The Government's Response to the Health Select Committee's First Report of Session 2007-08 on the National Institute for Health and Clinical Excellence

Presented to Parliament by
the Secretary of State for Health
by Command of Her Majesty
March 2008

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Introduction

This Command Paper sets out the Government's response to the Health Select Committee's report on the National Institute for Health and Clinical Excellence (NICE). The Government welcomes and endorses the Committee's expression of support for and confidence in NICE. NICE enjoys the Government's full support and separate reports by the World Health Organisation on NICE's technology appraisal and clinical guidelines programmes have commended the way in which it discharges its vital responsibilities.

As the Committee has acknowledged, NICE's role is challenging and it operates in a changing environment. It is vital, therefore, that NICE is able to continue to evolve so that its guidance remains robust and relevant in the current context. As it approaches its tenth year, NICE has shown itself to be capable of evolving to respond to new challenges and new demands, and the Government shares the Committee's confidence that it will continue to do so in the future.

In recent years NICE has developed important new programmes of work such as the optimal practice review programme and the public health work which it took on from the former Health Development Agency. In developing these strands of work NICE continues to break new ground, keeping the NHS at the forefront of international approaches to the evaluation of health-related interventions. NICE also continues to develop and improve the way it conducts its work, striving to further improve clarity and transparency, to engage effectively with a wide range of stakeholders and to ensure that its products meet the needs of patients, professionals, the NHS and an increasingly broad audience beyond. The Government recognises that implementation of NICE guidance is not always straightforward, and believes that NICE should be commended for the considerable steps it has taken to develop better implementation support for the NHS.

The Committee's report makes a number of helpful recommendations that will be important in informing NICE's future development and the way in which its guidance is used to improve patient care. The focus of the Committee's work has for understandable reasons been primarily on NICE's technology appraisal and clinical guidelines programmes, but we wish to highlight in addition the significant contribution made by NICE's wider work on public health and interventional procedures.

The Government's specific responses to the Committee's recommendations follow.

Role of NICE

1. We note that it is not the role for Ministers to directly or indirectly seek to influence the NICE decision-making process.

The Government welcomes the Committee's endorsement of NICE's independence from Government. NICE was established as an independent body to provide authoritative advice to the NHS on the clinical and cost effectiveness of healthcare interventions as part of a range of measures to reduce variation in prescribing. The Government is committed to ensuring that NICE can continue to formulate its guidance on the basis of the available evidence, free from political interference.

2. It is clear that the environment in which NICE operates has changed considerably since the Institute was established in 1999. It is also clear that there is a vital role for NICE in the rationing of healthcare and in encouraging best clinical practice. In the future the role of NICE will be ever more important and demanding with new expensive drugs and a slower rate of growth in NHS expenditure. There remains, however, concern about aspects of how NICE does its job.

The Government welcomes the Committee's endorsement of NICE's role in helping to secure value from NHS spending on drugs and other health-related interventions.

Appraisal process

3. It seems to us appropriate that topics are selected for interventional procedures, clinical guidelines and public health guidance. It is not appropriate, however, to limit technology appraisals to selected, often new and expensive, products. Instead, as we recommend below, all new drugs should be assessed.

The Office of Fair Trading (OFT) report on the Pharmaceutical Price Regulation Scheme (PPRS) published in February 2007, suggested that all new drugs ought to be appraised for clinical and cost-effectiveness. The Government is currently seeking to renegotiate the PPRS taking into account the issues raised by that report. The Government is therefore not able to comment on this recommendation in detail at this stage, though we welcome the Committee's input and will reflect further on how this recommendation might be addressed.

The topic selection processes currently in place already ensure that NICE appraises the great majority of significant new drugs. Topics selected for NICE's work programmes are selected against a range of published criteria and not just on the grounds of cost. The criteria include a potentially significant resource impact on the NHS, alignment with health priorities and whether there is significant variation in practice.

The Government's Cancer Reform Strategy, published in December 2007, builds on the progress made since the publication of the NHS Cancer Plan and sets the direction for cancer services for the next five years. The Strategy makes a commitment that all new cancer drugs and significant changes to licensed indications will by default be appraised by NICE. This commitment will be implemented during 2008.

15. A shorter, less in-depth initial evaluation of medicines at an early point would be useful. It is important that clinicians have access to independent information about new therapies as soon as they are available. However, a quick, in-depth, fully consultative evaluation for all new medicines by the time of launch is not possible. We therefore recommend that NICE should examine all new medicines for their indications as set out in the marketing authorisation. Assessment should be carried out during the period between licensing and launch. It should be brief and published prior to, or at the time of, launch. There should be no formal appeal process and only limited consultation. These brief assessments should be followed by a larger scale multiple technology appraisal for selected products (an MTA or STA as appropriate) at a later date, when more evidence is available. The technology appraisal should include current levels of consultation. The guidance issued at this later stage should be definitive, overriding that issued earlier.

