev 72.

¹³⁷ ABPI give the example of the medicine EPO, used to treat patients with kidney failure, which had an estimated QALY at launch in 1990 of £103,000 but which, following changes in the management of patients, now has a QALY of around £3–9,000 (Ev 92). For discussion of wider costs and benefits see, for example, Ev 233 (The Pituitary Foundation), Ev 231 (RCGP).

¹³⁸ Q447.

¹³⁹ Q110.

threshold and has not discussed a threshold per se at all".¹⁴⁰ However, the King's Fund argued that, whether it is arrived at implicitly or explicitly, "NICE has a responsibility explicitly to justify the threshold that appears to have emerged as its decision rule".¹⁴¹ The decision about how much money the NHS should be prepared to spend to improve an individual's health or save their life is fraught with difficult judgements which go beyond the technical, as illustrated by Professor Walley:

"... it may be that a new therapy is uniquely effective but constitutes very poor value for money, i.e. a conflict between clinical effectiveness and cost-effectiveness. Whether it should be funded is therefore a matter for judgement or appraisal, to include the financial, social, ethical and legal implications of its use or non-use. The rules or values for such appraisal are not clear. We require open debate about how we value such trade-offs."¹⁴²

104. This was clearly understood by Professor Rawlins: "We certainly recognise that some of our decisions, or the basis upon which they are made, require value judgements. We fully recognise with those value judgements that we are no more competent than anybody else to make them".¹⁴³ **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.**¹⁴⁴ **We agree with the many witnesses who argued for a review of NICE's appraisal methodology, and the publication of clear criteria.**¹⁴⁵ **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 QALYs, 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 base by encouraging pharmaceutical companies to collect this type of data routinely.**

Cost-effectiveness and affordability

105. A further area of confusion and concern over NICE's remit and methodology relates to the issue of affordability. Although Lord Hunt and NICE were clear that affordability was not an issue for NICE, but was rather a matter for government, some witnesses felt that the boundary between cost-effectiveness and affordability was very blurred. Mr Cayton of the Alzheimers' Society argued that: "one of NICE's biggest problems was being given this second task, which in a sense people have referred to as really a political decision, of doing cost-effectiveness as well as clinical effectiveness".¹⁴⁶ Dr Cunningham of Lambeth, Southwark and Lewisham Health Authority suggested that:

"In a sense NICE was set up to give robust guidance on the basis of evidence, and it appears now to be almost being asked to do resource allocation by the Department of Health. It seems sensible to separate these two functions more clearly, particularly the selection of the portfolio which NICE considers and the decisions which are made when NICE has made its pronouncements."¹⁴⁷

106. As the Government has now issued directions for mandatory implementation of all NICE guidance, the funding and provision of treatments would appear to "follow automatically"¹⁴⁸ from a positive NICE appraisal, or be automatically withheld following

¹⁴⁰ Q447.

¹⁴¹ Ev 210.

¹⁴² Ev 23.

¹⁴³ Q315.

¹⁴⁴ Q315.

¹⁴⁵ Ev 2 (Consumers' Association); Ev 246 (Aventis).

¹⁴⁶ Q123.

¹⁴⁷ Q146.

¹⁴⁸ Q82.

a negative one. This may create the impression that, because it is likely that NICE recommendations will be implemented whatever the cost, NICE is essentially making decisions about how money is spent in the NHS, or ministers are somehow making decisions through NICE. As Professor Walley put it, “because it is not apparent when the Minister has made a decision that the funding will be available, there is a perception, which I do not think is actually true, that at some point the Minister has influenced the process before it has got to the final stage”.¹⁴⁹ This confusion may be consolidated by the wording of NICE’s Framework Document, which states that NICE should have regard to “the effective use of available resources”, and by the fact that NICE calculates and publishes the net budget impact of its recommendations, although NICE is clear that this plays no part in the appraisal process.¹⁵⁰

107. Decisions about the affordability of NICE’s recommendations are, we believe, properly a matter for government. We also believe that there is a need for decisions about the affordability of NICE’s recommendations to be seen to be made entirely separately from NICE’s decisions about clinical and cost-effectiveness. While we have received no compelling evidence that these decisions are not being taken independently, the widespread perception that the three elements are linked urgently needs to be dispelled. We therefore recommend that the Government should take steps to clarify its own role in taking decisions about whether or not individual pieces of NICE guidance will be funded. One solution would be for the Department of Health to issue a separate document alongside each piece of NICE guidance, stating the costs (both financial and staffing) of implementation of the guidance, and on the basis of this indicating whether or not, and in what circumstances, the guidance was to be implemented.

¹⁴⁹ Q82.

¹⁵⁰ Q312.

V. INDEPENDENCE

108. NICE's independence from Government and from the manufacturers, organisations and individuals who have a stake in its processes is clearly essential if it is to carry out its work properly and to maintain its credibility. The particular importance of NICE's independence from Government was emphasised by the Kennedy Report,¹⁵¹ the Government's response to which committed it to remove the requirement for approval of the Secretary of State for Health and the National Assembly for Wales for the dissemination of NICE guidance, and to give NICE the power to determine its own committee membership and structure.¹⁵² However, while a reduction in government control may represent a theoretical increase in NICE's independence, for NICE to establish itself as truly independent it must demonstrate this in practice.

109. Some witnesses have expressed confidence in NICE's independence. Dr Crayford, for example, described the membership of NICE's committees as "heavyweight and unbiased".¹⁵³ NICE's controversial decision not to recommend the use of beta interferon for the treatment of multiple sclerosis in the NHS has also been cited as an example of its independence.¹⁵⁴ However, as we have noted, other contentious decisions, including NICE's revised guidance on Relenza, have led to the concern voiced by Dr Duerden that "maybe NICE had been got at".¹⁵⁵

NICE's relationship with the pharmaceutical industry

110. Many witnesses in particular questioned NICE's independence in relation to the pharmaceutical industry, a perception which may be compounded by the fact that NICE's Framework Document states: "the Institute will also wish to ensure that, in carrying out its statutory functions, it is sympathetic to the longer-term interest of the NHS in encouraging innovation of good value to patients". The tension between NICE's role in securing clinically and cost-effective treatments for NHS patients and its simultaneous role in supporting the pharmaceutical and other healthcare industries by "encouraging innovation" is perhaps heightened by the fact that the same sponsor branch in the Department of Health is responsible both for NICE and for the pharmaceutical industry.

111. The ABPI felt that these two aims were not irreconcilable, suggesting that if NICE was able to appraise new treatments quickly and promote access for patients, "the interests of industry would follow on behind, and it would be encouraging innovation".¹⁵⁶ NICE argued that, in this context, its remit was to promote clinically innovative practice and end unnecessary 'therapeutic conservatism' by promoting the use of clinically effective and cost-effective new treatments. This type of innovative practice could reach beyond pharmaceuticals to encompass a broad range of treatments and interventions, and could also refer to the innovative use of existing treatments.¹⁵⁷ Lord Hunt, however, seemed to recognise the possible conflict, arguing that "from where I sit, because I have to deal with both sides (if we are talking about sides), I believe we can take a very robust, balanced approach".¹⁵⁸

112. Professor Rawlins told us that, where there were doubts about a treatment, NICE aimed to "default in the interests of patients" who might benefit from it, an approach clearly also beneficial to the pharmaceutical industry:

¹⁵¹ *Learning from Bristol: The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary, 1984–1995*, Recommendations 40–41.

¹⁵² *Learning from Bristol: The Government's Response to The Report of the Public Inquiry into children's heart surgery at the Bristol Royal Infirmary, 1984–1995*, para 4.8.

¹⁵³ Ev 71; see also Ev 232 (Royal College of Paediatrics and Child Health).

¹⁵⁴ *Effectiveness, Efficiency and NICE*, *BMJ* 2001 322, 943–944.

¹⁵⁵ Q33.

¹⁵⁶ Q284.

¹⁵⁷ Q320; Q322.

¹⁵⁸ Q547.

“There are a number of individual appraisals, which we could go into if you wish, where there has been some doubt – it has not necessarily been beyond reasonable doubt but on the balance of probabilities – that patients would be advantaged by having access to a particular medicine, and so I believe that in encouraging innovation we should encourage that sort of use of treatments.”¹⁵⁹

113. Serving the interests of a particular group of patients who might benefit from a treatment, and by extension, the healthcare industry supplying that treatment, may have an opportunity cost for those NHS patients who will not receive the treatment, but who may suffer from cutbacks elsewhere. The impact of mandatory funding on the NHS is discussed more fully later in this section. However, it is clear that NICE must maintain the confidence of both the NHS and the public more generally that it is serving the interests of NHS patients rather than those of the pharmaceutical industry. We have already recommended that NICE should make improvements to the transparency of its decision-making processes, and that in future these should be governed by a clear, published set of criteria. We recognise that NICE has already made efforts to clarify some of its processes, but we see this as pivotal to NICE’s success and would caution against any complacency in this area.

