House of Commons

Health Committee

National Institute for Health and Clinical Excellence

Eighth Report of Session 2012–13

HC 782

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Volume I

Volume I: Report, together with formal minutes, oral and written evidence

Additional written evidence is contained in Volume II, available on the Committee website at www.parliament.uk/healthcom

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The Health Committee

The Health Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Department of Health and its associated bodies.

Membership

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Andrew George MP (*Liberal Democrat, St Ives*)
Barbara Keeley MP (*Labour, Worsley and Eccles South*)
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The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the Internet at www.parliament.uk/healthcom.

The Reports of the Committee, the formal minutes relating to that report, oral evidence taken and some or all written evidence are available in printed volume(s).

Additional written evidence may be published on the internet only.

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The staff of the Committee are David Lloyd (Clerk), Martyn Atkins (Second Clerk), Stephen Aldhouse (Committee Specialist), Frances Allingham (Senior Committee Assistant), and Ronnie Jefferson (Committee Assistant).

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1 Mr Stephen Dorrell was elected as the Chair of the Committee on 9 June 2010, in accordance with Standing Order No. 122B (see House of Commons Votes and Proceedings, 10 June 2010).

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Summary

On 19 July 2012, the then Secretary of State for Health wrote to the Chair of the Committee noting that the appointment of the current Chair of NICE was due to expire on 31 March 2013 and asking the Committee to undertake a pre-appointment hearing with the Department's preferred candidate. In preparation for the hearing, the Committee decided to issue a call for written evidence and then hold two sessions of oral evidence.

Social care and integrated care

From April 2013, NICE will have new responsibilities in relation to social care, which will be reflected in its new name: the National Institute for Health and Care Excellence. This is a significant change, and one that reflects the developing recognition that in order to improve the quality of care, and to make budgets go further, greater integration of services across health and social care is necessary.

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.

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.

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

It is not just clinicians and care staff who need guidance to help build integrated care. Commissioners also have a key role. 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 move to value-based pricing

Much of the discussion in the Committee's meetings related to the proposed move to value-based pricing of drugs. Defining what that actually means, however, has not been straightforward. The Government says that there must be a much closer link between the

price the NHS pays and the value that a medicine offers as opposed to the current system, in which NICE makes its assessment based on the manufacturer's suggested price. The Committee understands that, in practice, discussions do take place between the sponsors of a new drug and NICE about the price at which the drug would satisfy cost effectiveness criteria and the Committee agrees with NICE that this flexibility is desirable. Against that background it is far from clear what substantive change is implied by the concept of value-based pricing.

There has been extensive discussion of the principle of value-based pricing but it remains a source of concern that so little progress has been made on defining this nebulous concept. In any event, with a limited number of health technology appraisals for new drugs and treatments 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 System.

The consultation document on this issue was issued two years ago in December 2010, and the response to the consultation was published in July 2011. We do 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.

Cancer Drugs Fund

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. On 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;
- 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;
- 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.

Research data

It has recently been argued that some pharmaceutical companies keep information about drugs trials out of the public domain and thereby undermine the quality of information available to regulators, clinicians and patients about the efficacy and safety of drugs. 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."

We recommend 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 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.

We do not believe it should be either legal or considered ethical to withhold research data about pharmaceutical products. We are therefore concerned that this simple principle is not universally applied in practice, and also concerned by the implication of Sir Andrew Dillon's evidence to us 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 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.

Patient voice

It is clearly very important that those who have particular conditions should have their views represented in any discussions within NICE on whether or not to approve drugs designed improve that condition. It was argued in evidence that there is currently no clear role for patient groups. NICE did not agree that their role was not clear, but accepted that the experience could be improved. 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.

Clinical guidance

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 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.

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.

1 Introduction

Background

1. On 19 July 2012, the then Secretary of State for Health wrote to the Chair of the Committee noting that the appointment of the current Chair of NICE was due to expire on 31 March 2013 and asking the Committee to undertake a pre-appointment hearing with the Department's preferred candidate. The Secretary of State said that it was his aim to select a candidate before Christmas and expressed the hope that the Committee would be able to hold its hearing before Christmas. The Chair replied, agreeing to the request.

2. In preparation for the hearing, the Committee decided to issue a call for written evidence and then hold two sessions of oral evidence. The terms of reference in the call for evidence were as follows:

> The term of office of the current Chair of the National Institute for Health and Clinical Excellence (NICE), Sir Michael Rawlins, ends on 31 March 2013 and the Department of Health has indicated that it will shortly be advertising the post. The Health Committee will be holding a pre-appointment hearing for the Government's preferred candidate for the post of Chair of NICE towards the end of the year.
>
> In advance of that hearing, the Committee has decided to hold a short inquiry into the work of NICE, examining the way that it has discharged its current functions and looking forward to the changes in its role that will come into effect from 1 April next year, when its name will change to the National Institute for Health and Care Excellence and its status will change to that of an executive non-departmental public body. The Committee would therefore welcome written submissions on the work of NICE and in particular is interested in:

- NICE's role in relation to evaluating the effectiveness and cost effectiveness of drugs and other clinical interventions (through medical technology appraisals) including how its role will be affected by the intended introduction of value-based pricing for drugs purchased by the NHS
- The role of NICE Quality Standards in the new NHS system architecture, in particular the status of NICE guidelines in determination of commissioning priorities
- The continuing role of NICE clinical guidelines (on treatment for specific conditions) in improving the quality of healthcare, in particular in the context of analysis of effectiveness of established treatment procedures and review of variations of outcome
- The effect of the new public health system architecture on NICE's continued role in respect of public health guidance
- What effect NICE's new responsibilities in relation to evaluating social care interventions might have on its work overall and how this will relate to the integration of health and social care services

3. In all we received 73 memoranda. In our oral evidence we heard from: Sir Michael Rawlins, Chair, and Sir Andrew Dillon, Chief Executive, NICE; Professor Peter Johnson, Chief Clinician, Cancer Research UK; Dr Linda Patterson OBE, Clinical Vice-President, Royal College of Physicians of London; Laura Weir, Chair, Patients Involved in NICE; Stephen Whitehead, Chief Executive, Association of the British Pharmaceutical Industry; Professor Peter Smith, Professor of Health Policy at Imperial College London and senior research associate at the Nuffield Trust; Professor Peter Littlejohns, Professor of Public Health, King's College, London; and Professor Albert Weale, Professor of Political Theory and Public Policy at University College London. We are grateful to all of those who contributed to our inquiry.

4. The Secretary of state wrote to the Committee on 7 December to inform us that the Government's preferred candidate for Chair of NICE was Professor David Haslam CBE. The Committee held the pre-appointment hearing on 11 December and subsequently endorsed Professor Haslam's appointment.[2] This report examines issues that we discussed during the oral evidence sessions leading up to the pre-appointment hearing.

2 Health Committee, Sixth Report of Session 2012–13, *Appointment of the Chair of the National Institute for Health and Care Excellence, HC* 831. The Secretary of State made the substantive appointment on 14 December 2012.

2 Social care and integrated care

5. From April 2013, NICE will have new responsibilities in relation to social care, which will be reflected in its new name: the National Institute for Health and Care Excellence. NICE said in its memorandum;

> Our new responsibilities in social care, set out in the Health and Social Care Act, will allow us to apply, appropriately adapted, a similar approach to developing evidence-based guidance and standards that we provide for the NHS to decision-making in the social care sector. The changes also provide us with the opportunity to ensure that our health, public health and social care guidance is aligned to allow a more integrated approach to the delivery of services across these sectors. For example, in dementia, where we have already produced healthcare guidance and standards for the NHS, we are looking at how guidance for the social care sector (including care homes and other services provided by local authorities) can be joined up so that there is a single evidence-based pathway available that describes a high-quality integrated service, from prevention, diagnosis and treatment to longer term follow-up care.[3]

6. This is a significant change, and one that reflects the developing recognition that in order to improve the quality of care, and to make budgets go further, greater integration of services across health and social care is necessary. As Professor Haslam said during his pre-appointment hearing:

> If you were designing a system from scratch, you would not split it into health and social care. The public doesn't recognise that. The public doesn't understand our tribalism; it just wants decent care.[4]

7. Patients Involved in NICE told us:

> If we are to move the integration of services beyond rhetoric to reality then integrated guidance from NICE (for commissioners, patients, carers and professionals) is a good starting place. To produce social care guidance, NICE will need to work differently; the clinical emphasis of its work will need to be rebalanced against evidence regarding the personal outcomes and benefits to people using services and their carers.[5]

8. Sir Andrew Dillon told us:

> One of the great things about being given now, or from next April, the responsibility to produce quality standards and guidance in social care is that we have built and have access to a resource that allows us to scope individual topics—whether they come from a clinical guideline route or a social care referral route—in the most appropriate way for the people who are going to use them. In future, it will change

3 Ev 40

4 Evidence taken before the Health Committee on 11 December 2012, HC 831–i, Q2.

5 Ev 55

> the way in which we can look at topics. We are going to take advantage of that as we review existing clinical guidelines and re-scope them and as we put together the new topics specifically for social care.[6]

9. Sir Michael Rawlins added that

> one of the flaws in our guidelines, which is that they are single conditions, and by the time people get to 80 they say, "I will have five simultaneously." We have to produce guidelines that accommodate that. Nobody in the world has ever done this, but we are going to do it. We can't cover every possible combination, otherwise it would take years to produce a single guideline, but what we can do is provide advice on, say, the three or four most common co-morbidities that occur in someone with heart failure, such as chronic bronchitis, which is very common, and so on. It will be that sort of approach. NICE is going to be evolutionary, I hope, in the future and can't just rest on what it has done in the past.[7]

10. It was clear from the exchanges that we had with Sir Michael and Sir Andrew that NICE understands the need to move beyond guidance for the treatment of conditions and embrace a philosophy of integrated care for patients. Sir Andrew quoted the example of NICE's original guidance on dementia, on which "the Social Care Institute for Excellence worked with us to produce parallel advice, which was integrated and cross-referenced".[8] He said that it was not possible to give the same guidance to a whole range of professionals:

> The advice that you would give to a general practitioner or to a physician in practice in a hospital for an acute episode is not going to be the same, though it ought to be complementary to the advice that you might give to somebody who is looking after someone in a residential home or in a domiciliary care setting. We want to make sure that the range of advice to everybody who has some responsibility for looking after people with dementia is consistent. It is a spectrum of advice, because the needs that we might have when we are living with dementia vary, depending on the setting that we are in. We are trying to get setting-specific guidance.[9]

11. **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**.

