HOUSE OF COMMONS

Health Committee

Oral evidence: Work of NICE, HC 612

Tuesday 2 September 2014

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Watch the meeting

Members present: Dr Sarah Wollaston (Chair), Rosie Cooper, Andrew George, Robert Jenrick,
Barbara Keeley, Mr Virendra Sharma, David Tredinnick, Valerie Vaz

Questions 1-89

Witnesses: **Professor David Haslam**, Chair, and **Sir Andrew Dillon**, Chief Executive, NICE, gave evidence.

Q1 Chair: Professor David Haslam and Sir Andrew Dillon, thank you very much for coming. Perhaps you would start by introducing yourselves to the Committee and those following this.

Professor Haslam: My name is Professor David Haslam. I am chair of the National Institute for Health and Care Excellence. I have been chair since April last year.

Sir Andrew Dillon: I am Andrew Dillon, chief executive of NICE. I have been chief executive since 1999.

Q2 Chair: Perhaps we can start by looking at value-based assessments. To open this, could you explain to those following the debate where we are now with value-based assessments, because there seems to be some ongoing uncertainty?

Professor Haslam: Where we are at the moment is that we have had a very considerable consultation, receiving a lot of comments from members of the public, patients, patient organisations, industry, health care professionals and so on. The consultation ended in June. The results of that are currently being finalised, and we have a meeting in Kendal on 17 September when the board will be looking at this. That is the brief detail of where we have got to.

Q3 Chair: How soon after 17 September are we likely to see your conclusions?

Professor Haslam: It is a public board meeting. Prior to the meeting, the papers will be published. I cannot predict what the board discussion will be and where it will go, but it is all in the public domain. We hold these meetings in public.

Q4 Chair: How closely are you liaising with the Department of Health about what happens next?

Professor Haslam: Very closely indeed. Andrew has regular contacts with them.

Sir Andrew Dillon: We have certainly kept in touch with them. They know what the consultation proposals are. The Department of Health have acted like any other stakeholder and submitted their own comments. They have not attempted to influence the outcome in any way other than put to us their reasoned arguments on our proposals. Those proposals go into the paper that the board is going to receive on 17 September, weighed in the balance with all the other comments that we have had. The response to consultation has been good, with a wide range of views being expressed on all the proposals we put forward. It has been an interesting analysis for us as we have looked at those comments.

Q5 Barbara Keeley: The NICE consultation paper on value-based assessment sets out two new value elements that will be available to appraisal committees considering a new medicine: burden of illness and wider societal impact. I am sure you have had lots of comments back on both of those. There was controversy some months ago because the Government were apparently considering proposals to take into account the benefits that successful treatments could have for the economy, such as the value of people going back to work. That seemed to have an element of taking into account age, so the wider societal impact at 30 would be different from what it would be at 70. Could you comment on that, and explain what methodology will be used to incorporate those two elements into the technology appraisal?

Professor Haslam: As to the impact on age, you are absolutely right. The more the board and senior team in NICE looked at this, the more apparent it became that there were problems related to age. While you can absolutely understand the benefits for UK plc of getting people back to work and the benefits to the Exchequer of getting people well, earning and paying taxes, the more you begin to unpick the impact of that, the more you realise that, potentially, if you follow it to its logical conclusion, you discriminate against people of retirement age. Sadly, you discriminate against women. Tragically, on average women still earn less than men. The board probably spends more time discussing ethical issues than these complex financial issues. The more we looked at the ethics—almost the morality—of it, the clearer it became that we could not go down a route that discriminated on grounds of age or risk any gender discrimination either. That seemed to be really important to us.

As to the methodologies we used for these two, both relate to the quality-adjusted life year. We had different methodologies. For the wider societal impact, technically, the way we did it was to subtract the total QALYs expected as a consequence of having a condition from the QALYs expected for someone who did not have the condition, so you could do a measurement like that. As for the burden of illness, the proposal was to work in a different way. The maths of this gets quite complicated. We took the QALYs for the condition as

compared with the QALYs people would expect to have over the rest of their lives without the condition. It came up with a slightly different way of measuring it. The main point of this was to try to move away from the risk of age discrimination.