Independence from government and selection of topics

114. Much of our evidence used the concept of independence to comment on the issue of NICE’s relationship with the Government more widely. In section IV, we discussed the need to draw a clear distinction between NICE’s role in assessing cost-effectiveness and the Government’s role in assessing affordability. Another key concern is the selection of topics for NICE’s work programme by the Department of Health and the National Assembly for Wales.

115. NICE’s work programme is of critical importance because it involves prioritising the assessment of some treatments or clinical areas above others. The implementation of NICE guidance is now mandatory, but without ring-fenced additional funding the provision of treatments NICE has recommended may be at the expense of other equally or perhaps more effective treatments which have not been appraised by NICE. The selection and agreement of topics for NICE’s work programme is therefore the process which ultimately determines those treatments and services to which NHS patients may be able to have guaranteed access, and those to which they will not have guaranteed access. This was illustrated by North West Lancashire Health Authority, who told us:

“We are aware of many different types of intervention, which can have a great and sustained effect on the quality of patients’ lives, that are forced into a lower priority position as a result of not having been considered (yet) by NICE. Photodynamic therapy for age-related macular degeneration, surgical techniques for the treatment of intractable angina, and neuro-surgical interventions for Parkinson’s disease are examples that fall into this category.”¹⁶⁰

116. The critical role of the topic selection process was clearly recognised by NICE, who emphasised the importance of being given “the right topics, topics that the NHS collectively regards as important aspects of clinical practice on which it wants consistent service to be provided for patients, on which it wants consistency of access”.¹⁶¹ **Some witnesses (including, for example, the BMA) argued that NICE should be able to determine its own work programme, suggesting that this would facilitate a more neutral, rational appraisal of the costs and total health benefits of various treatments, drawing on public and professional concerns, and that it would significantly improve**

¹⁵⁹ Q321.

¹⁶⁰ Ev 227.

¹⁶¹ Q313.

NICE's credibility.¹⁶² However, NICE itself does not ask for this additional responsibility. We feel that this very high-level prioritisation is rightly the job of Government, rather than that of a body which is not publicly or politically accountable for such a function.

The topic selection process

117. According to NICE, the Department of Health has made considerable improvements to the topic selection process since it first began, enabling NICE to have “a much more robust say in what counts”.¹⁶³ Despite this, Professor Rawlins told us that “the process is still somewhat opaque and obscure”.¹⁶⁴ This view was endorsed by NICE's stakeholders, many of whom argued that the Department of Health-led Technology Advisory Group needed to be more transparent and inclusive.¹⁶⁵ This was echoed in NICE's own suggestion that its work programme should be “constructed in a more open and inclusive manner”, and in its acknowledgement that at present “there is insufficient opportunity for NHS staff to propose either appraisal or clinical guideline topics”.¹⁶⁶

118. During our inquiry, the Department of Health and the National Assembly for Wales published a consultation paper covering the selection of topics for NICE's work programme.¹⁶⁷ The key proposals of this are the establishment of a web-based topic-proposal system, the use of a network of advisers to nominate ‘peer reviewers’, a wider membership of the Technology Advisory Group, and amended topic selection criteria. **We welcome in principle the idea of a web-based topic proposal system, 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 leave the NHS, and in particular patients, under-represented.¹⁶⁸ 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.**

NICE's current topic focus

119. As well as shortcomings in the topic selection process, many witnesses gave us useful illustrations of what they felt were problems with NICE's current focus as determined by the topic selection process. Most were in agreement that NICE's focus placed undue emphasis on expensive drug treatments at the margins of healthcare, when it should in fact be considering the treatments which are of the greatest benefit to the population as a whole. We were told by Ealing, Hammersmith and Hounslow Health Authority that:

“a more systematic review of the impact of health care interventions would have resulted in [guidance] having been developed for common conditions such as femoral neck fracture, stroke, depression, hypertension and dyslipidaemia.”¹⁶⁹

120. Lambeth, Southwark and Lewisham Health Authority argued that “It would be very helpful if [NICE's] programmes were extended to cover major areas of morbidity and mortality which more reflect the priorities we are all facing locally. It would help us to be

¹⁶² Ev 197–98.

¹⁶³ Q301.

¹⁶⁴ Q301.

¹⁶⁵ For example, Ev 50 (CancerBACUP); Ev 46 (National Cancer Alliance); Ev 92 (ABPI).

¹⁶⁶ Q325.

¹⁶⁷ *Clinical Guidance from the National Institute for Clinical Excellence – Timing and Selection of Topics for Appraisal*, Department of Health/ National Assembly for Wales, March 2002.

¹⁶⁸ Proposed membership includes 12 representatives from the Department of Health/ National Assembly for Wales, 3 representatives from NICE, 4 from the NHS and 2 from patient organisations (*Clinical Guidance from the National Institute for Clinical Excellence – Timing and Selection of Topics for Appraisal*, Department of Health/ National Assembly for Wales, March 2002, Annex B).

¹⁶⁹ Ev 205.

able to deal more with the affordability issues because the NICE guidance portfolio would be more relevant to the needs we are facing every day”.¹⁷⁰ In its written submission to us, the authority outlined several areas in which, as would seem reasonable, NICE’s ‘priorities’, extrapolated from the areas in which NICE guidance had the potential to lead to the highest NHS spending increases, were different from locally-assessed priorities:

Key health priorities of emerging primary care trusts compared with top NICE priorities

Lambeth	Southwark	Lewisham	NICE*
Coronary heart disease (CHD) and stroke	Coronary heart disease and stroke	Coronary heart disease and stroke	Cancer
Sexual health	Sexual health	Sexual health	Obesity (also prevents CHD)
Older people	Older people		Rheumatoid arthritis
Mental health	Mental health	Mental health	Hepatitis C
Children	Diabetes	Diabetes	Acute CHD
	Disabilities		Alzheimer’s disease

*priorities derived from proportionate increased NHS spend implied by guidance from March 2000.¹⁷¹

121. NICE’s work to date has also demonstrated an overwhelming focus on drug treatments, although, as pointed out by Lambeth Southwark and Lewisham Health Authority, “drugs are not necessarily the most important component of treatment and care from a patient’s perspective, and should be considered as part of the overall pathway for treatment”.¹⁷² Further to this, Professor Walley told us of his impression that: “some of the priorities of NICE, as documented by the issues on which they give guidance, are more priorities for perhaps their commercial sponsors than for the NHS”.¹⁷³ He cited NICE’s appraisal of two drugs used to treat obesity, arguing that a wider framework for managing obesity would be more useful to the NHS than isolated guidance on two drugs. While we hope that NICE’s increased focus on broad clinical guidelines rather than individual technology appraisals will begin to remedy this, the basis on which areas are selected is still clearly crucial.

¹⁷⁰ Q148.

¹⁷¹ Ev 74.

¹⁷² Ev 74.

¹⁷³ Ev 24.

122. The current criteria for the selection of topics for NICE’s work programme seem open to wide interpretation.¹⁷⁴ They are as follows:

Technology appraisals

- Is the technology (or appropriate use of the technology) likely to have a significant impact on patient care?
- Is the technology (or appropriate use of the technology) likely to have a significant impact on other government health-related policies?
- Is the technology (or appropriate use of the technology) likely to have a significant impact on NHS resources?
- Is NICE likely to be able to “add value”, eg by resolving uncertainty over the appropriate use of the technology?

Clinical guidelines

- Is NICE likely to “add significant value”, eg by resolving existing uncertainties?
- Is the proposal likely to have a significant positive health benefit for patients (ie, have good potential to reduce disability, morbidity or mortality)?
- Is the proposal likely to contribute a significant positive impact to the implementation of government health policies, including the NHS Plan, and NSF and Taskforce priorities?
- Is there sufficient current evidence to support the development of the proposal?
- Is the proposal likely to have a significant impact on NHS resources?
- Will the proposal help resolve an unacceptably wide variation in health outcomes and/or clinical practice?

123. Although some areas of national priority have received significant attention (cancer treatments, for example, constitute ten out of NICE’s 31 completed technology appraisals), other priority areas have not (for example, to date only one of NICE’s completed technology appraisals has covered a mental health intervention).¹⁷⁵ In the summary table submitted to us by the Department of Health, the second most frequent classification of technology appraisals was ‘other’ perhaps suggesting an undue focus on treatments outwith clearly defined areas of clinical priority.¹⁷⁶

124. Although a significant number of the clinical guidelines NICE currently has in progress are within identified government priority areas (ten are in the area of cancer, six in mental health, three in coronary heart disease and two in diabetes), many of NICE’s 32 “in progress” guidelines do not fall obviously within the areas outlined as clinical priorities for the NHS, including “pre-operative investigations”, “routine antenatal care” and “infertility”.¹⁷⁷

¹⁷⁴ Ev 173.

¹⁷⁵ NC62 Appendix F (*not printed*).