6 Q 157

7 Q 157

8 Q 155

9 Q 156

12. NICE's new role in relation to social care poses considerable challenges. As Professor Haslam noted "NICE has a worldwide reputation in terms of health; it does not yet have a significant reputation in social care. That is an important line that we have to go down, particularly because of the importance of the increasing integration between health and social care."[10]

13. We asked him how NICE might bring the health and social care worlds together in one system. He said:

> First off, it takes time. It is not something that you can legislate for. You have to build up trust and understanding and bring people together. I see my role as chair very much, hopefully, as working closely with senior people from the social care world to understand, indeed, their fears about NICE. I suspect that, because of NICE's reputation as a health organisation, they feel that social care is somehow going to get lost in that—that it is a bit of an adjunct. I do not see it that way. I see the whole thing as very joined up.[11]

14. Professor Littlejohns talked about how NICE should assess the evidence on how integration works best.

> Where the evidence is around the clinical pathway, including the social care components, NICE has a very strong role to play. One of the difficulties, though, with integration is the interface historically between the primary and secondary care sectors within the health arena, and of course now with the social care environment and a whole new mechanism around local authorities. We need to develop the evidence base around what is working at that interface. NICE can only work if the evidence is there.[12]

15. **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.**

16. **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.**

17. It is not just clinicians and care staff who need guidance to help build integrated care. Commissioners also have a key role. One of Sir Michael Rawlins' key priorities for his successor was to ensure that NICE was attuned to the importance of commissioners. He said:

10 Evidence taken before the Health Committee on 11 December 2012, Q 1.

11 *Ibid*, Q 4.

12 Q 89

> ...a few years ago we did, on a pilot basis, produce some commissioning guides, which, at the time, everyone said were very helpful because an individual [Primary Care Trust] could plug in its own population and gender and all that sort of stuff and pull out the numbers of referrals for endoscopy that they ought to be commissioning for. I think probably NICE should return to that and develop, on the basis of those, some sort of clinical commissioning group standards. We have to move forward in that direction as well as sustain what we have been doing in the past.[13]

18. **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.**

13 Q 167

3 Health Technology Appraisals: cost effectiveness and other issues

Cost effectiveness and value-based pricing

19. Technology appraisals are the function for which NICE is best known. As NICE put it in its memorandum to the Committee:

> In this programme we assess the clinical and cost effectiveness of (mainly new) health technologies. These are primarily new pharmaceutical and biopharmaceutical products but have also included procedures, devices and diagnostic agents. This programme is intended to ensure that all NHS patients have equitable access to the most clinically- and cost-effective treatments that are available. In doing so we work openly and transparently with the life sciences industry. We have, to date, published 264 technology appraisals with 34 planned or already published in 2012–2013.[14]

20. One of the issues that was extensively discussed in written and oral evidence was the issue of cost effectiveness. The Association of the British Pharmaceutical Industry (ABPI) expressed concern that NICE gave too much weight to cost effectiveness in examining new drug therapies:

> The focus of NICE in HTA [health technology appraisal] decision making is we believe disproportionately on cost effectiveness. Although NICE considers a range of factors, the ultimate decision-making metric remains as the Incremental Cost Effectiveness Ratio. Appraisal Committee deliberations are therefore focused primarily on the perspective of health economists rather than that of clinicians and patients. A more balanced view of the various elements of value is required and a full account should be given by Appraisal Committees of what factors were taken into consideration and, importantly, the impact of those factors on the final decision, so that stakeholders properly understand how conclusions were reached.[15]

21. Professor Johnson of Cancer Research UK was sympathetic to that analysis:

> There is a very tight focus a lot of the time in the way that NICE considers health technologies on the immediate costs and benefits and not the rather broader consideration of what effect it might have in other parts of the patient pathway. A failure to take into account the broader value of particular healthcare interventions does restrict their vision of what constitutes "worthwhile" for the NHS.[16]

22. Professor Smith, on behalf of the Nuffield Trust, argued that

> The principle of cost-effectiveness is one that has proved very hard to challenge. It arises from the desire to spend a limited budget as effectively as possible. That gives

14 Ev 41

15 Ev 49

16 Q 11

> rise to the decision rule of cost-effectiveness. The work of NICE, which is internationally recognised, has embedded that within our health system.[17]

23. Laura Weir, of Patients Involved in NICE, thought, however, that the issue of cost effectiveness had been over-played:

> ...it is a common misconception about NICE, probably fuelled by the media, that it weights cost-effectiveness more heavily than clinical-effectiveness. The truth is it has to see them both together; those calculations have to be done together, and that is why we have the QALY—the quality adjusted life year. It will weigh the cost of a medicine against the quality and length of life that a treatment will give. Where medicines only offer a marginal clinical benefit but they cost a lot, that is when patient access schemes will often come to the fore and where patient groups will lobby companies to reduce their price, because, after all, if the price is lower, there is a higher chance that patients will be able to get that medicine on the NHS.[18]

24. Although the high reputation of NICE, both in the UK and abroad, is largely based on respect for its work on assessment of the cost effectiveness of new drugs, it is the broader concern about the implications of this focus on health economics which lies behind much of the recent rhetoric about value-based pricing.

