The Government's Response to the Health Select Committee's Eighth Report of Session 2012-13 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 2013

Cm 8568 £6.25

The Government's Response to the Health Select Committee's Eighth Report of Session 2012-13 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 2013

Cm 8568 £6.25

Any enquiries regarding this publication should be sent to us at mbnicesponsorteam@dh.gsi.gov.uk or NICE sponsor team, Department of Health, 5W09, Quarry House, Quarry Hill, Leeds LS2 7UE.

This publication is available for download at www.official-documents.gov.uk

ISBN: 9780101856829

Printed in the UK by The Stationery Office Limited
on behalf of the Controller of Her Majesty's Stationery Office

ID 2542417 03/13 28248 19585

Printed on paper containing 75% recycled fibre content minimum.

THE GOVERNMENT'S RESPONSE TO THE HEALTH SELECT COMMITTEE'S EIGHTH REPORT OF SESSION 2012-13 ON THE NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

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 re-establishment of NICE as a new statutory body, the National Institute for Health and Care Excellence, under the Health and Social Care Act 2012, gives it a key position in the reformed health and care system. The Government welcomes the Committee's report which makes a number of helpful recommendations that will be valuable in framing NICE's future development.

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

Social care and integrated care

1. We welcome the fact that NICE is to take on responsibility for producing clinical guidance and quality standards in relation to social care. There is a real opportunity for NICE to help evolve a different model of care by creating integrated standards and clinical guidance. We agree that this should not just be about providing guidance to people in different disciplines who are treating and caring for people with a specific condition, but should also involve advising about the most common associated co-morbidities, including mental illness. This broader guidance will also need to take account of what individuals want for themselves. This approach would reflect an important development of a philosophy which emphasises treatment of people not conditions.

The Government welcomes the Committee's support for the extension of NICE's role to social care and agrees that this presents a valuable opportunity to support a more integrated approach to the delivery of services across the NHS, social care and public health sectors. NICE has been asked to develop a healthcare quality standard on "long-term conditions, people with comorbidities, complex needs" and has also been asked to develop a social care quality standard on "management of physical and mental co-morbidities of older people in community and residential care settings". These, like all NICE quality standards, will be developed in collaboration with the sector and through engagement with service users. We will continue to look for opportunities with NICE and the NHS Commissioning Board for NICE to develop guidance relating to co-morbidities.

2. One of the key themes of the Committee's work in this Parliament has been the need to move to a more integrated system in order to maintain both quality of care and access to care. As NICE takes on its new responsibilities in relation to social care, it is important for it to work with the full range of health and care providers to ensure that an adequate evidence base is created on which it can base its guidance.

The Government agrees that it is important for NICE to work with a full range of health and care providers. NICE has an excellent track record of working closely with a full range of stakeholders, and we have every confidence that NICE will continue to do so as its remit is extended to social care.

Clearly, the available evidence base is an important factor to consider in asking NICE to develop guidance on a topic. NICE routinely identifies in its final guidance priorities for further research, and we expect that it will continue to do so in the future.

3. NICE should be proactive in assessing interventions where evidence exists to support efficacy and cost effectiveness, and should ensure that their appraisal of cost effectiveness is based on an assessment of quality of life as well as increased life expectancy.

The Government agrees that NICE should continue to give consideration to both quality and quantity of life in its work. NICE's published methods guides for its clinical and public health guidance programmes explain how it takes these issues into account.

4. The Committee has repeatedly underlined the pivotal role which it believes commissioners should play in the development of the more integrated care system which is required. The Committee has also repeatedly stated that it believes that more integrated care delivery requires more integrated commissioning. We therefore agree with Sir Michael Rawlins that NICE should initiate the production of guidance for commissioners and that the emphasis of that advice should be on how to deliver integrated care.

The Department agrees that one of the key aspects of delivering integrated care is more integrated commissioning. The Care and Support White Paper committed the Department to developing, in collaboration with partner organisations, a framework *"that will support the removal of barriers to making evidence-based integrated care and support the norm over the next five years".* We will set out our plans in a Common Purpose Framework to be published with our collaborative partners in the spring. This will include setting out the valuable role that key stakeholders including NICE can play in supporting the commissioning and delivery of integrated care.