¹⁷⁶ Ev 169.

¹⁷⁷ NC62 Appendix G (*not printed*).

125. The Government’s consultation document proposes new, integrated selection criteria for both clinical guidelines and technology appraisals:

- Is there a need for guidance? In particular:
 - Does the proposed guidance relate to one of the NHS clinical priority areas? and/or
 - Does the proposed guidance address a condition which is associated with significant mortality or morbidity?
 - Does the proposed guidance relate to one or more interventions which could significantly reduce avoidable mortality or avoidable premature mortality, relative to current standard practice, or if used more extensively would do so?
 - Does the proposed guidance relate to one or more interventions which if more extensively used would impact significantly on NHS resources (financial or other)?
 - Does the proposed guidance relate to one or more interventions which could without detriment to patient care be used more selectively, thus freeing up NHS resources for use elsewhere in the NHS?
- Will NICE be able to add value by issuing guidance, taking into account the following factors:
 - Is the evidence base sufficient to develop robust guidance across most or all of the interventions to be covered by proposed guidance?
 - Is there evidence and/or reason to believe that there is or will be inappropriate practice and/or significant variation in clinical practice and/or variation in access to treatment in the absence of guidance?

126. **We welcome the amendments to the selection criteria proposed by the Government in its consultation document, as we feel they offer a clearer, more consistent and more rational framework for the selection of topics. However, we recommend that these criteria are explicitly underpinned by the principle of maximising total health benefit to all patients. The process by which topics are assessed against these criteria must also be inclusive and transparent, and should be backed up by a clear and public explanation of why particular topics have been prioritised for assessment by NICE.**

127. So far, NICE has recommended the vast majority (28 out of 31) of the treatments and interventions it has appraised either for routine or selected use.¹⁷⁸ Recent research suggests that the net financial impact on the NHS of NICE technology appraisals to date has been increased costs of between £135.2 million and £154.8 million.¹⁷⁹ Several witnesses have suggested that a more useful approach would be to aim to provide guidance on what treatments the NHS should be cutting back on, selecting topics accordingly. According to Dr Crayford, “there is an infinite number of things in which we could invest. What we need help with is in excluding things from this list, not lengthening it”.¹⁸⁰

128. This is a potentially very sensitive area, as it is even more difficult to withdraw funding for a drug patients are already being treated with than to withhold a new treatment from patients. However, Professor Rawlins agreed on the importance of “getting rid of useless treatments or inferior treatments”, and hoped that engaging the NHS in setting NICE’s work programme might help identify such treatments.¹⁸¹ **We welcome the fact that this is reflected in the Government’s proposed selection criteria, and recommend that the Department of Health gives explicit consideration to devoting a larger**

¹⁷⁸ Ev 170.

¹⁷⁹ *From Guidance to Practice – why NICE is not enough*, Sadler and Dent, *BMJ* 2002; 324: 842–845 (6 April).

¹⁸⁰ Ev 71.

¹⁸¹ Q375.

proportion of NICE’s clinical guidelines programme to appraising treatments and interventions where the evidence suggests that it may be appropriate for the NHS to reduce rather than expand use.

Beta interferon and independence

129. Several witnesses mentioned NICE’s appraisal of beta interferon and the Government’s subsequent decision to fund the drug in the context of further research as an issue of contention. Dr Andrew Bamji, a consultant rheumatologist, argued that in the case of beta interferon, “even though the clinical evidence of benefit is weak, patient pressure has forced a change of attitude by the Government which effectively overturns the NICE ruling. If this can happen then NICE’s position as an independent body is fatally compromised”.¹⁸² Although Lord Hunt told us that the course of action pursued by the Government was, in fact, one of the recommendations of NICE’s original guidance, and while this development clearly occurred outwith NICE’s processes and as such cannot be argued to have had a direct impact on NICE’s independence, it is possible to understand how stakeholders could view this as undermining NICE’s role. **We recommend that the Government, working together with NICE, should ensure that any subsequent decisions which could appear to run contrary to NICE recommendations are issued in a way that is sensitive to the potential risk such decisions may pose to NICE’s credibility. Such decisions should be clearly communicated to stakeholders, and could be issued in collaboration with NICE.**

The wider prioritisation debate

130. The final issue that has arisen from our inquiry is the role of NICE in relation to the wider debate on prioritisation in the NHS as a whole. Many of our witnesses felt very strongly that the new mandatory implementation of NICE guidance meant that NICE’s work programme now feeds into this prioritisation process in a way not intended when it was originally set up. We have already heard that considerable confusion exists over the separation of the affordability and cost-effectiveness functions, and we have recommended that the Government should attempt to clarify this. However, even with affordability and agenda-setting decisions placed firmly with government, our evidence suggests that there is still a need for further debate and clarification. Professor Walley described the issues in useful theoretical terms:

“Does NICE advice carry with it added resources to the NHS, or as seems to be the case, redistribution of existing resources? If this latter is the case, then all possible alternative uses of the resources need to be considered and a review confined to a single therapeutic area or technology is inadequate. A broader approach is necessary, to cover a wide range of, or even all, NHS activities.”¹⁸³

131. Croydon Health Authority offered a more practical perspective:

“Health authorities can only prioritise fairly if all competing demands are considered at once. Because of the way in which it has been set up, NICE does not do this, as it considers new treatments at the margin of healthcare. In contributing to the prioritisation debate in the NHS as a whole, it is therefore flawed. Until NICE has evaluated things like the benefit of funding new nurses for our local A&E department at the Mayday Hospital, then its recommendations to fund certain treatments, which are by default at the expense of this sort of development, cannot be rational for local health economies.”¹⁸⁴

¹⁸² Ev 193.

¹⁸³ Ev 24.

¹⁸⁴ Ev 71.

132. For NICE to conduct a full appraisal of the costs and benefits of every possible service improvement in the NHS would clearly be an unworkable aim within its present constitution and funding. However, in establishing NICE and making its guidance mandatory, the Government has provided a centralised valuation system for one area of service provision, namely new and/or controversial drug treatments and health interventions, without balancing this against guidelines for any other elements of service provision. This was illustrated very clearly by Mr Newdick, an academic in the field of health law, who argued that “NICE’s recommendation of a treatment for reducing the symptoms of *influenza* by one day commands the same access to resources as recommended *cancer* treatments”. Concluding his written evidence, Professor Walley argued that “there is a need for a rapidly responsive source of guidance for the NHS, but also for a body to take a broader view of NHS priorities: this seems to be beyond NICE at the moment”.¹⁸⁵

133. As Lord Hunt suggested, weighing competing priorities is inevitable for those who manage NHS budgets.¹⁸⁶ However, NICE raises difficult issues by introducing a systematic process for prioritisation in one area without extending the principles and expertise informing this more widely. In his written evidence, Mr Newdick suggested that primary care trusts need to be given a framework within which to consider new drugs and treatments which are not subject to NICE guidance, a point he developed in oral evidence, and argued for the introduction of “a system for gauging affordability ... according to a systematic series of values and a framework of ethics, which would be vague and imprecise, but would give us some idea about a limit on the demands that can reasonably be made on a cash-limited system”.¹⁸⁷

134. Prioritisation of healthcare spending is an issue of overwhelming importance, and during the course of this inquiry it has become clear to us that a more open debate on healthcare prioritisation needs to take place. Our inquiry has persuaded us that, with so many competing interests vying for attention and funding in an area where resources are finite, it is not sufficient to have implicit healthcare prioritisation. We feel that NICE has been laid open to unfair criticism in respect of the ‘rationing’ debate, as a consequence of the lack of clarity in policy here.

135. Clearly, it would be beyond the scope of the present inquiry for us to make specific recommendations in this area. **We do, however, wish to record our view that the Government must work to achieve a comprehensive framework for healthcare prioritisation, underpinned by an explicit set of ethical and rational values to allow the relative costs and benefits of different areas of NHS spending to be comparatively assessed in an informed way. Such a framework would need to secure the input of the wider population as well as NHS patients and staff, policy makers and academics. Although we are not seeking a detailed response on this point, we would welcome an acknowledgement on the part of the Government that this is a key issue, and we would not be convinced if the Government were to argue that prioritisation were already subject to such a framework.**

¹⁸⁵ Ev 25.

¹⁸⁶ Q508; Q510.

¹⁸⁷ Q55.

CONCLUSIONS

136. We welcome the introduction of NICE as an institution which can offer advice on treatments and interventions based, where possible, on strong, reliable evidence. We also recognise that NICE is a new organisation, and would wish to stress that our conclusions and recommendations are intended to support NICE in learning from its early experiences and developing its processes accordingly.