16. Since providing an evaluation of all drugs at launch will be a more rough and ready process, it would be inappropriate to use the same threshold range as the full assessment. One of the aims of the new process is to ensure that treatments which are obviously cost effective are available at an earlier stage than at present. We therefore recommend that a threshold below the current range be used in these early assessments. This could be raised for individual products in special circumstances, for instance where no other treatment exists. At the time of the full assessment, the cost per QALY threshold could increase.

The Government is currently seeking to renegotiate the PPRS and those discussions may have relevance to NICE's appraisal process. The Government is therefore unable to comment in detail on these recommendations at this stage, though we will reflect further on the Committee's recommendations.

It is important to highlight, however, that NICE's reputation is built in large part on the transparency and robustness of its processes. In considering whether any shortened appraisal process would deliver benefit, the Government would have to consider carefully whether an interim process with more limited stakeholder engagement and a lower threshold would be sufficiently robust to be credible with stakeholders and defensible against any legal challenge. It would also be important to consider whether a requirement to run two separate appraisal processes might mean that final NICE guidance takes longer to produce.

The Government recognises that the speed of NICE's guidance is important to stakeholders and changes made since 2005 to the topic selection and technology appraisal processes are intended to support the development of timely guidance. NICE and the Department of Health introduced the Single Technology Appraisal (STA) process in November 2005. The STA process seeks to make NICE guidance available on treatments soon after they are launched in the UK market. The Government continues to work with NICE to ensure that the STA process works as it should.

New topic selection arrangements introduced in 2006 give NICE a greater role in the early stages of topic selection and are intended to ensure that important new drugs and other technologies are more consistently identified at an early stage.

NHS spending

4. Witnesses were concerned that NICE's focus on acute treatments, in particular medicines, could skew NHS spending towards selected new and expensive (NICE approved) drugs for acute illness.

The Government recognises that a large proportion of NICE appraisals relate to treatments for acute conditions. This reflects current trends in drug development and drug discovery, where the prevalence of new drugs for conditions such as cancer means that many new drugs initially impact on secondary care.

NICE has, however, carried out appraisals of significant drugs such as statins which are mainly used in primary care. In addition, its clinical guidelines programme has addressed other major areas of primary care prescribing, such as antihypertensives. Around 72 per cent of NHS spending on drugs is in primary care.

19. Many PCTs struggle to afford to implement NICE technology appraisals, as well as clinical guidelines. As more interventions are evaluated it is feared that the position will become unsustainable. Funding is essentially ring-fenced for technology appraisals, leaving PCTs little room for manoeuvre in their budgets to reflect local needs and priorities.

It is important to recognise that the NHS would face pressure to fund new drugs in the absence of NICE. NICE ensures that NHS decisions on investment in healthcare interventions are informed by an independent assessment of the best available evidence.

The financial impact of NICE guidance needs to be seen in the context of significant funding increases for the NHS. The gross annual cost to the NHS of implementing all NICE technology appraisals published between 1999-2000 and 2007-08 is currently estimated at around £1.3 billion. This compares with NHS revenue expenditure growth between 1999-2000 and 2007-08 of an estimated £43.8 billion[1]. NICE technology appraisals are not an unfunded pressure on the NHS. The impact of NICE technology appraisals is taken into account in forecasting likely trends in drugs expenditure and these forecasts inform PCT allocations.

The Government recognises that the NHS faces a challenge in planning for implementation of NICE guidance. The Audit Commission report, "Managing the financial implications of NICE guidance" published in September 2005 acknowledged this and cited a need for better financial planning to prepare for implementation of NICE guidance. NICE recognises that it has a role to play in helping the NHS implement its guidance. Its Implementation Directorate now develops interactive costing tools for publication alongside its guidance and publishes a forward planner on the NICE website.

Disinvestment

5. In our previous report we recommended that NICE give more emphasis to examining old technologies to encourage disinvestment. This the organisation has failed to do as fully as we expected. Its statement that few interventions have absolutely no benefit may be true but is irrelevant. Many treatments

[1] This is an estimate based on forecast outturn for 2007-08. Additionally, in 2007-08 NHS expenditure is reported in stage 2 resource accounting terms whilst in 1999-2000 expenditure was reported in cash terms, the figure is calculated by making an approximation of what the 1999-2000 expenditure is in resource terms.

currently used are not costeffective as many studies attest. NICE should adopt a similar standard of costeffectiveness in assessing such treatments as it uses in its technology appraisals. The organisation must now give more emphasis to disinvestment. One approach would be to undertake more MTAs, which would reveal the existing treatments that provide poor value for money.