Q6 Barbara Keeley: Do you have anything to add?

Sir Andrew Dillon: Maybe in slightly different terms, in both cases we were trying to estimate the burden of illness. What do you carry as a burden if you get a disease compared with the burden you would carry if you were proceeding through life without that disease? For wider societal benefit, as David said, we were concerned with one of the methodologies we looked at, which resulted from some research that the Department of Health commissioned, as that seemed to place particular emphasis on the contribution you make through productive employment. That is fine and important, and as an economic technique it is entirely valid, but we felt that applying the outcome of that to our appraisals might expose us to the risk that our advisory committees would need to bias their recommendations in some circumstances in favour of people of working age, and we wanted to try to avoid that. Once again, we wanted to look at something that was broader. Looking at the extent to which having a disease compromised your ability to contribute to society, we wanted to see whether or not we could use that as an indication of the potential impact of wider societal benefit. It is simply a different approach, but both are very difficult to quantify and guard against, particularly in relation to the question of whether any approach you take happens to promote the interests of people at the beginning of their lives and disadvantages those at the end of life, or vice versa. It was quite difficult for us to puzzle through an approach that seemed to minimise the risk of that happening. Even in doing that, it was clear that the risk existed. Therefore, in the document, as you have probably seen, we wanted to make absolutely clear that our advisory committees were given the ability, in circumstances where they felt it was likely that a push to bias unreasonably a group of a particular age had the potential to influence their decision unreasonably, to adjust for that.

Q7 Barbara Keeley: As a supplementary point in terms of the burden of illness, do you take carers into account? The burden of illness is obviously on the person involved and there is a question about the economic impact of that, but there is a definite economic impact if the carer cannot work. Is that taken into account? The benefit could be that, given a certain drug, people would not need so much input from family carers. Where there is illness, there is a point at which family carers have to give up work, and that has a definite impact on the Exchequer that we do not always think through.

Sir Andrew Dillon: This is something NICE have already done. When we looked for the first time at particular treatments for Alzheimer's disease, we were encouraged to take that into account. That was some years ago now. Even under the methodologies we have in place at the moment, we have the flexibility to take into account both the potential benefit of treatments to patients and the indirect benefits to carers.

Q8 Valerie Vaz: I am still not clear whether what you are saying is that the value of a QALY is different under the burden of illness than the wider societal impact. Is it right that you have two different values for a QALY?

Sir Andrew Dillon: Probably the easiest way of explaining it is that we make assumptions, as we have done since we started, about the reasonable opportunity costs for the NHS to bear of a new treatment coming in. We have a fixed amount of money. If we buy something new, we are not going to spend the money on anything else, so we are going to lose the opportunity to deliver some health gain that we could otherwise have done. The general approach we take is to make sure that the amount of health gain we are going to obtain from a new treatment is at least equivalent to the amount of health gain we displace. Using QALYs, that translates to about £20,000 per quality-adjusted life year. At that incremental cost-effectiveness ratio, we can be more or less confident that we are not displacing more than we are gaining.

As the cost per QALY goes up, the risk is that we are displacing more than we are gaining, so we need to be confident that the reasons for doing that are consistent with the ambition of the NHS to deliver the best care it can. We need to be consistent and objective in the circumstances in which we would accept a higher cost per QALY. As you can see, in the document is a series of what are described as modifiers. Those modifiers are factors we take into account which, if satisfied either individually or together in some combination, would justify accepting a higher cost per quality adjusted life year.

Q9 Valerie Vaz: I take it from the response that the answer is that there is a different value for each QALY under the burden of illness and the wider societal impact. Is that right? The phrase I keep hearing and reading among the journals is that a QALY is a QALY. That does not apply to this new system.