The quality and credibility of NICE's work

137. NICE has been expected to meet exacting delivery targets from its inception. As well as this, it has been obliged, by developing scientifically robust appraisal methodology and inclusive and transparent processes, to establish credibility with, and to ensure the engagement of, a diverse range of stakeholders. At just under three years old, NICE is a relatively new organisation, and it would be unlikely that its processes would be fully watertight. Our main recommendations in this area are intended to bring about improved processes for stakeholder involvement, a more robust appeals procedure, and improved transparency about its evidence and its decision-making. Our confidence in NICE is strengthened by the fact that it is already taking steps in many of the areas where we have highlighted room for improvement.

138. Rather than a conclusive assessment, this short inquiry should be seen as the first step in a continuous process of scrutiny and improvement, in which we intend to play an ongoing role. One of NICE's main challenges at this still early stage in its development is to establish itself with its stakeholders. Of these, the most heterogenous and daunting is probably the NHS, which is why it is perhaps unsurprising that NICE does not yet appear to have won the full confidence of those who work in the service, or to have wholly established the place of its work in relation to the multiplicity of other pressures and policies competing for priority in the NHS. We have recommended that NICE concentrate on improving its involvement of NHS trusts and strategic health authorities, and other recommendations concerning the focus of NICE's work and the selection of its work programme will support this. We hope that by the time we revisit NICE, these reforms, together with NICE's growing maturity as an organisations, will have enabled it to have fully imbedded itself within the NHS family.

139. The quality and credibility of NICE's work can only be as good as the evidence on which it is based. While we recognise the importance of using the best available evidence, we are also sympathetic to the numerous difficulties attached to procuring the highest quality information. Because of this, we have made several recommendations connected to enhancing the quality of information NICE is able to use in its work, covering:

- more data on quality of life and cost-effectiveness
- improved information-sharing with the Committee on Safety of Medicines
- an information-sharing agreement with the ABPI.

140. The area within which NICE works is populated by many expert groups and organisations. Although these groups may have differing remits, interests and viewpoints, they frequently have similar levels and types of expertise to NICE. The fact that many of these bodies already have well established reputations in the clinical areas they serve means that it is vital for NICE to engage constructively with them, and where appropriate share expertise. In section I we have recommended that NICE works to strengthen its relationships with expert organisations, including the British National Formulary and the Drug and Therapeutics Bulletin. Further to this, we are aware that although much of NICE's role essentially involves quality-assuring the research evidence available to the NHS, NICE itself is not supported by any means of independently quality-assuring its own work, and we have therefore recommended that the Government should consider options for rectifying this.

The focus, organisation and implementation of NICE's work

141. The concept of NICE guidance has been broadly welcomed by the NHS. However, some of our witnesses felt that the reality of NICE had raised difficulties, many of which were outside NICE's direct control. Difficulties surrounding the timing of NICE guidance and the focus of its work programme can be traced to the variety of competing aims NICE has faced from its inception:

- the need for guidance on specific controversial treatments, balanced against the need for comprehensive clinical guidelines on treatment of conditions as a whole
- the need for appraisals of new treatments, balanced against the need for appraisals of existing treatments that may be ineffective or suffer from inequitable provision
- the need for guidance to be timely, balanced against the need for that guidance to be of the highest scientific standard

142. While none of these aims are mutually exclusive, it would not be reasonable to expect NICE to have achieved all of them in such a short timeframe, or within the confines of its current structure or capacity. Drawing on the concerns raised in our evidence, we have therefore recommended that the Government should refocus NICE's efforts in several respects.

143. Firstly, we have recommended that a significantly increased proportion of NICE's resources should be devoted to NICE's clinical guideline development programme, which should be extended to cover all major causes of morbidity and mortality, as identified by a new, more inclusive and more transparent topic selection process. These changes in focus are supported by NICE, and are broadly supported by government. However, we are concerned at NICE's ability to deliver them without a significant increase in capacity, and therefore we recommend that the Government should extend NICE's funding to fully support these activities.

144. Alongside this, we have recommended that rapid 'interim' appraisals of all selected new treatments should be published to coincide with the launch of the relevant technology, with a proviso for later review where necessary. For a number of years there will clearly be a continuing need for NICE to appraise the backlog of existing treatments and interventions which suffer from inequitable provision, or are of questionable cost or clinical effectiveness. This function should be distinct from NICE's "new technology" function in order to ensure that both activities are occurring concurrently, and to raise confidence in the NHS that NICE is achieving a balance between them, and should be carried out as part of NICE's main clinical guidelines function.

145. To improve the clarity and impact of this refocused work programme, we have also recommended that NICE should develop clearer cross-referencing between technology appraisals and guidelines, clearer links with NSFs, and that the legal status of NICE technology appraisals and guidelines should be clearly communicated to the NHS by the Government.

146. The success of NICE's endeavour is critically connected to the thorough and systematic implementation of its guidance, which is again outwith NICE's direct remit. While the impact of the Government's recent directive in this area is not yet known, it is clear from our evidence that monitoring of implementation has not been rigorous. We have therefore recommended that the Government ensures that CHI (and later CHAI) is able to conduct appropriate monitoring of the implementation of NICE guidance.

NICE in its wider context

147. Many of the issues raised by this inquiry reach beyond the specific role of NICE, focusing on NICE's relationship with the Government and its place in the wider debates on funding and prioritisation within the NHS. Considerable confusion currently surrounds the role NICE plays in assessing the affordability of treatments in the NHS, and to this end we have recommended that the Government ensures that there is clarity about its own role in settling issues of affordability. NICE's methodology is obviously still evolving, and we hope it will continue to be subject to regular review and 'fine-tuning' by NICE itself. Cost-effectiveness is an issue subject to the difficult combination of being both emotive and little understood, and we feel that our evidence reveals a need for greater clarity about both the determinants of cost-effectiveness, and the attendant value-judgements these necessitate. We have therefore recommended a full-scale review of NICE's methodology, followed by the publication of clear criteria.

148. The Government's decision to fund further research on beta interferon under a scheme of risk-sharing following NICE's negative appraisal of the drug has also raised concern and confusion, pointing to the need for further clarification and development of the relationship between the Government and NICE. We have therefore recommended that the Government ensures that all its work on health technology research and pricing takes full account of NICE's work, and that any subsequent government decisions which could appear to run contrary to NICE recommendations are issued in collaboration with NICE to minimise the potential risk to NICE's credibility.

149. In addition to the clear value of its guidance to clinicians, patients and commissioners of care, NICE has generated great interest in its work because of the central position it holds in the highly charged debate about prioritisation within the NHS. NICE's role in prioritisation has come under even greater scrutiny since the Government directed that implementation of NICE's recommendations will be a mandatory requirement for health authorities, which means that NICE's decisions may now have a direct impact on spending priorities in local health economies. This makes the process through which topics are selected for NICE's work programme doubly critical. We have recommended that the transparency and inclusiveness of the Government's topic selection process is improved, and that topic selection should be informed by the total health benefit to all patients.

150. The mandatory funding of NICE recommendations also raises the question of how the NHS should value other competing calls on its resources which will not be assessed by NICE, including, for example, nursing services. While NICE has served as a focus for these difficult issues, we do not feel that this is a debate NICE is qualified, or should be expected, to lead unsupported, and we have therefore recommended that the Government should work to establish a broad framework of values to guide the NHS in its consideration of spending priorities. These values should also inform the Government's prioritisation of topics for NICE appraisal and guidance.

LIST OF CONCLUSIONS AND RECOMMENDATIONS

- (a) **It is clear that expectations of NICE have been high, and in addition to the challenges of its remit, NICE has also faced the same logistical and operational challenges as all nascent organisations. In this context, we welcome the support we have seen for the establishment of NICE, and we recognise that this represents an improvement on the previous situation (paragraph 6).**

Credibility

- (b) **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).**
- (c) **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 (paragraph 31).**

Inclusiveness

- (d) **We recommend that NICE takes steps to improve current methods of involving the NHS in the development of technology 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 (paragraph 36).**
- (e) **We welcome NICE's attempts to achieve better relationships and open channels of communication with stakeholders – particularly the NHS and patient groups. The future credibility of NICE rests on it being responsive to criticisms, and to it 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 (paragraph 38).**

Improved transparency

- (f) **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 (paragraph 40).**
- (g) **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 (paragraph 43).**

The appeals system

- (h) **Improvements 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).**
- (i) **The current role of the Chair in the appeals system seems to 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 that this creates between the Chair and the everyday business of NICE may be to the detriment of the organisation as a whole (paragraph 49).**

Improved clarity

- (j) **We recommend that NICE should strive to improve clarity and co-ordination within and between its own workstreams, and should work closely with the Government to ensure clarity about the relationship between its own work, NSFs and other policy initiatives in the NHS (paragraph 54).**

A shift in focus from technology appraisals to clinical guidelines

- (k) **We recommend that the Government should fundamentally shift the emphasis of NICE's work away from appraisals of specific treatments or interventions in isolation from the wider condition-management framework, towards producing guidance relating to classes of drugs or relevant groups of drugs, and/or on the treatment of particular conditions. In addition, we endorse the recommendation of the Kennedy Report that NICE's guideline development programme should be extended to cover all major causes of mortality and morbidity. This may necessitate an increase in NICE's capacity and/or a change in its organisational structure (paragraph 59).**

The timing of NICE guidance

- (l) **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 expanded 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).