The Government agrees that disinvestment is an important aspect of NICE's work and believes that NICE has made progress in developing this area since the Committee's last report. The Government recognises that NICE can amplify what it is already doing in its optimal practice review programme and that NICE's work in this area is still evolving. The further development of this work will need to be considered alongside other NICE business priorities.

NICE's work on existing interventions of doubtful cost-effectiveness is incorporated into its mainstream guidance development programmes so any recommendations are based on the same methodology, including the same cost per QALY range.

The Government agrees that Multiple Technology Appraisals (MTAs) can play an important role where a number of drugs are available in the same class. Drugs will continue to be appraised as MTAs where it is appropriate to do so. It is also important to recognise the role of NICE's clinical guidelines programme in supporting optimal use of resources. Because NICE's clinical guidelines assess the clinical and cost effectiveness of a range of interventions across a whole pathway of care, they are well-suited to identifying ways in which existing resources can be better used. As part of its optimal practice review programme, NICE has published 60 "recommendation reminders" highlighting potentially cost-saving recommendations from its existing portfolio of technology appraisals and clinical guidelines. These cover a range of topics including Diabetes, Depression and eating disorders.

NICE has also developed and published a series of commissioning guides, which relate to its clinical guidelines and allow NHS commissioners to assess the appropriate level of local commissioning to fulfil NICE's clinical guideline recommendations.

Quality Adjusted Life Years

6. **We heard much criticism of the use of QALYs. Some of the criticisms seem to be the special pleading of disappointed parties. It is vital that a method which allows comparison of the benefits and costs of different treatments for different conditions is used in cost-effectiveness evaluations. However, it is also vital that the system is accurate and reflects the real costs to society and the benefits to patients. We recommend that:**

    - **Research is undertaken to follow up specific guidance to see whether the predictions of the cost-effectiveness analysis are borne out in practice;**
    - **Wider benefits and costs, such as costs borne by carers and social care services, be more fully incorporated into NICE's assessment. We were told that this would have to be a decision for Parliament.**

The Government agrees that it is important that NICE's initial cost effectiveness assessments are reviewed over time. When NICE publishes guidance, it sets a date after which NICE will consider whether it is appropriate to carry out a review. The review date is usually set around three years after the publication of guidance but can be shorter or longer depending on whether more evidence is likely to be available. A review will include consideration of evidence on whether the cost effectiveness ratio calculated for the original appraisal is still appropriate.

It should be recognised that NICE already takes account of the impact of treatments on publicly-funded social care costs and, where relevant, can look at health-related benefits to carers. NICE can also conduct sensitivity analyses to expose potentially significant impacts on other areas of public spending.

The suggestion that NICE take into account wider costs and benefits has instinctive appeal, but closer examination reveals a number of complexities and potential perverse effects which warrant further exploration. For example, attaching a greater weight to impacts on economic productivity would have the effect of prioritising interventions for adults of working age, effectively deprioritising interventions for older people or for people who are too ill to return to work even with treatment. The impact on the consistency, manageability and timeliness of NICE's appraisal process also needs to be considered.

The Government agrees, however, that the issue of how NICE takes into account the wider benefits and costs is an important one and that it warrants further consideration. In the first instance, we propose to convene discussions to explore the issue in more detail with key stakeholders, including the NHS, patient representatives and the pharmaceutical industry.

17. The threshold or ceiling NICE employs (measured in pounds sterling per QALY) to decide whether a treatment is cost-effective, and so should be available in the NHS, is not based on empirical research. Nor is the threshold directly related to the NHS budget, since the threshold has remained constant while the budget has increased hugely since 1999.

18. The threshold used by NICE does not take into account the funding decisions made by PCTs generally. For interventions not assessed by NICE, PCTs appear to use thresholds which vary from treatment to treatment but for the most part seem to be lower than the NICE threshold.

23. While the measures listed above would mitigate the problems PCTs face, the fundamental problem which has to be addressed, according to several witnesses, is NICE's cost-effectiveness threshold. Given the uncertainties, for example about the thresholds used by PCTs, we are not in a position to decide authoritatively whether the current threshold, or threshold range, is appropriate. We recommend that more work similar to that undertaken by Professor Smith and colleagues at York University takes place on the thresholds used by NICE. We are encouraged that NICE has commissioned its own research in this area.

Whilst it is widely acknowledged that the QALY is the best available tool for assessing cost-effectiveness, the threshold or range used by NICE remains a difficult issue and the committee has acknowledged that there is little consensus in this area. It is important to recognise that NICE's Appraisal Committees do not use a set cost per QALY threshold, and that they consider estimates of a treatment's cost per QALY as part of a broad range of evidence.