This Framework will be co-produced by a number of partners including the NHS Commissioning Board and the Local Government Association (LGA) who will be central to discussions, along with NICE, on its role in relation to this recommendation.

NICE has already developed a number of resources for commissioners that are designed to support local implementation of its guidance. For example, in 2010, it published two guides that support implementation of the joint NICE and Social Care Institute for Excellence (SCIE) clinical guideline on dementia focusing specifically on memory assessment services and end of life care for people with dementia. More recently, NICE has published a similar guide relating to the management of hip fracture and the prevention of cardiovascular disease.

Cost effectiveness and value-based pricing

5. There has been extensive discussion of the principle of value-based pricing, but it remains a source of concern to the Committee that so little progress has been made on defining this nebulous concept. The practical implications of the move to value based pricing appear to be relatively modest: with a limited number of health technology appraisals taking place each year (around 30), the majority of drugs will for the foreseeable future continue to be procured under a variant of the current Pharmaceutical Price Regulation Scheme.

6. The consultation document on value-based pricing was issued two years ago in December 2010, and the response to the consultation was published in July 2011. The Committee does not regard it as acceptable that the arrangements for value-based pricing have still not been settled and that those who will have to work with those arrangements are still unclear about what value-based pricing will mean in practice. Industry needs certainty about how it should bring its products to the NHS, and patient groups and clinicians need to understand what their role will be and how they can make their views heard. Given the length of time since the consultation began, the apparently modest implications of the proposed changes, and the fact that the new regime is due to be effective from January 2014, we recommend that the Department of Health should bring this uncertainty to an end no later than the end of March 2013.

As the Committee notes, the Government set out proposals in the consultation *A new value-based approach to the pricing of branded medicines*, which ran from December 2010 to March 2011, and published a response to the consultation in July 2011. Following the consultation, the Government has taken forward a programme of work, in collaboration with external experts and stakeholders, to develop the value-based pricing (VBP) assessment model.

During 2012, we held a series of engagement events with a wide range of participants including representatives of patients, clinicians, the NHS, taxpayers, industry and other interested parties. These included technical workshops, in October and in November 2012, on the evidence base to inform the development of the VBP assessment mechanism, and in February 2013, we held a further workshop, examining potential equalities impacts of VBP. These events have offered a range of interested parties, including industry, patient groups and clinicians, opportunities to understand the Government's detailed proposals for how the value assessment of medicines would change under VBP, and to feed in views. The interests of all NHS patients will be taken into account in finalising the new pricing arrangements for branded medicines.

We have already made it clear that NICE will have a central role in the value-based pricing system, including in undertaking an assessment of the costs and benefits of different medicines, drawing on its world-leading expertise. We can now go further, and confirm that NICE will be responsible for the full value assessment of medicines under the future system. Work to develop the new system builds on NICE's existing technology appraisals processes, but it is also capable of incorporating a broader assessment of a medicine's benefits and costs, taking into account factors such as burden of illness and wider societal benefits. Importantly, it imposes no requirements on companies to collect additional data.

Determining what represents value is a societal judgement and it is therefore appropriate that the Government sets the overall framework for VBP, including any key weightings that will be used in its operation to reflect the broader components of a new medicine's value, for example, in treating a particularly

severe condition, or reducing a patient's care needs. However, some aspects of VBP, such as the management of any cases where the value assessment does not support the proposed list price, will be considered as part of the negotiations between the Department of Health and the branded pharmaceutical industry on new arrangements for the pricing of branded medicines.

The Government shares the Committee's view that it is important to finalise the new pricing arrangements, including VBP, as soon as possible.

Cancer Drugs Fund

7. The Cancer Drugs Fund was established to help provide cancer treatments which would not otherwise be available in the period up to January 2014, when it was considered that the introduction of the new value-based pricing system, with its perceived greater flexibility than the current NICE approach, would mean that it would no longer be required. From the evidence of our inquiry, the Committee considers that three things need to be done before the Fund ceases to operate:

- **There needs to be an assessment of the outcomes for those patients whose treatment has been paid for by the Fund, to see what impact it has had;**

The information generated through the Cancer Drugs Fund provides an unprecedented opportunity to assess the benefits that these drugs deliver in real-world clinical practice, and to build the evidence base for the future. The Chemotherapy Intelligence Unit in Oxford is carrying out a national audit of Cancer Drugs Fund usage. Monthly data collection commenced in April 2012, with retrospective data also being collected for 2011/12. The analysis of these data will provide information on the treatment received and on patient outcomes. This information will become increasingly robust as greater numbers of patients are treated. The outcome data from the Cancer Drugs Fund should offer valuable insights into the difference between outcomes observed in clinical trials and those realised in NHS practice.