The legal status of NICE guidance

- (m) 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).

Implementation and monitoring of NICE guidance

- (n) 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 implementation (paragraph 76).
- (o) Our inquiry has not probed the budgetary and financial impact of NICE guidance in detail, and so we are not able to make an informed assessment of whether or not PCTs will be able to afford to implement all NICE guidance. However, it is clear that in making the implementation of NICE Health Technology Appraisals mandatory in a healthcare system which operates within fixed budgets, there is the potential to give the provision of certain, NICE-approved treatments priority over other, perhaps equally important treatments and services not considered by NICE. This is a broader issue warranting consideration by the Department of Health rather than by NICE, and is discussed in greater detail in section V (paragraph 80).
- (p) 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 (paragraph 81).

Improvements on information and evidence

- (q) We recommend that the Government should take steps to ensure the submission of all relevant clinical information to NICE. The definition of what types of information are deemed ‘relevant’ to NICE will obviously require careful consideration, and to this end we suggest that NICE should work with the ABPI to establish guidelines on which types of information must be routinely supplied to NICE, and which types must be made available on request. If the ABPI is prepared to require companies’ compliance with these guidelines as a condition of continued membership, it may be possible to

avoid the alternative of legislation in order to ensure that no important information is withheld from NICE (paragraph 85).

- (r) **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 outputs (paragraph 86).**
- (s) **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 a 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).**
- (t) **We recommend that NICE should consider options for improving its evidence base in respect of patient experience and quality of life, including the possibility of working with governments, at national and E.U. level, and with the pharmaceutical industry to promote the routine inclusion of condition-specific quality of life measures into controlled clinical trials carried out prior to licensing by the pharmaceutical industry. NICE may find it profitable to draw on the expertise of the new Commission for Patient and Public Involvement in Healthcare when this body is established. The Government should consider extending the remit of this body to include explicitly the securing of appropriate patient input into NICE processes (paragraph 94).**

Quality assurance of NICE's work

- (u) **We recommend that NICE should ensure that the academic centres to which it contracts its assessment work are adequately resourced to enable them to conduct Health Technology Assessments to the highest possible standard. Increasing the resources NICE directs at this area of its activity may enable it to improve the quality of its work and recruit more scientists of the highest calibre and experience. In addition to this, we are concerned that with the considerable expansion in NICE's coverage we have suggested, there may be workforce as well as funding issues. There are at present only a limited pool of skilled academics available within the UK, especially in the field of health economics, and the pharmaceutical industry is competing to recruit from the same pool. NICE and the Government must work together to address this problem (paragraph 98).**
- (v) **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).**

Greater clarity over criteria for evaluating clinical and cost-effectiveness

- (w) 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).
- (x) 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.¹⁸⁸ We agree with the many witnesses who argued for a review of NICE's appraisal methodology, and the publication of clear criteria.¹⁸⁹ 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 base by encouraging pharmaceutical companies to collect this type of data routinely (paragraph 104).

Affordability of NICE's recommendations

- (y) Decisions about the affordability of NICE's recommendations are, we believe, properly a matter for government. We also believe that there is a need for decisions about the affordability of NICE's recommendations to be seen to be made entirely separately from NICE's decisions about clinical and cost-effectiveness. While we have received no compelling evidence that these decisions are not being taken independently, the widespread perception that the three elements are linked urgently needs to be dispelled. We therefore recommend that the Government should take steps to clarify its own role in taking decisions about whether or not individual pieces of NICE guidance will be funded. One solution would be for the Department of Health to issue a separate document alongside each piece of NICE guidance, stating the costs (both financial and staffing) of implementation of the guidance, and on the basis of this indicating whether or not, and in what circumstances, the guidance was to be implemented (paragraph 107).

Selection of topics for NICE's work programme

- (z) Some witnesses (including, for example, the BMA) argued that NICE should be able to determine its own work programme, suggesting that this would facilitate a more neutral, rational appraisal of the costs and total health benefits of various treatments, drawing on public and professional concerns, and that it would significantly improve NICE's credibility.¹⁹⁰ However, NICE itself does not ask for this additional responsibility. We feel that this very high-level prioritisation is rightly the job of Government, rather than that of a body which is not publicly or politically accountable for such a function (paragraph 116).
- (aa) 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

¹⁸⁸ Q315.

¹⁸⁹ Ev 2 (Consumers' Association); Ev 246 (Aventis).

¹⁹⁰ Ev 197–98.

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 leave the NHS, and in particular patients, under-represented.¹⁹¹ 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 (paragraph 118).

- (bb) We welcome the amendments to the selection criteria proposed by the Government in its consultation document, as we feel they offer a clearer, more consistent and more rational framework for the selection of topics. However, we recommend that these criteria are explicitly underpinned by the principle of maximising total health benefit to all patients. The process by which topics are assessed against these criteria must also be inclusive and transparent, and should be backed up by a clear and public explanation of why particular topics have been prioritised for assessment by NICE (paragraph 126).
- (cc) We welcome the fact that the need to evaluate treatments and interventions where the evidence suggests that it may be appropriate for the NHS to reduce rather than expand use is reflected in the Government's proposed selection criteria, and recommend that the Department of Health gives explicit consideration to devoting a larger proportion of NICE's clinical guidelines programme to work in this area (paragraph 128).

Policy on beta interferon

- (dd) We recommend that the Government, working together with NICE, should ensure that any subsequent decisions which could appear to run contrary to NICE recommendations are issued in a way that is sensitive to the potential risk such decisions may pose to NICE's credibility. Such decisions should be clearly communicated to stakeholders, and could be issued in collaboration with NICE (paragraph 129).

Prioritisation within the NHS

- (ee) Prioritisation of healthcare spending is an issue of overwhelming importance, and during the course of this inquiry it has become clear to us that a more open debate on healthcare prioritisation needs to take place. Our inquiry has persuaded us that, with so many competing interests vying for attention and funding in an area where resources are finite, it is not sufficient to have implicit healthcare prioritisation. We feel that NICE has been laid open to unfair criticism in respect of the 'rationing' debate, as a consequence of the lack of clarity in policy here (paragraph 134).
- (ff) We wish to record our view that the Government must work to achieve a comprehensive framework for healthcare prioritisation, underpinned by an explicit set of ethical and rational values to allow the relative costs and benefits of different areas of NHS spending to be comparatively assessed in an informed way. Such a framework would need to secure the input of the wider population as well as NHS patients and staff, policy makers and academics. Although we are not seeking a detailed response on this point, we would

¹⁹¹ Proposed membership includes 12 representatives from the Department of Health/ National Assembly for Wales, 3 representatives from NICE, 4 from the NHS and 2 from patient organisations (*Clinical Guidance from the National Institute for Clinical Excellence – Timing and Selection of Topics for Appraisal*, Department of Health/ National Assembly for Wales, March 2002, Annex B).

welcome an acknowledgement on the part of the Government that this is a key issue, and we would not be convinced if the Government were to argue that prioritisation were already subject to such a framework (paragraph 135).

ANNEX – BACKGROUND

151. NICE was established as a Special Health Authority in April 1999.¹⁹² NICE is accountable to the Secretary of State for Health in England and to the National Assembly for Wales for its resources, delivery of its work programme and for the guidance it produces for the NHS.¹⁹³ In the last financial year its funding was £12, 575, 000. This was set to increase to approximately £13 million this year, and approximately £15 million the following year.¹⁹⁴

152. The formal aims of NICE, as set out in its Framework Document, are to:

“Promote clinical excellence and the effective use of available resources in the NHS through the development and dissemination of guidelines for the management of certain diseases or conditions, guidance on the appropriate use of particular interventions, audit methodologies and the dissemination of these to support frontline staff and patients ... the Institute will promote the appropriate use of those interventions which offer good value to patients and to discourage the use of those which do not.”

153. In reaching its decisions, Annex C to NICE’s Framework Document specifies that NICE should have regard to:

- The broad clinical priorities of the Secretary of State and the National Assembly for Wales (as set out for instance in National Priorities Guidance and in National Service Frameworks, or any specific guidance on individual referrals)
- The degree of clinical need of the patients with the condition or disease under consideration
- The broad balance of benefits and costs
- Any guidance from the Secretary of State and the National Assembly for Wales on the resources likely to be available and on such other matters as they may think fit
- The effective use of available resources

154. In addition, the Framework Document states that “The Institute will also wish to ensure that, in carrying out its statutory functions, it is sympathetic to the longer-term interest of the NHS in encouraging innovation of good value to patients”.