As the Committee is aware, NICE has commissioned work on the cost per QALY range, focusing on the value of interventions displaced by NICE recommendations in PCT decision-making. NICE has also been reviewing the level of the threshold range it currently applies and its implementation as part of its reviews of the "Guide to the methods of technology appraisal" and "Social value judgements: principles for the development of NICE guidance" documents. The Government commends NICE's efforts to set the threshold on a more scientific footing, and the work of other researchers to support NICE in this judgement. The cost per QALY range NICE uses attempts to take into account the overall NHS budget.

NICE and the National Institute for Health Research (NIHR) have also commissioned two pieces of relevant research. Although these do not address the specific issue of the QALY threshold, they address important related issues. They are:

i. a feasibility study looking at methods to determine public opinions on the monetary value that should be attributed to different health gains, measured in QALYs. This study is due to be submitted for peer review shortly and is expected to be published later this year.

ii. a study looking at whether gains in health, measured in QALYs, are valued differently by the public for different beneficiaries. For example, whether a gain of one QALY is valued greater for a child than for an adult with the same condition. This research is expected to be published this year.

The Government will consider with NICE the need for further research in the light of the above activity.

24. During the inquiry, doubt was cast on whether NICE alone should continue to determine the level of the threshold. We consider the present situation is unsatisfactory. We recommend that a separate body, with representation from NICE, the Department, PCTs and others should set the level, or range, to be used. NICE's threshold should be closely linked to that used by PCTs. The threshold should also relate to the size of the NHS budget. The new body should decide whether orphan drugs continue to be treated differently from other treatments.

36. The affordability of NICE guidance and the range, measured in cost-per-QALY, it uses to decide whether a treatment is cost-effective is of serious concern. The threshold it employs is not based on empirical research and is not directly related to the NHS budget, nor is it at the same level as that used by PCTs in providing treatments not assessed by NICE, which tends to be lower. Some witnesses, including patient organisations and pharmaceutical companies, thought NICE should be more generous in the cost per QALY threshold it uses, and should approve more products. On the other hand, some PCTs struggle to implement NICE guidance at the current threshold and other witnesses argued that a lower level should be used. However, there are many uncertainties about the thresholds used by PCTs. Accordingly we cannot authoritatively at this stage recommend a change in NICE threshold. Nevertheless, we recommend that it be reviewed. We do recommend that an independent body determine the threshold used when making judgements of the value of drugs to the NHS.

The Government recognises that there are some arguments for the establishment of a separate mechanism to advise on the cost per QALY range that NICE should use in its assessments. For example, such a mechanism could be perceived as more independent than NICE, could broaden the debate on NICE's use of the cost per QALY and could be seen to make the process for establishing the QALY range or threshold for NICE's appraisals more explicit by separating it from other issues.

Balanced against these potential benefits are a number of other considerations. These include:

- The interplay between NICE's use of the cost per QALY and its overall appraisal methodologies.
- The additional process costs generated from the establishment of a separate mechanism for addressing the QALY threshold.

- The evidence on Quality Adjusted Life Years available to a separate body would not be any better than that available to NICE.
- NICE is already an independent NHS body and it is not clear whether another body would in fact have a greater practical or perceived independence.
- Greater NHS involvement in the cost per QALY threshold can be delivered through NICE. NICE has recently carried out public consultations on the "Guide to the methods of technology appraisal" and "Social value judgements: principles for the development of NICE guidance" documents which include NICE's policy on the use of the cost per QALY. NICE will consider the responses it has received through the consultation.

On balance, the Government is not convinced that any potential benefits of establishing a separate mechanism of the kind envisaged by the Committee outweigh the likely disadvantages.

NICE's position on the appraisal of orphan drugs is set out in its Social Value Judgements document. This has recently been the subject of a full public consultation and the results of that exercise are awaited.

Research

7. NICE does not have all the information it needs to assess and compare treatments. First, while access to EMEA documents and other changes have improved NICE's access to information, it still does not have access to all the relevant information which is available. Secondly, clinical trials undertaken by pharmaceutical companies understandably focus on generating data about the drug's efficacy and safety, which is required for the licensing process; such trials are not usually designed to generate the type of data on cost-effectiveness which NICE requires. Third, in some areas, without commercial sponsors, notably public health and many physical and psychological therapies, there is little research about the cost-effectiveness of different interventions.

10. More publicly funded research should be undertaken to assist the development of public health guidance and other areas without commercial sponsors.