Sir Andrew Dillon: It is a weight for the QALY in circumstances where the particular features of the condition or intervention justify it. What we are doing in the paper is to make clear what we have been doing for 15 years in practice in making those adjustments, and how we think those adjustments might be applied in circumstances where we are taking into account the burden of illness explicitly and wider societal benefit.

Q10 Valerie Vaz: Turning to your previous answer about age, surely when you are assessing the wider societal impact, that will include age, so whether or not you like it, you are going to be discriminating against people who are older and have lesser value in terms of their impact in society.

Sir Andrew Dillon: The reality is that if you are 20, there are diseases and conditions that, left untreated, mean you might expect perhaps just a few years of extra life. If there is an intervention that has the ability to restore a normal anticipated life, there are decades of opportunity to make a contribution to society. If you are 60, as I am, or 70 or 80, in terms of your capacity to benefit in total, you just have less to run. The problem is that, once you start to measure it, you cannot avoid recognising the impact of the point at which you are in your life, and lots of other things too, about what you do. This was the concern we had about the methodology that the Department of Health researched. It was very specifically taking into account factors relevant to particular age groups. It does not matter which way you do it. Once you choose to measure, as we have been asked to do, there is no way out

of the fact that you have to exercise some judgment which is almost certainly influenced by age, but the point we made in the document is that it is just one modifier in a whole sequence of modifiers. It is not going to make the difference between being able to say yes or no. We said to our advisory committees very specifically, assuming the methodology is introduced in this form, that we would not expect them to allow that single modifier to make the difference between saying yes or no, so we could stay the right side of what is morally and legally the right thing to do.

Q11 Valerie Vaz: Can I turn to the consultation paper and the current and new flexible decision-making approach? These new assessments are coming in. Although it looks like a hierarchy, I am assuming it is not. You are not giving more weight to burden of illness, or—

Sir Andrew Dillon: No.

Q12 Valerie Vaz: Has it been spelt out in the consultation that it is all of equal weight?

Sir Andrew Dillon: We hope so. We certainly asked the question what share of the multiplier of 2.5, which you can see is proposed in the document, each of those modifiers should have, so we made no assumption about it.

Q13 Valerie Vaz: So they are all of equal weight.

Sir Andrew Dillon: They could all be equal. That was the question we asked. We had a series of responses to that, which we are looking at as part of the consultation review.

Q14 Valerie Vaz: Have you done an assessment on displaced services? Obviously you will get a new technology and you will do an assessment on that; what about an assessment on the displaced services?

Sir Andrew Dillon: This is an important point, and it is one focused on particularly by the group of economists who responded to us and also published on this as well. They are very concerned, as they have been for some time, about the methodology that NICE have used to assess new drugs. It is not new and is not triggered particularly by these proposals. They have always been concerned about the point I mentioned earlier relating to the £20,000 per QALY. Some of those economists believe it should be a much lower number than that, but, at whatever level you set it, if you go above it, you are risking displacing more than you are gaining. They are concerned that even our current methodology, let alone the proposed revised one, does not adequately take into account the impact of introducing something new into the system at a higher cost per QALY.

It is an important point, but it illustrates the difference between what NICE do and what economists do, with enormous respect, because we use them frequently and extensively to support us in our methodology and in the individual topics that we look at. They quite properly are guardians of the methodology we use; we are the users and appliers of that in the difficult world of decision making for the NHS. The advisory committees that NICE

set up have a methodology, but they also have discretion to do what they believe is the right thing: the right balance between the interests of a particular group of patients in the case of a drug that might benefit and the broader group of patients in the NHS for whom there will be consequences with any decision to do anything new.