155. NICE’s *technology appraisals* are based on a review of evidence of clinical and cost effectiveness for a particular technology, and give recommendations about whether and in what circumstances the technology should be used in the NHS. Although technology appraisals can and have covered a wide range of ‘technologies’, including surgical procedures, medical devices and screening technologies, the majority have focused on pharmaceuticals.¹⁹⁵ Recent high-profile examples include beta interferon for the treatment of multiple sclerosis (published in February 2002) and zanamivir (Relenza) in the treatment of influenza (published in October 1999, with a revised version published in November 2000). At the time of giving evidence to us, NICE had produced 31 technology appraisals.

156. Clinical guidelines provide wider guidance on the management of whole diseases or clinical conditions, and cover several different treatment options. At the time of giving evidence to us NICE had published four sets of clinical guidelines covering myocardial infarction, fetal monitoring, induction of labour, and pressure ulcers. These guidelines

¹⁹² SI 220, February 1999; SI 2219, August 1999.

¹⁹³ *National Institute for Clinical Excellence*, Framework Document.

¹⁹⁴ Q427.

¹⁹⁵ Ev 128.

were commissioned by the Department of Health from academic and professional bodies prior to NICE's formation, and were quality-assured by NICE.

157. To date, NICE has been involved in overseeing nine national *clinical audit* projects and has commissioned a further seven, and is managing four Confidential Enquiries. This function is currently planned to be transferred to the Commission for Health Improvement.

158. In addition to these functions, in April 2002 NICE assumed responsibility for *the Safety and Efficacy Register of New Interventional Procedures (SERNIP)*, a programme which, under NICE, will assess the safety and efficacy of selected new interventional procedures. This was previously managed as a pilot project by the Academy of Medical Royal Colleges.

Structure¹⁹⁶

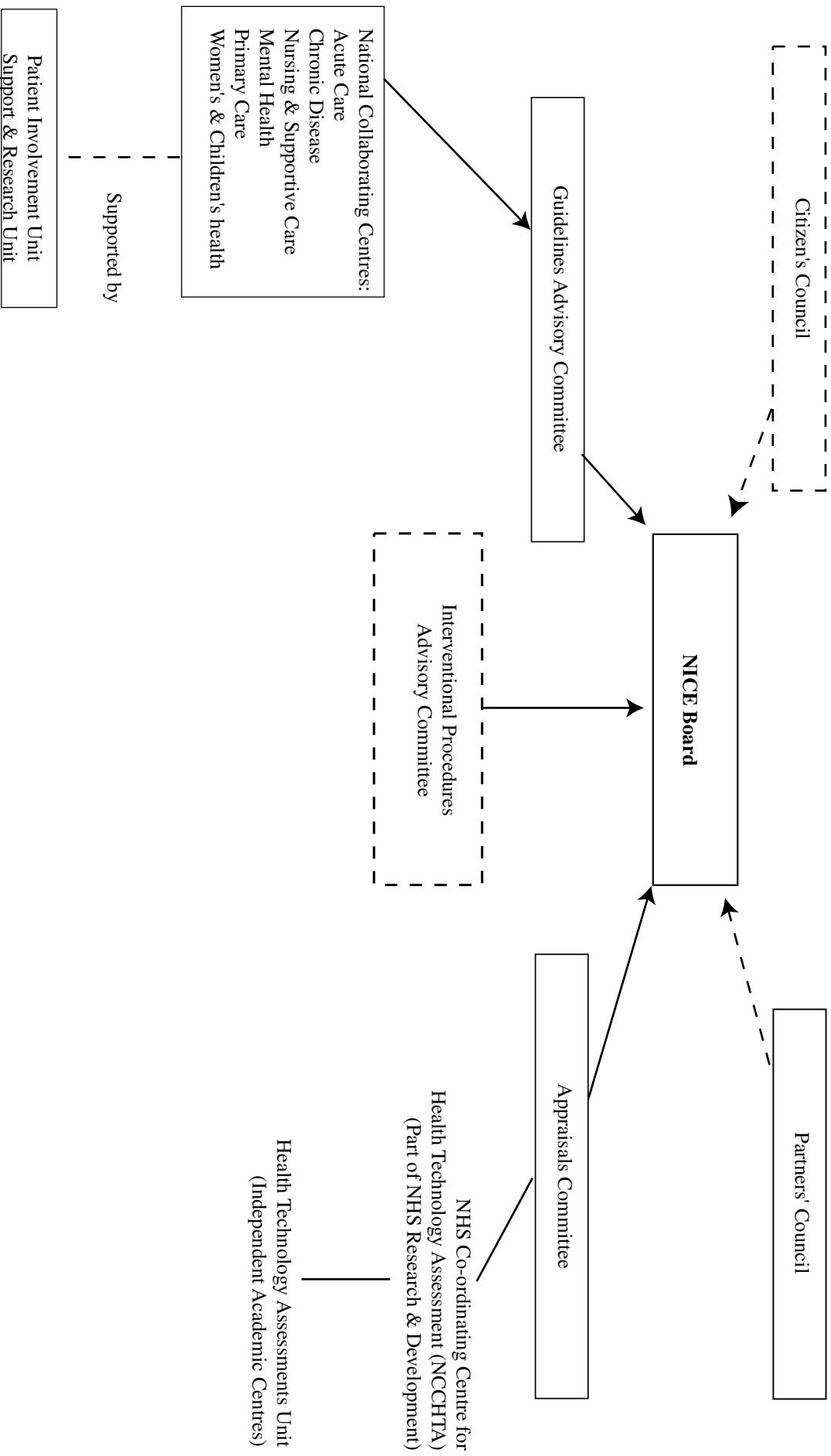
159. NICE's Chair and Board of seven non-executive Directors are appointed by the Secretary of State for Health and the National Assembly for Wales. They are supported by four executive members (chief executive, planning and resources director, clinical director and director of communications) who are appointed by NICE subject to the approval of the Secretary of State and the National Assembly for Wales. Board meetings are held in public, at venues throughout England and Wales. NICE relies on a central staff of approximately 40 individuals based in its London office, supplemented by a network of professional relationships with health service, academic and other professional organisations.

160. Reporting to the Board are three advisory Committees – the *Appraisals Committee*, the *Guidelines Advisory Committee* and the newly created *Interventional Procedures Committee*. The size of these Committees ranges from 21 to 43, and their membership is drawn largely from health professionals, NHS managers, patient representatives and academics. These Committees make recommendations to the Board in each of their respective areas.

161. The *Partners' Council*, chaired by NICE's Chairman, is a body which meets approximately three times a year to advise NICE on a range of issues and provides a forum for exchange of ideas and the formulation of strategy. It currently has 39 members drawn from patient organisations, the NHS, organizations concerned with assuring quality, the healthcare industry, health professionals, and unions. NICE has also recently announced the establishment of a *Citizens' Council*, which will provide advice to the Institute on topics relating to social, ethical or moral questions arising from NICE's work. The Council will have up to independent 30 members. Although the Partners' Council is a statutory part of NICE, it has an advisory function rather than forming part of the formal governance arrangements for signing off NICE's work.

¹⁹⁶ See Figure 1.

Figure 1: The Structure of NICE



162. In addition, NICE has created multi-disciplinary *National Collaborating Centres* (NCCs) to develop clinical guidelines and clinical audit in six broad areas: acute care, chronic disease, nursing and supportive care, mental health, primary care and women's and children's health. The NCCs are based in the Royal Colleges and supported by two cross-cutting units based at academic centres: the National Guidelines and Audit Patient Involvement Unit, based at the College of Health, gives advice on patient and carer involvement and provides support and training to patients and carers who are involved in guideline development groups, and the National Guidelines Support and Research Unit, based at the University of Newcastle, provides advice on methodological issues, and training and education support.

How NICE works¹⁹⁷

163. Topics are selected for technology appraisals and clinical guidelines by Ministers and the Welsh Assembly.¹⁹⁸ Topic selection is a three-stage process, of which the first stage is the identification of a pool of potential topics NICE might consider. According to the Department of Health, the 'pool' of topics for technology appraisals is influenced by: new technologies identified by the National Horizon Scanning Centre, a unit of the University of Birmingham, which is funded by the NHS R&D programme; topics suggested by professional and patient groups and by the wider NHS; proposals from the National Clinical Directors and other Department of Health (DH) or National Assembly for Wales (NAW) policy branches; and completed research carried out under the auspices of the National Health Technology Assessment programme. Topics for clinical guidelines are informed largely by the needs of the National Service Frameworks.

164. Suggestions for technology appraisals are considered by the Technologies Advisory Group. The membership of this group is not published, but is "mainly staffed by officials in the Department of Health and National Assembly for Wales", with representatives from NICE.¹⁹⁹ Topics for clinical guidelines are considered by the Clinical Priorities Group.

165. The topic lists proposed by the Technologies Advisory Group and the Clinical Priorities Group are then put forward to the Joint Planning Group, a smaller group jointly chaired by the Chair of NICE and by a senior Department of Health official, which considers logistical and capacity issues for NICE's work programme, and 'signs off' a final recommendation to the Minister and National Assembly for Wales.