The Government agrees that the quality and relevance of information provided to NICE by pharmaceutical companies is important. NICE guidance can have considerable financial implications for pharmaceutical companies and it is in the industry's interest to develop the information NICE needs. Sir David Cooksey's "A review of UK Health Research funding" published in December 2006 recognised this and recommended that NICE engage with the pharmaceutical industry at an early stage to inform the design of clinical trials. NICE has already begun to pilot an early engagement facility with the pharmaceutical industry.

The Government agrees that there is an overall shortfall in good quality research evidence on the cost-effectiveness of different public health interventions, and other physical and psychological therapies. This is now a priority that the Government is taking action to address. In line with commitments made in the 2004 public health white paper "Choosing Health", the Government has increased significantly its investment in public health research, both through National Institute for Health Research (NIHR) national research and development programmes, and through new public health research funding collaborations.

Over time, these initiatives are expected to contribute new, high quality research evidence on the cost-effectiveness of public health interventions, and help address the knowledge deficits in this area.

The Medical Research Council and NIHR are working together with the Office for Strategic Co-ordination of Health Research to co-ordinate investment and activities in public health research. As part of this, NIHR will be taking the strategic lead in research on obesity and on infection.

8. We recommend that NICE be granted the right to see all the evidence the MHRA uses when making its decisions. We appreciate that this would mean that there would be some commercial-in-confidence material that NICE could not make public when it published its guidance.

NICE's appraisals relate to the clinical and cost effectiveness of a technology, whereas the pharmaceutical regulatory authorities require information on safety, quality and efficacy. Data from licensing trials will set out how well a drug works in the body, what side effects it may have and on whom it is meant to be used. The trials do not address issues of cost-effectiveness, and as such they only constitute a part of the evidence base that NICE needs to consider.

As the Chair and Chief Executive of NICE made clear when giving evidence to the Committee, it is relatively straightforward for NICE to identify whether evidence from specific trials has been omitted from manufacturers' submissions and to discuss access to confidential information where that is required for an appraisal. NICE is currently able to treat information as commercial in confidence if requested to do so by the manufacturer, and has not asked the Department of Health for powers to compel companies to provide more information. We do not believe that a persuasive case for taking such powers has yet been made.

9. We welcome the fact that both NICE and drug companies are aware that they need to collaborate closely to ensure that clinical trials are undertaken with the needs of NICE appraisal in mind. The Government should encourage all countries in which large-scale clinical trials take place to adopt a similar policy. We support the mandatory registration of all clinical trials so that the results of all negative trials are accessible. We recommend that NICE assesses and reports the quality of the research it receives.

The Government welcomes the Committee's endorsement of NICE's work with the pharmaceutical industry to support the availability of better evidence on the clinical and cost-effectiveness of new drugs.

The Government will consider how it can support the Committee's recommendation on practice in other countries in the context of future discussions, but the Government ultimately has little influence over the relationships other states develop with the pharmaceutical industry.

The Government strongly encourages voluntary registration of trials of health interventions and notes the Committee's support for the mandatory registration of clinical trials. However, most clinical trials take place abroad and the UK unilaterally taking action to mandate the registration or publication of all clinical trials data would not significantly improve access to evidence on health interventions. Our legal advice is that such a move would in any event be incompatible with EU law. All clinical trials of investigational medicinal products do, however, have to be placed on the EU's medicines agency (EMEA) register. This is currently confidential, although there are plans to make parts of it public.

The Government supports the principle of open access to information about health research and the findings from health research. The Government actively encouraged the World Health Organisation's initiative to promote voluntary registration of all trials of health interventions on public registers.

In order to carry out an appraisal of a treatment, NICE's Appraisal Committee must critically assess the information it receives and it will summarise this consideration in the appraisal documentation. The Government recognises that the Appraisal Committee's assessment of the quality of the evidence it has received could on occasions be made more accessible to a lay audience. However, it is important to recognise that the audience for NICE's critical assessment of the information submitted is primarily a specialist one.

Use of experts

11. Many witnesses thought that too few experts with the relevant detailed expertise were involved in the process of producing guidance. Since they have a permanent membership, Appraisal Committees are unlikely to have such experts. They do consult experts, but this is unsatisfactory because such experts appear for the day alone. We therefore recommend that Appraisal Committees appoint specialist advisers, without voting rights, to work with the Committee throughout consideration of a technology appraisal or clinical guideline. This will improve guidance and ensure public and patient confidence in the system. Decisions about which experts should be appointed should remain the responsibility of NICE following consultation with the appropriate clinical bodies.

28. Improvements to the system of evaluating medicines and greater involvement of experts in the technology appraisal and guideline development processes should also result in guidance that is more acceptable to clinicians.