25. A move to value-based pricing was included in the Coalition's Programme for Government:

> We will reform NICE and move to a system of value-based pricing, so that all patients can access the drugs and treatments their doctors think they need.[19]

In the Foreword to a consultation on moving to value-based pricing issues in December 2010, the then Secretary of State wrote;

> The current system of pricing medicines has tried to achieve a balance between reasonable prices for the NHS and a fair return for the industry to develop new medicines. However, it does not promote innovation or access in the way this Government is looking for. Also, too often, the NHS has been in the position of either having to pay high prices that are not always justified by the benefits of a new medicine, or having to restrict access.
>
> We are determined to create a system that gives patients access to the most effective medicines. There must be a much closer link between the price the NHS pays and the value that a medicine delivers. Pharmaceutical companies need a pricing system that is more stable and transparent, and that gives clear signals about priority areas, so that research efforts are directed to greatest effect...This consultation document outlines a new system which aims to recognise and reward innovation, in particular

17 Q 68

18 Q 36

19 *The Coalition: our programme for Government*, Cabinet Office, May 2010, page 25.

by encouraging a focus towards genuine breakthrough drugs which address areas of significant unmet need.[20]

26. Chapter 4 of the consultation document set out the current state of plans for value-based pricing:

> The key principle of value-based pricing is to ensure NHS funds are used to gain the greatest possible value for patients. So the Government would set a range of thresholds or maximum prices reflecting the different values that medicines offer.
>
> The value of new products would be assessed and their benefits compared with the benefits that could be gained if the funds required were used to help patients elsewhere in the NHS. This comparison is normally expressed with a cost-effectiveness threshold. It requires the use of a "common currency" for quantifying benefits in a consistent and comparable way across the full range of health-related conditions.
>
> One (but not the only) option would be to use Quality Adjusted Life Years (QALYs), the 'currency' currently used by NICE in its technology appraisals. A QALY is the amount of health represented by a year of life at full health. It gives an idea of how much extra length of life and the quality of life a person might gain as a result of treatment – and health gains from different treatments can be expressed in terms of the number of QALYs to which they are equivalent. If we used the QALY in value-based pricing, the threshold would be expressed as a cost per QALY gained.
>
> In the existing system, a standard cost effectiveness threshold is applied to all new products, with some flexibility to take account of additional relevant factors, including societal preferences. However, the mechanism for taking wider factors into account is not completely transparent, and this may lead to perceptions that important factors are not adequately reflected in the assessment process.
>
> By contrast, under the new system of value-based pricing, the Government would apply weightings to the benefits provided by new medicines, which would imply a range of price thresholds reflecting the maximum we are prepared to pay for medicines. These thresholds or maximum prices would be explicitly adjusted to reflect a broader range of relevant factors so they could be used to calculate the full value of a new product.
>
> The Government proposes that the price threshold structure is determined as follows:

i. there would be a basic threshold, reflecting the benefits displaced elsewhere in the NHS when funds are allocated to new medicines;

ii. there would be higher thresholds for medicines that tackle diseases where there is greater "burden of illness": the more the medicine is focused on diseases with unmet need or which are particularly severe, the higher the threshold;

20 *A new value-based approach to the pricing of branded medicines*, Department of Health,16 December 2010.

iii. there would be higher thresholds for medicines that can demonstrate greater therapeutic innovation and improvements compared with other products;

iv. there would be higher thresholds for medicines that can demonstrate wider societal benefits.

> Designing the new system to be both stable and transparent would allow companies to predict well in advance how prospective products may fare, and to focus their research efforts on the treatments that society values most. Companies would be informed of these weightings – allowing them to orient their research and development investments appropriately.
>
> In introducing this system, the Government would move away from a system of negotiations once every five years under the PPRS [Pharmaceutical Price Regulation Scheme] to a more stable framework. This greater predictability and transparency will give companies greater certainty for making long term investment decisions.[21]

27. It is notable that, despite the fact that the Coalition Government has now been in office for over two and half years there remains very little detail about how an alternative "value-based" pricing system might work.[22]

28. We asked Sir Michael Rawlins, the current chair of NICE, how he thought value-based pricing would work. He told us:

> In the past we have looked at cost-effectiveness in relationship to the incremental cost-effectiveness ratio—the increased amount of money you get in terms of the increased numbers of quality adjusted life years gained. We have had a threshold, but we have always encouraged our advisory committees to be flexible about the use of the threshold, and there may be circumstances when they feel they ought to be giving a positive recommendation even when things are above our threshold range. End-of-life care is an example.
>
> This has all been subjective and it has not been objective. Maybe you could reasonably criticise us for not having tried to create an objective approach rather than a subjective approach, but I think part of value-based pricing is to produce some objectivity into it. One would weight the QALY. One might weight double the value of the QALY for end-of-life treatments, for example. That is one component to it and that is how I see value-based pricing at that end.
>
> The second component is what they call the economic perspective. When we are looking at costs and benefits, we look at it for the health service... There could be a case for going wider. One could take into account the benefits to carers more or time off work or unemployment. The perspective can be very wide. I am agnostic about this whole perspective business, because there are difficulties about how far you will

21 *Ibid*, chapter 4

22 See, for example, Qq 20 and 21

> want to go and when you have a lot of unemployment what is the sense of compensating that in a macro scale. So I am more neutral about the perspective.[23]