- **If there is clear evidence of beneficial outcomes, then that evidence needs to be built on in constructing the new value-based pricing scheme, and applied to treatments for conditions other than cancer;**

Through value-based pricing (VBP), the Government's aim is to ensure that the medicines appraisal process is capable of incorporating all the elements of value that a medicine for any condition gives to patients and society. Whilst VBP will focus primarily on new medicines, it is possible that a small number of existing drugs could be assessed under VBP. Clinical audit data from the Cancer Drugs Fund would be available to support either this kind of assessment or any future review by NICE of its existing technology appraisal guidance of drugs made available through the Fund.

- **A defined funding mechanism needs to be developed which will allow drugs which have been paid for by the Fund to continue to be available to individual patients.**

NHS organisations will continue to be legally required to fund cancer treatments recommended by NICE in its technology appraisal guidance. We will ensure that there are arrangements in place to protect individual patients who are receiving treatment with drugs funded by the Cancer Drugs Fund as the planned end of the Fund approaches. In the context of work to develop new pricing arrangements for branded medicines, we are also exploring ways in which new patients can continue to benefit from innovative cancer drugs at a cost that represents value to the NHS

Information about clinical drugs trials

8. The Committee believes there should be both a professional and legal obligation to ensure that all regulators, including NICE, have access to all the available research data about the efficacy and safety of pharmaceutical products. All information arising from drug trials should be in the public domain in an accessible and properly anonymised form, including any negative information – as Stephen Whitehead of the ABPI said, "negative trials often give you as much information that is helpful as positive trials."

The Medicines and Healthcare products Regulatory Agency (MHRA) and the European Medicines Agency (EMA) are responsible for the regulation of medicines used in healthcare. When applying for marketing authorisation of a new medicine, a company is legally required to provide MHRA with the results of all clinical trials relevant to the evaluation of the product concerned (whether the results are favourable or unfavourable).

Following the marketing of a drug, licence holders are required to supply the regulator with new information, including data from clinical trials, that may have an impact on the drug's balance of benefits and risks. This requirement covers data from clinical trials conducted both within and outside the terms of the licence.

The MHRA has begun publishing public assessment reports following approval of new medicines, in line with requirements in EU Directive 2001/83, which took effect from 2005. These reports provide details of the information which the MHRA assessed when making its decision to approve marketing authorisation. They include a summary of the clinical trials included in the application and their evaluation by the MHRA in relation to the treatments or uses for which the company sought marketing authorisation. The reports are available to NICE and to other interested parties.

The current EU Clinical Trials Directive (2001/20/EC) and its implementing guidance requires the submission of a summary clinical trial report to the competent authorities by all sponsors for each completed trial, within one year of completion. The European Commission and the EMA are currently

developing the EU Clinical Trials Register to allow publication of these summary reports and this is expected to be available late in 2013. There is also a strong focus on transparency in the proposed EU Clinical Trials Regulation which is currently being negotiated.

9. The Committee also recommends that the pharmaceutical industry should introduce a new code of practice covering research. This should include an obligation to make public all data about drugs which are in current clinical use once they have been through an appropriate peer review process. These are measures that pharmaceutical companies can take now without waiting for the new Clinical Trials Regulation to be approved.

The Government welcomes the voluntary publication of research data by industry. A model clinical trials agreement for pharmaceutical research has been agreed by the UK Health Departments, the Association of the British Pharmaceutical Industry (ABPI) and the BioIndustry Association. This agreement makes it a requirement for pharmaceutical companies to ensure that the results of a clinical trial will be published on a free, publicly accessible clinical trial results database within one year of the medicine first being approved and commercially available in any country. Where a clinical trial is under review by a peer-reviewed journal, the results will be posted on a database at the time of journal's publication.