The Government agrees that the involvement of experts in NICE's guidance development processes is vital, and it is important that NICE continues to demonstrate to stakeholders that it engages with specialists appropriately throughout the development of its guidance.

NICE recognises the importance of expert opinion in the development of its guidance. Appraisal committees are able to call on clinical specialists and patient experts who can appear in person to advise the committee. Moreover, organisations representing clinical specialists in the treatment of patients and patient experts can request to be a stakeholder in any NICE appraisal. All registered stakeholders are consulted during the development of guidance and can feed any concerns or comments into the appraisal committee. NICE also plans to hold its appraisal committees in public, which will further increase transparency.

We regard a decision on whether to make use of specialist advisers in the way suggested as an operational matter for NICE itself.

Consultation

12. The wide consultation which takes place during the development of NICE guidance is greatly valued. While we agree that it is difficult for some organisations to respond within the often brief time limits, we recognise that a long consultation period would slow the guidance production time further. Nevertheless, the situation would be improved if NICE were to give interested stakeholders greater warning of forthcoming consultations, to allow them to organise their resources in time to respond effectively.

The Government welcomes the Committee's endorsement of NICE's consultation processes and agrees that it is important for stakeholders to be aware of when and how they can contribute to NICE consultations. How best to ensure that stakeholders are fully aware of these opportunities is an operational matter for NICE.

13. Some consultees complain that their views are ignored. We understand that NICE does not have the resources to respond individually to each consultee. NICE could, however, issue a standard response to inform every consultee how it will respond and setting out how the system works.

The Government recognises that stakeholders need to understand NICE's process for considering their comments and that NICE has a role in helping them to do so. NICE's Appraisal Committees consider all the comments they receive from stakeholders and respond to each one in the form of a table published on NICE's website. We agree that there may be scope to go further in ensuring that consultees clearly understand how their comments will be treated, though decisions on how to take this forward are an operational matter for NICE.

Appeals

14. We note the pressure to change the grounds for appeal, but consider changes might cause more problems than they solved. Allowing additional evidence at the appeal stage would extend the process significantly, and might discourage companies from producing high quality trial data at the time of first assessment. It also might risk more "gaming" appeals. We make recommendations in the next section which we expect will lead to fewer appeals being brought in the first place.

The Government agrees that no conclusive argument has yet been presented for a change to the existing arrangements for appeal.

Implementation

20. A number of steps were proposed by witnesses to alleviate the situation. To improve coordination between NICE and PCTs, we support the wider use of implementation consultants, who would provide information both from NICE to the PCTs and from the PCTs to NICE.

The Government welcomes the Committee's endorsement of the implementation consultant network that has been established by NICE. The wider use of implementation consultants will need to be considered by NICE in the context of overall business priorities.

21. There must be incentives for clinicians to be very careful about the use of expensive drugs. We recommend that current exclusion of high-cost drugs from the payment by results tariff be reviewed.

The Department of Health is currently developing the national tariff for 2009-10 based on a new version of healthcare resource groups (HRGs). HRGs are the underpinning currencies of the tariff and are clinically meaningful groups of diagnoses and procedures which consume similar levels of NHS resources. One of the main benefits of the new HRG currencies is that they are more sensitive than the previous currencies, making them better able to differentiate between routine and complex cases. We are exploring the potential of the new HRGs to build the impact of high cost drugs and other excluded items within the national tariff prices.

26. There need to be additional measures to improve the implementation of clinical guidelines. There should be more help for PCTs to implement guidelines. We recommend that the Department ensure that PCTs are aware of the assistance that is available and develop other ways of helping PCTs to plan and prioritise clinical guidelines.

The Government recognises that the complex nature of the topics addressed by some clinical guidelines can pose implementation challenges, and agrees that both NICE and the Department of Health have key roles in supporting local NHS organisations in managing these. The importance of financial planning for NICE guidance has also been highlighted by the Audit Commission.

NICE's Implementation Directorate has taken steps to improve considerably the support that it makes available to the NHS to plan for and implement its guidance. All NICE clinical and public health guidance published since January 2005 is accompanied by an interactive costing tool which allows NHS commissioners to estimate the impact NICE guidance will have on local budgets. NICE now also publishes a forward planner on its website. The forward planner lists forthcoming NICE guidance, including an indicative cost based on the draft guidance where available.

The National Prescribing Centre (NPC), which is funded by the Department of Health and NICE, is responsible for the promotion of high quality cost-effective prescribing in the NHS. As an aid to planning in the NHS, the NPC issues an annual forward planner that highlights NICE guidance and significant new drugs that are likely to impact on the NHS over the next 18 months. The planner is intended for use by organisations and individuals in the NHS to support service and budgetary planning.