29. In the current system, NICE makes its assessment based on the manufacturer's suggested price. As it says in the consultation document:

> NICE does not have a role in relation to the pricing of medicines, though the scrutiny of its appraisal process may encourage drug companies to set prices which satisfy its cost-effectiveness criteria. However, if NICE concludes that a drug may offer some benefits but that these are not sufficient to justify the price at which the drug is available, NICE's only option is to recommend that the NHS restricts its use of that drug. There is no scope for NICE in England, or its parallel bodies in the rest of the UK, to enter into pricing negotiations or to recommend an NHS price.[24]

30. Although this is the theoretical position, the Committee understands that, in practice, discussions take place between the sponsors of a new drug and NICE about the price at which the drug would satisfy cost effectiveness criteria and the Committee agrees with NICE that this flexibility is desirable. Against that background it is even less clear what substantive change is implied by the concept of value-based pricing. Under the proposed system, NICE will no longer make that recommendation. It will still be asked for its expert advice, and it may run a process more or less the same as the one it uses now. The recommendations, and discussions about price with manufacturers, will be the job of Government, that is (it appears) the Department of Health.

31. It is also clear that there will need to be some extension or updating of the current PPRS in order to provide for payment for those drugs already approved for use in the NHS.

> As it would not be feasible to carry out a value-based pricing assessment for each individual branded medicine that is already available, our intention is that branded medicines that are on the market prior to 1 January 2014 would be covered by new arrangements sitting alongside value-based pricing.
>
> For branded medicines already covered by PPRS at the end of 2013, a successor scheme to the PPRS will be required. The details of this will be developed alongside value-based pricing. Following the outcome of this consultation and in line with longstanding practice in this area, the Department of Health will engage with relevant representatives of the pharmaceutical industry on the details of these arrangements.[25]

32. **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**

23 Q 125

24 Consultation document, paragraph 2.8

25 *Ibid*, paragraphs 4.2 and 4.3.

foreseeable future continue to be procured under a variant of the current Pharmaceutical Price Regulation Scheme.

33. **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.**

Cancer Drugs Fund

34. We discussed the operation of the Cancer Drugs Fund during our inquiry. The scheme, introduced in 2011 and due to run till 2014, was designed to help provide access to and funding for cancer drugs which have not been approved by NICE for use in the NHS. Cancer Research UK told us:

> The Cancer Drugs Fund has enabled around 21,000 patients to access treatments they may not have otherwise had and has helped to reduce the perception that cancer patients are not able to access treatments. However, this is a finite amount of money for a limited period. This means that it is especially important that the new value based pricing system offers an authoritative solution to funding clinically- and cost-effective drugs on the NHS. The Cancer Drugs Fund is due to come to an end in 2014 and it is currently unclear what this will mean for drugs that are paid for via this route. It is essential that thought is given to how the removal of the fund will impact upon NICE's work and reputation going forward.[26]

Professor Johnson of Cancer Research UK said that "it has done a great deal of good in terms of patients' access to treatment, but at the moment we don't have the data on what the outcomes and the impact have been on quality and duration of life."[27]

35. Sir Andrew Dillon, Chief Executive of NICE, told the Committee that:

> The effect...of the Cancer Drugs Fund is that it has expanded the amount of money that the NHS has available to fund the exceptional treatment decisions that it makes all the time, both in relation to NICE guidance and circumstances where individual patients present and there is an argument put forward by the attending physician for access to a treatment that is not, on a straight reading of NICE guidance, indicated for that patient, and in other circumstances where, as a result of the local decision making, for some reason, particular treatments are not routinely made available. The Cancer Drugs Fund has expanded that and more patients are likely to have had

26 Ev 61

27 Q 35

> access, through those exceptional treatment decisions, to treatments that either NICE has not actually made a recommendation on, either because we are still in the process of doing it or because it is not something that we have looked at anyway, or where we have made a recommendation but there is a strong case, in the view of the patient and their attending physician, to get access to the drug.[28]

36. Laura Weir, of Patients Involved in NICE, said that:

> In my role as Chair of Patients Involved in NICE I don't just represent the cancer charities but quite a number of conditions. I think the Cancer Drugs Fund was sold to us as something that would help speed up access to cancer medicines and make sure that people were able to access the medicines they needed. I would say that that is applicable across all condition areas... I think there are some lessons there for value-based pricing because, whatever our definition of "value" is, it must fairly and consistently apply across all conditions.[29]

37. Professor Haslam, the incoming Chair of NICE, expressed similar views:

> ...the Cancer Drugs Fund has led to more patients receiving more drugs. We don't know what the outcomes have been and we don't know what the impact of that has been on other sections in the health service...If [the Fund] is going to be reviewed, I would want to look at it across the board...there are other conditions that are as serious as cancer and we should not discriminate against those because they do not have as frightening a name.[30]

38. **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;**
- **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;**
- **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.**

28 Q 130

29 Q 35

30 Evidence taken before the Health Committee on 11 December 2012, HC 831-i, Q 40.

Information about clinical drug trials

39. Another issue that we discussed in the context of health technology appraisals was the availability to NICE of all the relevant information about a drug. It has recently been argued that some pharmaceutical companies keep information about drugs trials out of the public domain and thereby undermine the quality of information available to regulators, clinicians and patients about the efficacy and safety of drugs.[31]