The technology appraisals process

166. Once a technology is referred to NICE, staff begin the appraisal process by identifying formal consultees. These will include the Department of Health and National Assembly for Wales, the manufacturers or sponsors of the technology, relevant national, professional organisations, and national patient organisations. Consultees will also include the Health Technology Board for Scotland and two health authorities, although these organisations do not have a right of appeal.

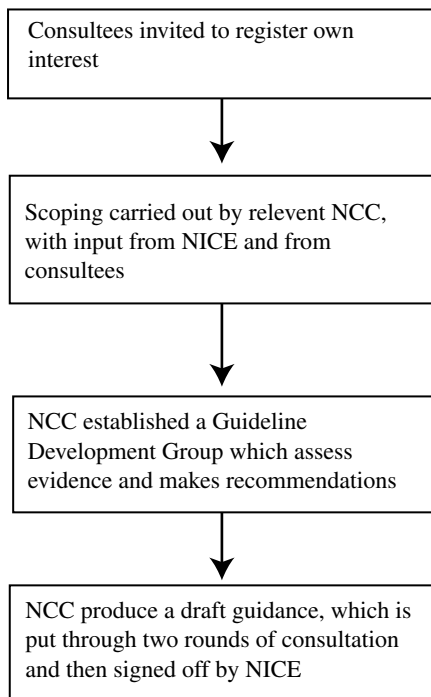
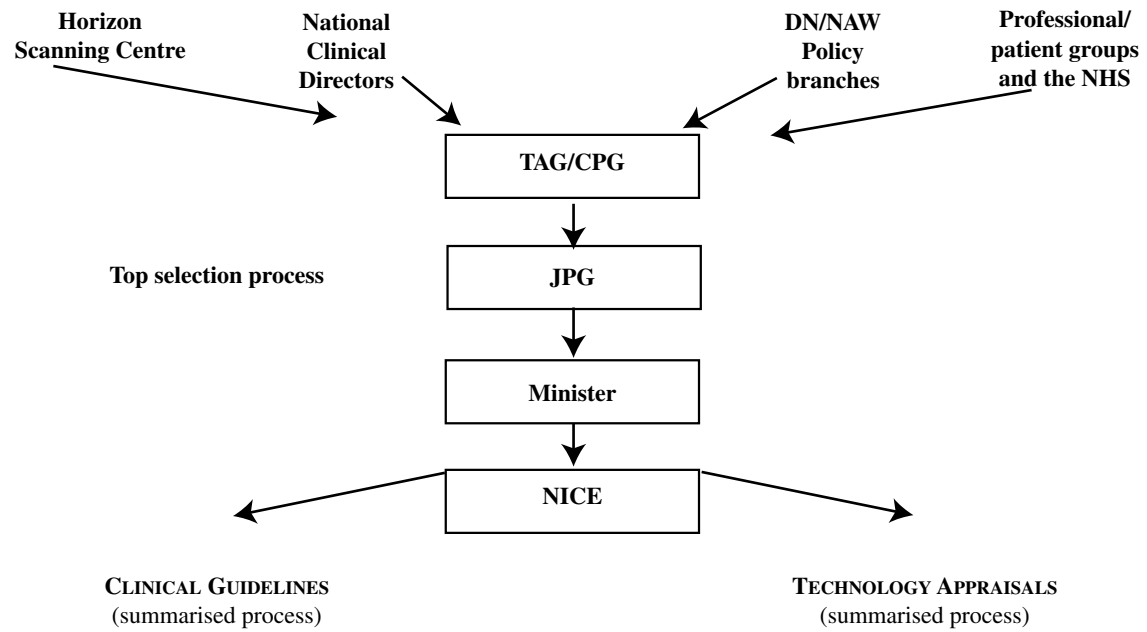
167. NICE then conducts a literature search and prepares a draft scope, aiming to identify all the relevant questions and issues the appraisal should address. Prior to publication, a draft version of this is sent to all consultees for comment.

¹⁹⁷ See Figure 2.

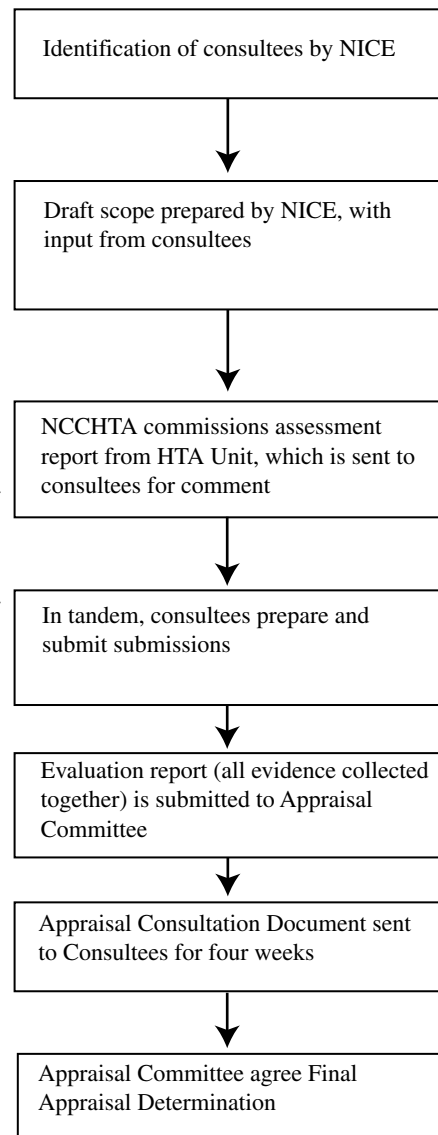
¹⁹⁸ Ev 122.

¹⁹⁹ Q543.

Figure 2: How NICE works



16 weeks



The appeals process is not reflected in this diagram

168. On behalf of NICE, the NHS Co-ordinating Centre for Health Technology Assessment (NCCHTA), which is run by the NHS Research and Development Programme, commissions an assessment report based on the final scope, usually from one of a number of academic centres known as Health Technology Assessment Units, which are part of the NHS R&D programme. Once completed, this is sent to all consultees who are given ten working days to comment on it. In tandem with this, all consultees have 16 weeks in which to make submissions to NICE setting out their views on and experiences of the technology under appraisal. NICE staff then compile the evidence, including the assessment report and consultee submissions, into what is known as the 'evaluation report', which is submitted for consideration by the Appraisal Committee.

169. Four patient representatives and two clinical experts, nominated by the formal consultees and selected by the Chairman of the Appraisal Committee, are invited to attend a Committee meeting at which they are 'given the opportunity to make observations about the technology and its use in the NHS'. This is usually followed by questions from the Committee, and if the patient representatives and clinical experts wish they may support their oral contribution with a 'written perspective' on the technology under appraisal. The Appraisal Committee then discusses the evaluation report and the drafting of the Appraisal Consultation Document (ACD) in private.

170. The ACD is then sent together with the assessment report to all consultees for a four week consultation period. Following this period, the Appraisal Committee meets a second time to consider the original evidence and the ACD in the light of any comments made by consultees, and to agree the Final Appraisal Determination (FAD).

171. Following the circulation of the FAD, all consultees except the Health Technology Board for Scotland and the NHS health authorities have a 15 day period in which to lodge an appeal. Appeals may only be made on one or more of the following grounds:

- The Institute has failed to act fairly and in accordance with its published procedures
- The Final Appraisal Determination is perverse in the light of the evidence submitted
- The Institute has exceeded its powers.

172. The decision about whether or not an appeal should be heard is taken by the Chair of NICE. An Appeal Panel constituted of five members is then appointed from NICE's Appeals Committee, all of whom will have had no involvement in the appraisal. The Panel is chaired either by the Chair of NICE or another member of the NICE board.

173. Following the appeal period, guidance on the use of the technology is then issued to the NHS.

The Clinical Guidelines development process

174. When a topic is selected, NICE publicises this and asks potential stakeholders to register their interest via the NICE website. Those that register will be consulted during the guidelines development process.²⁰⁰ NICE's National Guidelines and Audit Patient Involvement Unit supports the involvement of patients and carers who register.

175. Scoping is then carried out by the relevant National Collaborating Centre (NCC), who propose the patient groups that will be considered, the healthcare setting, the range of treatments to be assessed and how the Centre will assess the clinical and cost effectiveness. The scoping assessment is then circulated for comment to stakeholders and to the

²⁰⁰ Stakeholders will include the Department of Health and National Assembly for Wales, relevant national professional organisations, national patient organisations and manufacturers of medicines and devices used in the clinical area covered by the guideline. Stakeholders also include a number of primary care organisations and trusts who are invited to act as 'NHS stakeholders'.

Guidelines Advisory Committee Panel. The NCC then submits a workplan for developing the guideline which, together with the final scope and timetable, is posted on the website.