We encourage the ABPI to monitor adherence to the agreed code by its members, as this will show leadership from the pharmaceutical industry in demonstrating that transparency is an important part of its business.

10. The Committee also recommends that the GMC reiterates its guidance on drug trials to its members, and reminds them that failure to abide by these principles could lead to fitness to practice proceedings being taken against them.

This is a matter for the GMC to consider.

11. The Committee does not believe it should be either legal or considered ethical to withhold research data about pharmaceutical products. It is therefore concerned that this simple principle is not universally applied in practice, and also concerned by the implication of Sir Andrew Dillon's evidence that NICE are making appraisals of drugs without having access to all relevant data. The Committee welcomes the current review of these issues by the House of Commons Science and Technology Committee and recommends that Committee should examine the nature of both the legal and ethical principles which should cover these issues and how to make those principles enforceable in practice.

We welcome the forthcoming review and will take the opportunity to submit in detail our evidence and views about the area of clinical trials and data transparency.

Patient Voice

12. It is important for the credibility of NICE and for the decisions that it makes that the patient voice is effectively and openly represented in all its work.

The Government agrees it is important for NICE to put patients and the public at the heart of its work. NICE constantly strives to improve the way it involves patients, carers and the public in the development of its guidance and other products. NICE does this through its Public Involvement Programme which provides opportunities for patients, and organisations representing their interests, to contribute to developing NICE guidance and quality standards, and support their implementation. Additionally NICE's Citizens Council provides NICE with a public perspective on overarching moral and ethical issues that NICE has to take account of when producing guidance.

Clinical Guidance

13. We recommend that NICE clinical guidance should continue to be guidance rather than instruction. There will always be local variations and doctors and their patients must be able to come to individual judgements about what is the best treatment. Clinical guidance also needs to evolve and allow for innovation.

The Government agrees with this recommendation. NICE clinical guidelines are a valuable source of advice and guidance to support professionals, provider organisations and commissioners in the delivery of high quality, clinically and cost-effective care.

NICE clinical guidelines are also used to form the underpinning evidence base for the development of NICE quality standards. The Secretary of State and the NHS Commissioning Board are required to have regard to these quality standards in discharging their improvement duties in relation to the health service.

14. The Committee does recommend, however, that a clinician or commissioner who decides to depart from NICE guidelines should be expected both to report and explain the departure. Local and individual discretion is valuable and right – but it should be exercised in a disciplined and accountable manner.

The Government agrees that clinicians and commissioners should take full account of NICE's clinical guidelines. However, while clinical guidelines help health professionals in their work, they do not replace their knowledge and skills. It should also be recognised that the GMC's *Good Medical Practice*, which sets out the principles and values on which good practice is founded, requires doctors to provide effective treatment based on the best available evidence.

15. We consider that guidance is a process not an event, and therefore a regular re-examination of guidance is clearly very important to ensure that it remains best practice.

The Government agrees that NICE should keep its guidance under review to ensure that it can be relied upon as a statement of evidence-based best practice. NICE has arrangements in place to review and, if necessary, update its published guidance to ensure that it reflects the best available evidence.

Quality Standards

16. The NHS Commissioning Board should ensure that familiarity with and use of NICE quality standards is included as part of its accreditation programme for Clinical Commissioning Groups.

This is a matter for the NHS Commissioning Board to consider as it discharges its statutory duties.

Published by TSO (The Stationery Office) and available from:

Online
www.tsoshop.co.uk

Mail, Telephone, Fax & E-mail
TSO
PO Box 29, Norwich NR3 1GN
Telephone orders/General enquiries: 0870 600 5522
Order through the Parliamentary Hotline Lo-Call: 0845 7 023474
Fax orders: 0870 600 5533
Email: customer.services@tso.co.uk
Textphone: 0870 240 3701

The Houses of Parliament Shop
12 Bridge Street, Parliament Square
London SW1A 2JX
Telephone orders: 020 7219 3890/General enquiries: 020 7219 3890
Fax orders: 020 7219 3866
Email: shop@parliament.uk
Internet: http://www.shop.parliament.uk

TSO@Blackwell and other accredited agents

ISBN 978-0-10-185682-9