40. When we raised this with Sir Michael Rawlins, he acknowledged that pharmaceutical companies are not legally obliged to publish all the available data about drugs, and that "More importantly, they are not under a legal obligation to publish negative results".[32] He also acknowledged that NICE was not necessarily in a position to examine all the data about a new drug down to the level of individual patient data:

> I am not sure, to be honest, whether we would ever have the resources to do individual patient meta-analyses on every single thing we looked at. It is a big task to do that. What we do want to know is the summary statistics, the summary findings, the details of how the study was done and so on and so forth. For our purposes, looking particularly at the new products, necessarily always requiring individual patient data might be over the top.[33]

41. Sir Andrew Dillon, Chief Executive of NICE, told us that realistically there were few levers that NICE could use to ensure that it had all the information about drug trials that a pharmaceutical company held in its records:

> We don't know what we don't know. We get the medical directors of pharmaceutical companies to sign a statement that indicates, to their knowledge, that they have supplied all the data that is relevant to the appraisal that we are undertaking. Once we have that, it is then very difficult for us to be able to make a judgment that that may not be the case. Clearly, if there is some indication from elsewhere that there is data that the company is not making available, then we already pursue the companies. We pursue it anyway. That is something that we would do as part of the normal course of the appraisal. In the end, if there was something that was absolutely fundamental to a robust and credible set of recommendations being formulated, based on data that was not being released that we had reasonable confidence existed, then we could halt the process until that data was made available and we could make the reason for halting the appraisal public.[34]

42. The issue of transparency of research evidence about drugs goes much wider than just the effects on the NICE appraisal process. Much of what we discussed would be a matter for the MHRA as regulator, as Stephen Whitehead of the ABPI said,[35] and the legal framework is set by European law. In July 2012 the European Commission produced a proposal for a Regulation of the European Parliament and of the Council on Clinical trials

31 See Ben Goldacre, *Bad Pharma,* Fourth Estate, September 2012.

32 Q 103

33 Q 94

34 Q 111

35 Qq 43–44

on medicinal products for human use. The Commission envisages that this will repeal the 2004 Clinical Trials Directive, which set the framework within which present UK regulations on clinical trials are cast. We are pleased to note that our colleagues on the Science and Technology Committee have announced an inquiry which will examine these wider issues.[36]

43. Professor Haslam, in his pre-appointment hearing, summed up the situation succinctly:

> This whole complex issue of unavailable data...is an extraordinarily important area. I find it impossible to come up with a good argument as to why all data should not be released. But at the same time I very much recognise that the pharmaceutical industry has done a huge amount of good. You only have to look at a condition like AIDS to see the remarkable changes there have been for HIV-positive patients in the last few years. Therefore, we mustn't demonise the pharmaceutical industry. But, following this particular discussion about open data, they are in a difficult position, where they have to rebuild trust with professionals and the public. One of the ways of doing that would be to be much more open with their data.[37]

44. This issue also raises questions of professional obligation for those researchers who are members of regulated clinical professions. Sir Andrew Dillon told us that NICE requires the medical directors of pharmaceutical companies to sign a statement certifying that they have provided all information relevant to a particular appraisal. Beyond that, the guidance from the GMC for those doctors involved in drug trials is explicit:

> You must report adverse findings as soon as possible to the affected participants, to those responsible for their medical care, to the research ethics committee, and to the research sponsor or primary funder where relevant. You must make sure that bodies responsible for protecting the public, for example, the Medicines and Healthcare products Regulatory Agency, are informed.[38]

45. **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."**[39]

46. **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**

36 http://www.parliament.uk/business/committees/committees-a-z/commons-select/science-and-technology-committee/news/121213-clinical-trials-inquiry-announced/

37 Evidence taken before the Health Committee on 11 December 2012, HC 831-i, Q8.

38 *Good practice in research*, General Medical Council, April 2010, paragraph 16.

39 Q 41

pharmaceutical companies can take now without waiting for the new Clinical Trials Regulation to be approved.

47. **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.**

48. **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.**

Patient voice

49. It is clearly very important that those who have particular conditions should have their views represented in any discussions within NICE on whether or not to approve drugs designed improve that condition. Laura Weir from Patients Involved in NICE told the Committee that:

> ...there is no clear role for patient groups. We are invited to give oral evidence when NICE are approving a medicine and we are also invited to give a written submission before then. It is not clear whether NICE want us to literally comment on the assumptions going into their model or if they want a case study. Do they want to know how this drug has impacted on someone's life? Do they want us to produce more qualitative or quantitative evidence? It is very unclear where we fit in in the grand scheme of things.[40]

50. Sir Andrew Dillon, Chief Executive of NICE, disagreed with the suggestion that the role was not clear, but accepted that the experience could be improved:

> It is almost certainly the case that the experience of engaging with NICE by individuals who might sit on our advisory bodies, or by organisations that work with us across more than one piece of work, is not necessarily always as good as they would want. That is partly influenced sometimes by the nature of the outcome, but it is also influenced by the challenge of individuals, and indeed organisations sometimes with very substantial resources, engaging with what is, I quite understand, in some circumstances a complex and quite an intimidating process... We talk to the [Patients Involved in NICE] group all the time about ways in which we can improve their engagements, but we are very willing to do more, if we can, within the resources