The Government recognises its own role in supporting local NHS organisations to plan and prioritise, and the need to plan for NICE guidance is included in the "prioritising investment" competency for World Class Commissioning. These competencies have been developed by the Department of Health in partnership with the NHS and describe the knowledge, skills, behaviours and characteristics that PCTs will need to develop to reach world class status. The Department of Health, in close partnership with the NHS, is taking forward work to design the supportive and developmental framework that will underpin the competencies.

27. Better measurement of guidance implementation is also needed. Self-assessment is not enough. We recommend that the Healthcare Commission conduct more in-depth inspections of this element of practice.

Whilst the Healthcare Commission's annual health check (AHC) assessment is informed in part by self-declarations signed off by PCT and Trust Boards, it also draws on intelligence from other sources. Following the submission of the self-declarations, the Healthcare Commission will inspect approximately 20 per cent of trusts. Half of these will be chosen randomly and the other half will be chosen where screening information available to the Commission suggests that further questions need to be asked about aspects of the trust's declaration. This informs the selection of sites for the Healthcare Commission to visit in order to achieve a "rounded view" for the annual health check, with the resources available to them.

Once established, the Care Quality Commission will develop the criteria and methodology it will use to assure and review regulated health and adult social care. We will ask the Commission to reflect on the Committee's recommendations in the course of that work.

29. We also recommend greater involvement of Royal Colleges and other professional organisations in ensuring implementation. For instance, the approval of trusts as training organisations could be linked to uptake of guidance. Elements of clinical guidelines, particularly those covered by technology appraisals, such as risk assessment of VTE patients, should be mandatory.

The Government agrees that Royal Colleges have a role in the implementation of NICE guidance, and believes that NICE should be commended for the good relationship it has established with the Colleges in the development of guidance. The Department of Health will consider the Committee's specific suggestion on approval of trusts as training organisations with NICE and the Postgraduate Medical Education and Training Board (PMETB), the independent body responsible for the approval of the content of medical training.

NICE's clinical guidelines cover a whole pathway of care and can make a number of recommendations spanning all stages of care from the diagnosis to treatment of a condition. The Government recognises that, because of this, there are often different states of readiness across NHS organisations for the implementation of NICE clinical guidelines. Under the existing standards regime, NICE clinical guidelines are classified as developmental standards for the NHS and are not subject to the same performance management assessment as NICE's technology appraisals.

Where it is considered appropriate, Ministers are able to issue directions to the NHS to mandate specific activities. The Government is, however, mindful of the need to limit the burden of national targets on the NHS. We will continue to consider the issue, and will ask the new Care Quality Commission to be mindful of the Committee's recommendation in developing the criteria and methodology it will use to assure and review regulated health and adult social care.

Prioritisation

22. It is difficult for individual PCTs to decide which areas to prioritise and in which to reduce spending when their expenditure rises as a result of new NICE guidance. In the absence of NICE guidance on disinvestment, we recommend that groups of PCTs should work together to determine appropriate areas of spending in consultation with the public. Such groups should also examine existing treatments to determine which are not cost-effective.

The Government agrees that medicines management and prescribing are key issues for both NHS commissioners and providers, and that it is important NHS organisations liaise effectively on these issues. Guidance published by the National Prescribing Centre in June 2007 assists the NHS with this collaboration and seeks to ensure that the arrangements local bodies put in place to consider prescribing and medicines management issues are fit for purpose.

It is up to PCTs to consider the possible benefits of joint working in line with the Committee's recommendation, and some already do so. Individual PCTs are responsible for their own spending decisions and must ensure that they have fully involved and informed the public that they serve and other stakeholders such as clinicians. PCTs should prioritise their spending by having a clear understanding of the needs of different sections of the local population. PCTs, with their partners, will need to set strategic priorities and make investment decisions, focused on the achievement of key clinical and health and community outcomes. Local decision-making means that different localities may make different decisions on priorities depending on local circumstance.

On drugs for very rare conditions, PCTs already work together as part of the planning cycle and as part of Specialised Commissioning Groups (SCGs) to determine local investment in specialised services and rare conditions based on available evidence. These considerations should involve the public. These arrangements are in line with the recommendations of Sir David Carter's "Report of Commissioning Arrangements for Specialised Services", which was published in May 2006 and accepted by the Government.

25. Demand for NHS services will always exceed the ability to meet it. Not every treatment can be provided to every person. NICE has a vital role to play in the rationing arrangements and, working with Government, should make clear to the public how and why such decisions are made.