Professor Haslam: Judgment is extraordinarily important. If it is simply a matter of doing the sums and you come out with a figure to a number of decimal points, and that is a yes and that is a no, you could replace NICE with a computer. The important thing NICE brings is the ability to make a judgment and take into account these various complex issues, but to do it in a way that is also legally robust, which is an interesting tightrope to walk across.

Q15 Valerie Vaz: You have expanded your limit from £20,000 to £30,000 in the first instance to £50,000 when the rest of the NHS is being squeezed. Could you expand on that?

Sir Andrew Dillon: The range of £20,000 to £30,000 has been part of NICE's methodology for a considerable time. The totality of our methodology is consulted on every three years. Every three years, we go out and ask anybody who is interested whether we have got it right or whether we should change it. It is not something we make up ourselves and adjust as we see fit. The latest consultation is not the total methodology; it is simply a couple of important components to it.

At the moment, NICE allow their appraisal committees to support the use of a new drug up to about £50,000 per QALY in circumstances that are limited to what is described as the end-of-life treatments protocol. There are very specific circumstances for new drugs that are designed to extend life at the end of life. That has been applied frequently, particularly to new cancer treatments, and it works in some cases and not in others, or the criteria are satisfied in some cases and not in others. That allows us to support treatments at a higher cost per QALY.

Although the end-of-life treatments protocol has specific criteria that are particularly relevant to cancer treatments, before that protocol came in, the advisory committees were from time to time supporting the use of treatments at higher cost per QALY. For example, Glivec, or Imatinib, to treat chronic myeloid leukaemia, was supported at a cost per QALY above £40,000. This comes back to the difference between the rigid application of an economic methodology and the business of making a decision on behalf of the NHS. This is where the advisory committees are using their discretion to support the use of a treatment at a higher cost per QALY when all the modifiers, or those that are relevant to it, apply. The proposal we were putting out in value-based assessment was in effect to regularise that and to make it explicit in the methodology. The committees have had the ability to do it in the past and have done it, but in what circumstances we would expect them to do that is not explicit in the methodology. This enables us to be more specific and extend that ability, or quantify the circumstances in which it is appropriate for the committees to go above £20,000 and £30,000 per QALY.

Q16 Robert Jenrick: Assuming this is approved by the board, when do you intend to have the first assessments made?

Sir Andrew Dillon: This depends very much on the outcome of the board decision. It is pretty clear from the work we have done on the consultation comments so far that there is a wide range of views on each of the recommendations NICE have put out. It probably will not come as a great surprise that there is not a single recommendation we have made where everybody has come out and said this is the right thing to do. It does illustrate the complexity of the issues we are dealing with. They are really difficult, and that was why we had to take our time to formulate the proposals themselves. The fact that there is a diversity of views is not at all a surprise to us. We have to think very carefully about the proposition to put to the board in September. If the board want to proceed with one or more of the recommendations and they do not require any further work and do not feel the need to say, "People have supported it, but we need to clarify these issues," in those circumstances, we need to go back and think about it and deal with the issues raised before we do anything, but we could move quite quickly.

Q17 Robert Jenrick: What does that mean? Bearing in mind you anticipated bringing this in in January this year, do you have a sense of when you would be using this?

Sir Andrew Dillon: If any of the individual proposals were supported and there was no further work required on them, they could be implemented straight away.

Professor Haslam: It is not just that everybody disagrees in the same direction; there is no consistency at all in the responses we have, so working our way through that is going to be an interesting challenge for the board.

Q18 David Tredinnick: Sir Andrew, do you feel you have done enough to make value assessments of well established existing treatments, such as acupuncture? NICE have now agreed that acupuncture can be used for lower back pain, but that is widely at variance with its use in China, where, for example, it is used for many other different ailments. I have myself been treated successfully by the use of acupuncture for a number of other things, including carpel tunnel syndrome. Do you not think you should make more effort to look at treatments that have been out there, in this case for over 2,000 years?