40 Q 13

that we have available to change our processes where engagement is not clear or is not adequate and to do our best to support individuals when they work with us.[41]

51. NICE clearly does involve patients in its work, but Sir Andrew acknowledged that there is room for improvement. It is an area that needs to be kept under constant review. **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.**

41 Q 123

4 Clinical guidance and quality standards

Clinical guidance

52. Alongside health technology appraisals, NICE's main outputs are its clinical guidelines and, since the passage of the Health and Social Care Act 2012, its quality standards. NICE told us in its memorandum:

> NICE's quality standards are connected into the commissioning and delivery system for health and social care through the various incentive and payment programmes, including the Quality and Outcomes Framework (QOF) for primary care, the Commissioning Outcomes Framework (COF) and the Commissioning for Quality and Innovation (CQUIN) payment framework. They will be used by the NHS Commissioning Board, with whom we have begun to develop a close working relationship, to drive its commissioning processes. Quality standards also provide the opportunity for NICE to support better integration of services, by linking related health, social care and public health standards and by addressing broader topics, such as patient experience and end of life care.[42]

53. On clinical guidance, NICE said:

> NICE's clinical guidelines give advice on the most clinical- and cost-effective approach to the management of individual conditions. Our guidelines, and those produced by other organisations that are accredited by NICE, form the basis of NICE's quality standards, and as such play a vital role in showing commissioners and providers of services what high quality care looks like.[43]

54. There are a number of issues relating to guidance and standards. One is consistency; the clinical guidance represents best practice but it is not universally applied across the country. Should therefore NICE guidance be mandatory? Our evidence suggested not. Professor Smith, for example, suggested that information about the QALY gains of a particular treatment in different circumstances should be provided and a statement "as to what would usually be expected as the criteria for offering treatment".[44] Sir Andrew Dillon told us:

> We don't have the executive power to require the guidance to be applied. [Sir Michael] earlier talked about the particular force around technology appraisals through the NHS Constitution and the funding direction. Everything else that comes out of NICE is guidance. We had to argue the case for doing so with those who need to engineer it into their day-to-day professional and managerial practice. That is what we have been doing through our implementation of services since about 2004. We provide a lot of tools that lay out the clinical and the business case for the adoption of the guidance and we pursue that directly with providers from a national

42 Ev 39

43 *Ibid.*

44 Q 80

> level and through a small field team that we have, who are able to engage directly locally with providers and commissioners.[45]

55. Professor Weale argued that one reason why national best practice guidance often did not translate into implementation at local level was because of the restrictions imposed by budgets:

> It may come back to the question about the distinction between what, in principle, is a cost-effective intervention on the one hand and the fact that the hitherto PCTs are dealing with global budgets. If you are in a situation of having a global budget and find at the margin that you can't afford everything, then something has to go. It is pretty well researched now and we know that one of the things that PCTs do is adapt their referral criteria in order to be able to keep within their budgetary limits.[46]

56. Professor Smith argued that the extent to which guidance should become a requirement rather than remaining purely as guidance depended on the evidence underlying each piece of advice:

> Where the evidence is strong on cost-effectiveness, and where it is very clear which patients would benefit and which would not so that you can also specify clinical thresholds for who should receive treatment, the principle of national solidarity and the certainty in those sorts of situations should lead to a fairly clear mandatory requirement to follow that guidance. At the other extreme, where evidence is very insecure and, also, the capacity to benefit of different patients might be very different depending on things like their level of sickness, age and so on, then you have to start thinking about a more nuanced guidance at the local level, with information given to local providers but not necessarily making it mandatory. Nevertheless, whatever approach you adopt, we believe quite strongly that public reporting of what is done locally—so that variations can be explored, explained and justified—is absolutely central, whatever the degree of [compulsion].[47]

57. **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.**

58. **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.**

59. Relevance of guidance is also very important. Sir Michael Rawlins emphasised the need to keep it up-to-date:

45 Q 146

46 Q 74

47 Q 69

> ...we have to review it, otherwise people will lose confidence in it, quite apart from the fact that it is dated. If they see it has been issued six years ago, doctors or nurses will think, "It can't be up to date." We do have a programme of renewal, revision and re-looking at it on a routine basis.[48]

60. **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.**

Quality standards

61. Sir Andrew explained that quality standards are derived from clinical guidelines and are designed to act as a higher level guidance for commissioners. Professors Smith, Littlejohns and Weale argued that NICE has an important role to play in the new commissioning structures, and that quality standards could be instrumental in helping to provide consistency across the NHS. It would certainly make no sense for Clinical Commissioning Groups to develop their own standards; they should build on these. **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.**

48 Q 151

Conclusions and recommendations

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 (Paragraph 11)

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. (Paragraph 15)

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. (Paragraph 16)

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. (Paragraph 18)

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. (Paragraph 32)

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. (Paragraph 33)

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;
- 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;
- 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. (Paragraph 38)

Information about clinical drug 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." (Paragraph 45)

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. (Paragraph 46)

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. (Paragraph 47)

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. (Paragraph 48)

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. (Paragraph 51)

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. (Paragraph 57)

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. (Paragraph 58)

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. (Paragraph 60)

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. (Paragraph 61)

Formal Minutes

Tuesday 8 January 2013

Members present:

Mr Stephen Dorrell, in the Chair

Rosie Cooper	David Tredinnick
Mr Virendra Sharma	Dr Sarah Wollaston
Chris Skidmore	Valerie Vaz

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

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

Paragraphs 1 to 61 read and agreed to.