The Government welcomes the Committee's acknowledgement of NICE's vital role in the prioritisation of NHS resources and agrees that it is important that NICE communicates its decisions clearly to the public. The Government established NICE to provide guidance to the NHS on the clinical and cost effectiveness of new and existing treatments and remains fully supportive of NICE and its work.

The Government recognises that in some cases more can be done to better communicate the reasons for NICE's decisions. NICE recognises this and continues to work to improve the clarity and transparency of its recommendations. To this end, NICE plans to begin holding its Appraisal Committee meetings in public.

Status of NICE guidance

30. To combat public confusion over the status of technology appraisals and other types of guidance, we recommend:–

- **Recommendations made following technology appraisals should be referred to as 'NICE directives'; and**
- **Everything else should be referred to as guidelines or guidance.**

The Government notes the Committee's recommendation but does not believe that there would be benefit in drawing a distinction in the terms proposed by the Committee between the recommendations made in NICE's technology appraisals and its other guidance products.

Although NHS organisations are required to make funding available for recommendations made by NICE in its technology appraisals, NICE technology appraisals do not override the judgement of a clinician in the treatment of individual patients. The recommendations in all NICE guidance are based on the best available evidence and we expect clinicians to take them fully into account, but we believe that re-branding appraisal decisions as "directives" might be taken to imply that they are intended to override clinical decision-making. "NICE guidance" is the generic term used to describe all the products produced by NICE.

The Department of Health will, however, consider further whether there is more appropriate terminology that might helpfully be used in communicating more clearly the status of NICE guidance products.

PCT involvement

31. Greater involvement of PCTs in NICE assessments and a re-examination of the NICE cost per QALY threshold, which we recommend above, would produce guidance which NHS organisations find more affordable.

The Government agrees that PCT involvement in the development of NICE guidance is important. NICE recognises this and has started work with the NHS Confederation to look at how PCTs can work together to become more actively involved in the NICE guidance development process.

Drug pricing

32. Given that discussions between the Government and the pharmaceutical industry on future drug pricing arrangements are already underway, we do not make any firm recommendations on how a future system should operate. However, we agree with the Government that better mechanisms are needed to ensure that the NHS pays a fair and affordable price for medicines. Any change to the system of medicines pricing is likely to have profound consequences for NICE and the Institute should be involved in any changes that might affect how it works. Moreover, it should be funded for the alterations in practice it might be required to make.

33. We recommend that risk-sharing schemes be used with caution. They should not be used as a catch-all in cases of uncertainty over a drug's benefit. The Department must bear in mind the evidence that will be foregone in such cases. Uncertainty would be better addressed by the careful design and performance of a publicly funded randomised controlled clinical trial. Better use should be made of NICE's 'only in research' recommendation in this regard.

34. The short evaluation of all medicines at launch, which we recommended earlier, could be established in such a way that negotiations on drug pricing could be incorporated into the process. The NICE evaluation process could also take account of potential improvements in subsequent data about clinical and cost effectiveness, and its consequences for product pricing.

The Government is not able to comment on the recommendations relating to risk-sharing and drug pricing in detail in the context of the ongoing PPRS negotiation, but we welcome the Committee's input and will reflect on the recommendations.

The Government agrees that NICE's guidance should help inform future research needs. NICE guidance makes a number of research recommendations which highlight areas of uncertainty around the topic and suggest where further research would be beneficial. Research recommendations made by NICE are considered by the Health Technology Assessment (HTA) programme, which is coordinated by the National Coordinating Centre for HTA (NCCHTA) on behalf of the Department of Health's Research and Development Directorate.

Since 2005, the Director of the HTA Programme has met annually with NICE to receive and prioritise their research recommendations including those arising from public health guidance. The prioritised research recommendations are then taken forward ether directly for commissioning of research or for further development before commissioning.

Summary

35. To improve the evaluation process, we recommend that:

- **All drugs be assessed at the time of licensing, so that clinicians can prescribe useful and cost-effective products as soon as they are launched;**
- **There be more emphasis on disinvestment;**
- **Our last report on NICE recommended that the legislation be changed to accommodate the need to ensure that assessments of products take account of the wider benefits to society; we make the same recommendation here;**
- **NICE have access to the same material used by the licensing body, clinical trials be registered and there should be closer working between NICE and the industry to enable these early assessments to take place.**

37. To improve the implementation of NICE guidance we recommend:

- **More help for PCTs to implement guidance;**
- **Better assessment of the level of uptake;**
- **That PCTs should play a larger role in the development of guidance;**
- **Better use of experts in the development of guidance;**
- **A change in the terminology used by NICE, to clarify to patients what they can and cannot expect by right from their local NHS organisation; and**
- **That some elements of clinical guidelines should be made mandatory.**

We have responded to these recommendations individually above.

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