Sir Andrew Dillon: There are a number of ways in which we assemble the topics we look at. In most cases, we agree with the Department of Health—now with NHS England, as the main commissioner—what it is we look at. For example, we have a library of clinical guideline topics that we think tackle the principal causes of morbidity and preventable mortality that the NHS deal with on a day-to-day basis. Once we have got that topic we scope it out—in other words, we identify the key questions, particularly those that relate to uncertainty among health practitioners who are working in those areas. We try to identify new interventions and variations in the use of existing interventions. Once we have assembled that, we can do the research necessary to produce the guidelines. If, as part of that process, we identify treatments beyond what might be described as conventional western medicine, we have the opportunity to take them into account, but they need to be supported by the evidence. We have been able to support the use of acupuncture and herbal medicine in certain circumstances.

Professor Haslam: I have always been clear about this. It all comes down to the evidence. I do not think there is a discrimination between complementary and conventional medicine. If there is evidence, it is medicine.

Q19 David Tredinnick: Absolutely. The chief medical officer has herself written a book called "The Drugs Don't Work" and has expressed huge concerns about the failure of antibiotics, but acupuncture and herbal medicine can help where antibiotics help. Given the publication of that book and the panic we now have about antibiotic failure, surely there is a greater requirement to look at what is already around the landscape. I raise just one other point. Homeopathic medicine is used widely across the world. In France, about 80% of pregnant women use it; it is available in all chemists, but here there is a vociferous anti campaign, which I think has had too much influence over people like yourselves in authority. Don't you think that, if it is claimed there is not enough evidence, it behoves you to go out and try to find out why people are increasingly using this form of medicine and see what can be done to make an effective substitute?

Professor Haslam: We deal with the evidence that is there; we are not the research organisation that produces the evidence. If the evidence is presented to us, why would we wish to be prejudiced against something that is demonstrated to work? What we require is that evidence, but we are not the organisation that generates such evidence.

Q20 Andrew George: On the understandable concerns you have about the risk of going down the route of ageism and making ethical judgments, one assumes you would not, for example, sanction—even if it was clinically possible—a heart and lung transplant in a 97-year-old, but surely, rather than perhaps hiding behind a translucent formula or methodology, would it not be better to indicate through some examples what is simply unjustifiable, particularly in the older ages, as it were, from the point of view of both the hard edge of public resource but also the value to that person?

Sir Andrew Dillon: If you look at the catalogue of guidance that NICE have produced through the years, that is what we have done. It is a whole case series of advice to the NHS about how to maintain the tricky balance between limited resources and the inevitably unlimited ambition all of us have for what we would expect the NHS to give us, and take account of the moral and legislative framework that governs our expectations as users of the NHS about how its resources should be used.

In the consultation document, we have tried really hard to identify an approach to this that limits the potential, first, for anybody to think that there would be any systematic bias on age in NICE's appraisals, or any other aspects of their work, and, secondly, through the methodology we have suggested, to make it as difficult as possible for that to happen unwittingly. As I said earlier, as a failsafe mechanism we say publicly and very clearly that we would not allow it to happen, because we would work with our advisory committees to make sure they were alert to it and would themselves correct for it, and, even if they had not, in the quality assurance process NICE operate, before anything is published anything like that would be picked up. In the end, although those are important checks and balances, it could not get through anyway, because the public exposure that NICE gets before it gets anywhere near the NHS as formal advice would simply trigger

too much in the way of a response for us not to be aware of the potential for that happening.

Q21 Robert Jenrick: I want to turn briefly to the cancer drugs fund, which we have heard is set to continue until at least 2016. The nature of that fund has always seemed to be slightly at odds with NICE, perhaps even undermining your process. Can you explain how you see your future role with the cancer drugs fund under value-based assessment?