Summary agreed to.

Resolved, That the Report be the Eighth Report of the Committee to the House.

Ordered, That the Chair make the Report to the House.

Ordered, That embargoed copies of the Report be made available, in accordance with the provisions of Standing Order No. 134.

Written evidence was ordered to be printed with the Report.

Written evidence was ordered to be reported to the House for publishing on the Internet.

[Adjourned till Tuesday 15 January at 9.30 am

Witnesses

Tuesday 27 November 2012

Tuesday 4 December 2012

List of printed written evidence

List of additional written evidence

(published in Volume II on the Committee's website www.parliament.uk/healthcom)

4	Specialised Healthcare Alliance	Ev w6
5	The Work Foundation	Ev w7
6	Baxter Healthcare	Ev w8
7	Beating Bowel Cancer	Ev w10
8	The Royal College of Midwives	Ev w11
9	British Thoracic Society	Ev w12
10	HEART UK	Ev w13
11	British Society of Gastroenterology	Ev w15
12	Alzheimer's Society	Ev w15
13	Faculty of Pharmaceutical Medicine	Ev w17
14	Merck Serono Ltd	Ev w18
15	British Society for Rheumatology	Ev w19
16	Rare Disease UK	Ev w20
17	National Heart Forum	Ev w22
18	Genzyme Therapeutics	Ev w22
19	Johnson & Johnson	Ev w23
20	Ethical Medicines Industry Group	Ev w26
21	UK Council for Psychotherapy	Ev w30
22	Deltex Medical	Ev w33
23	Association for Family Therapy and Systemic Practice	Ev w37
24	British Heart Foundation and the British Cardiovascular Society	Ev w40
25	Bayer HealthCare	Ev w41
26	The Hepatitis C Trust	Ev w44
27	European Medicines Group	Ev w45
28	The Karen Clifford Skin Cancer Charity	Ev w48
29	AstraZeneca	Ev w49
30	BioIndustry Association	Ev w50
31	MS Society	Ev w51
32	Bristol-Myers Squibb Pharmaceuticals Limited	Ev w55
33	British Association for Counselling and Psychotherapy	Ev w58
34	British Association for Behavioural & Cognitive Psychotherapies	Ev w60
35	Novo Nordisk	Ev w61
36	Roche Diagnostics Limited	Ev w63
37	Association of British Healthcare Industries	Ev w66
38	Royal National Institute of Blind People	Ev w68
39	Cystic Fibrosis Trust	Ev w70
40	National Infertility Awareness Campaign	Ev w72
41	Arthritis and Musculoskeletal Alliance	Ev w73
42	Medtronic Ltd	Ev w74
43	Rarer Cancers Foundation	Ev w76
44	Prostate Cancer UK	Ev w80
45	Astellas Pharma Ltd	Ev w81
46	Shire plc	Ev w84
47	British Intro Diagnostics Association	Ev w88
48	GlaxoSmithKline	Ev w89

List of Reports from the Committee during the current Parliament

The reference number of the Government's response to each Report is printed in brackets after the HC printing number.

Session 2012–13

First Report	Education, training and workforce planning	HC 6-I
Second Report	PIP breast implants: web forum on patient experiences	HC 435
Third Report	Government's Alcohol Strategy	HC 132
Fourth Report	2012 accountability hearing with the General Medical Council	HC 566
Fifth Report	Appointment of the Chair of the Care Quality Commission	HC 807
Sixth Report	Appointment of the Chair of the National Institute for Health and Care Excellence	HC 831
Seventh Report	2012 accountability hearing with the Care Quality Commission	HC 592
Eighth Report	National Institute for Health and Clinical Excellence	HC 782

Session 2010–12

First Report	Appointment of the Chair of the Care Quality Commission	HC 461-I
Second Report	Public Expenditure	HC 512 (Cm 8007)
Third Report	Commissioning	HC 513 (Cm 8009)
Fourth Report	Revalidation of Doctors	HC 557 (Cm 8028)
Fifth Report	Commissioning: further issues	HC 796 (Cm 8100)
First Special Report	Revalidation of Doctors: General Medical Council's Response to the Committee's Fourth Report of Session 2010–11	HC 1033
Sixth Report	Complaints and Litigation	HC 786 (Cm 8180)
Seventh Report	Annual accountability hearing with the Nursing and Midwifery Council	HC 1428 (HC 1699)
Eighth Report	Annual accountability hearing with the General Medical Council	HC 1429 (HC 1699)
Ninth Report	Annual accountability hearing with the Care Quality Commission	HC 1430 (HC 1699)
Tenth Report	Annual accountability hearing with Monitor	HC 1431 (HC 1699)
Eleventh Report	Appointment of the Chair of the NHS Commissioning Board	HC 1562-I
Twelfth Report	Public Health	HC 1048-I (Cm 8290)
Thirteenth Report	Public Expenditure	HC 1499 (Cm 8283)
Fourteenth Report	Social Care	HC 1583-I (Cm 8380)
Fifteenth Report	Annual accountability hearings: responses and further issues	HC 1699
Sixteenth Report	PIP Breast implants and regulation of cosmetic interventions	HC 1816 (Cm 8351)