176. The development of the guideline is the responsibility of the relevant NCC. The NCC will establish a Guideline Development Group which carries out the developmental work, identifying and assessing different types of evidence, and then formulating recommendations for practice on the basis of its evaluation of the evidence.

177. Once the Guideline Development Group has made its recommendations, the National Collaborating Centre prepares draft versions of the full guideline, short form guideline and patient information leaflet. There are two rounds of formal consultation with documents sent for comment to the Guidelines Advisory Committee and to stakeholders. Redrafted versions are posted on NICE's website during the second period of consultation. The final set of documents is signed off by the Guideline Development Group, the Guideline Advisory Committee and finally by NICE itself. There is no procedure for appealing against the recommendations of a Clinical Guideline.

NICE and the wider quality agenda

178. NICE does not operate in isolation, but forms one part of the Government's wider 'quality' agenda. Set out in *A First Class Service*, this also included the establishment of national clinical standards through National Service Frameworks. The delivery of these standards is effected through the clinical governance programme, and their monitoring is carried out by the Commission for Health Improvement. National Service Frameworks (NSFs) provide a wider framework of standards for service delivery in key clinical areas, sometimes including maximum waiting times, and have so far been issued in the areas of mental health, coronary heart disease, services for older people, and diabetes. NSFs are currently being developed for children's services, renal services and long term conditions.

179. The Commission for Health Improvement was established in April 2000, and has embarked on a programme of reviews of clinical governance in NHS Trusts and Health Authorities, with the aim of having reviewed all NHS organisations by 2004. CHI reviews currently examine the arrangements NHS organisations have in place for implementation and monitoring of NICE guidance, although they do not conduct detailed audit of their implementation.

LIST OF ABBREVIATIONS

ABPI	Association of the British Pharmaceutical Industry
ACD	Appraisal Consultation Document
A&E	Accident and Emergency
BNF	British National Formulary
CERT	Campaign for Effective and Rational Treatment
CHAI	Commission for Healthcare Audit and Information (yet to be established)
CHI	Commission for Health Improvement
CPG	Clinical Priorities Group
CSM	Committee on Safety of Medicines
DH	Department of Health
DTB	Drug and Therapeutics Bulletin
FAD	Final Appraisal Determination
HA	Health Authority
HTA	Health Technology Assessment
HTBS	Health Technology Board for Scotland
JPG	Joint Planning Group
MCA	Medicines Control Agency
MDA	Medical Devices Agency
MRC	Medical Research Council
MS	Multiple sclerosis
NAW	National Assembly for Wales
NCC	National Collaborating Centre
NICE	National Institute for Clinical Excellence
NSF	National Service Framework
PCT	Primary Care Trust
QALY	Quality Adjusted Life Year
RCGP	Royal College of General Practitioners
SERNIP	Safety and Efficacy Register of New Interventional Procedures
SIGN	Scottish Intercollegiate Guidelines Network
TAG	Technology Advisory Group

PROCEEDINGS OF THE COMMITTEE RELATING TO THE REPORT

Thursday 20 June 2002
[Morning meeting]

Members present:

Mr David Hinchliffe, in the Chair

Andy Burnham
Mr Simon Burns
Jim Dowd
Julia Drown

Sandra Gidley
Dr Doug Naysmith
Dr Richard Taylor

The Committee deliberated.

Draft Report (*National Institute for Clinical Excellence*), proposed by the Chairman brought up and read.

Ordered, That the draft Report be read a second time, paragraph by paragraph.

Paragraphs 1 to 150 read and agreed to.

Annex read and agreed to.

Resolved, that the Report be the Second Report of the Committee to the House.

Ordered, That the Chairman do make the Report to the House.

Ordered, That the provisions of Standing Order No. 134 (Select committees (reports)) be applied to the Report.

Several papers were ordered to be appended to the Minutes of Evidence.

Ordered, That the Appendices to the Minutes of Evidence taken before the Committee be reported to the House.—(*The Chairman.*)

Several papers were ordered to be reported to the House.

[Adjourned till this day at a quarter past two o'clock.]

LIST OF WITNESSES
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Wednesday 16 January 2002

THE CONSUMERS' ASSOCIATION

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Dr Martin Duerden, Mr Christopher Newdick and Professor Tom Walley Ev 32

BRITISH NATIONAL FORMULARY

Professor Martin Kendall and Mr Dinesh Mehta Ev 32

BANDOLIER

Mr Andrew Moore Ev 32

MULTIPLE SCLEROSIS SOCIETY

Mr Glynn McDonald Ev 59

NATIONAL CANCER ALLIANCE

Becky Miles Ev 59

ALZHEIMER'S SOCIETY

Mr Harry Cayton Ev 59

CANCERBACUP

Joanne Rule Ev 59

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CROYDON HEALTH AUTHORITY

Dr Tim Crayford and Helen Marlow Ev 78

LAMBETH SOUTHWARK AND LEWISHAM HEALTH AUTHORITY

Dr Deirdre Cunningham Ev 78

NEWCASTLE AND NORTH TYNESIDE HEALTH AUTHORITY

Mr David Walker Ev 78

GLAXOSMITHKLINE

Mr Eddie Gray Ev 109

CAMPAIGN FOR EFFECTIVE AND RATIONAL TREATMENT

Mr Hugh McKinney and Mr David Campbell-Morrison Ev 109

ASSOCIATION OF THE BRITISH PHARMACEUTICAL INDUSTRY

Dr Trevor Jones, Mr Bill Fullagar and Dr John Patterson Ev 109

Wednesday 30 January 2002

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

Professor Sir Michael Rawlins, Mr Andrew Dillon and Professor David Barnett Ev 131

Wednesday 6 March 2002

DEPARTMENT OF HEALTH

Lord Hunt of Kings Heath OBE and Mr Andy McKeon Ev 176

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Mr Christopher Newdick [NC64]	Ev 19
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Bandolier [NC107]	Ev 28
Multiple Sclerosis Society [NC56]	Ev 42
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CancerBACUP [NC26]	Ev 49
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Mr Christopher Newdick [NC64A]	Ev 66
Helen Marlow, Croydon Health Authority [NC31]	Ev 68
Dr Tim Crayford, Croydon Health Authority [NC32]	Ev 70
Lambeth, Southwark and Lewisham Health Authority [NC47]	Ev 73
Newcastle and North Tyneside Health Authority [NC112]	Ev 77
Association of the British Pharmaceutical Industry [NC118]	Ev 88
GlaxoSmithKline [NC120]	Ev 101
Campaign for Effective and Rational Treatment (CERT) [NC23]	Ev 103
National Institute for Clinical Excellence [NC62]	Ev 120
Professor David Barnett [NC9]	Ev 130
National Institute for Clinical Excellence [NC62A]	Ev 153
Department of Health [NC1]	Ev 168

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Memoranda submitted by:

1. Dr Andrew Bamji [NC8]	Ev 193
2. Dr Sheila Bird [NC11]	Ev 196
3. British Medical Association [NC18]	Ev 197
4. UK Cochrane Centre [NC22]	Ev 198
5. Commission for Health Improvement [NC29]	Ev 200
6. Croydon Health Authority [NC31A]	Ev 200
7. Ealing, Hammersmith & Hounslow Health Authority [NC35]	Ev 201
8. Health Technology Board for Scotland [NC40]	Ev 208
9. King's Fund [NC46]	Ev 209
10. Dr Charles Kent [NC55]	Ev 212
11. Multiple Sclerosis Society [NC56A]	Ev 216
12. National Collaborating Centre for Mental Health [NC60]	Ev 217
13. National Institute for Clinical Excellence [NC62B]	Ev 218
14. NHS Centre for Reviews and Dissemination [NC65]	Ev 221
15. NHS Confederation [NC66]	Ev 224
16. Professor Aidan Halligan [NC68]	Ev 226
17. North West Lancashire Health Authority [NC70]	Ev 227
18. PACE [NC72]	Ev 227
19. Royal College of General Practitioners [NC80]	Ev 228
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21. Pituitary Foundation [NC97]	Ev 233
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23. Professor Alan Maynard [NC111]	Ev 235
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25. British Cardiac Patients Association [NC116]	Ev 241
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27. Aventis Pharma Ltd [NC122]	Ev 246
28. NHS Alliance [NC128]	Ev 251
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30. Iechyd Morgannwg Health Authority [NC41]	Ev 254
31. Cancer Research Campaign [NC115]	Ev 255

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Memoranda or supplementary memoranda submitted by:

American Pharmaceutical Group [NC4]
 Association for Quality in Healthcare [NC5]
 Association of British Health-Care Industries [NC6]
 Association of British Neurologists [NC7]
 Professor David Barnett [NC9]
 Barts and the Royal London Hospital [NC10]
 Professor Carol Black CBE [NC12]
 Boston Scientific Limited [NC13]
 Breakthrough Breast Cancer [NC14]
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