Sir Andrew Dillon: It is interesting that you make the connection between the two things. I might come back to that in a moment. I do not think it undermines NICE. The work we have done on cancer treatments and the forensic examination our advisory committees give to the evidence for their use in the NHS is an important resource for those who are responsible for managing the cancer drugs fund. What it has done is illustrate the difference with the standard assumption we make, which we were discussing earlier, as expressed through the cost-effectiveness threshold of around £20,000 to £30,000, even adjusted up to £50,000 on the basis of the end of life treatments protocol, between the ambition of the NHS to use cancer treatments and their willingness to pay as expressed through the cancer drugs fund.

NICE have no opinion at all on the decisions that the NHS or the Government more broadly make about how to prioritise NHS resources. Our job is to support those priorities and decisions. That was what we were set up to do. We give advice independently, but always aligned to the ambition that the service has for treating any particular disease or condition. The problem that can arise for NICE is that there is now a misalignment between the standard approach we take to our ambition and willingness to pay and, in effect, the ambition and willingness to pay as expressed through the cancer drugs fund.

The announcement last week that the Government want us to join NHS England, patient organisations and industry groups in looking long term at a new way of managing the entry of new cancer treatments into the NHS is really exciting for us. We think there are lots of interesting opportunities for an approach that will do a number of things, first and most importantly to make sure that the treatments we all feel should be available are available to patients, and, secondly, rather parochially from our point of view, that we realign the approach we are taking to looking at cancer treatments with whatever ambition the NHS ultimately turn out to have for it.

Q22 Robert Jenrick: The benefit of the cancer drugs fund has been widely publicised, and perhaps 20,000 patients receive drugs they might not otherwise have done. The concern of taxpayers is the lack of evidence about how we are measuring the success of the fund. Have you received any information from the Department of Health that evaluates the effectiveness of the cancer drugs fund in patient outcomes?

Sir Andrew Dillon: We have not been involved in the organisation of the fund and we do not have access to data that might be being collected by the Department of Health or NHS England, so the answer to that is no. Unconnected with the cancer drugs fund, we do know, because of the data collection arrangements now in place for information about the treatment and outcomes for patients receiving chemotherapy, which is a wonderful system for gathering information from that particular group of patients, that there is a great

opportunity to use that data to feed back information about the impact of decisions that are taken. Whether they are recommendations by NICE or through the cancer drugs fund, or recommendations by NHS England separately, we have a real opportunity to study the impact in routine clinical practice of new cancer treatments and bring that information back at a suitable point in the future and look again at the value for money of these treatments as they are being introduced. That is what I mean by a great opportunity for looking at a different and more integrated way of managing new treatments in the service.

Q23 Chair: Do you feel that in the long term it would be better to merge the cancer drugs fund with what you are doing in NICE, and also acknowledge a criticism often made that cancer is not the only very difficult, painful or distressing condition out there? Does that penalise those who suffer from other conditions that could be in a position to benefit from that funding?

Sir Andrew Dillon: It is inevitable that if you choose to spend money on one thing you cannot spend it on something else. If you allocate proportionately more money to one disease or condition, inevitably all other diseases and conditions are getting less. The NHS have always done this. From time to time, they have decided that they are doing less well than they should in one area and that is a priority, so they will allocate resources. They have done that for ever at national level, and it happens locally. In principle, that is fine; that decision can be taken, but once we have made the decision that we are going to allocate resources at a particular level and it has an impact, as the cancer drugs fund has had, on the judgment about willingness to pay and the threshold of acceptability for cost-effectiveness, all we are looking for at NICE is that we are part of that and that the way we operate is aligned with that.

Q24 Robert Jenrick: What do you mean by that? Do you mean that you might see the same criteria applying to the cancer drugs fund being applied elsewhere through NICE?

Sir Andrew Dillon: What I mean is that we would like to move away from a situation in which we apply our current threshold, as amended by the end-of-life treatments protocol, to say yes to some treatments and we cannot support routine use of other treatments. In most cases, the cancer drugs fund has then said yes to treatments that we have said no to. I do not think that makes any sense. It is not a criticism of the decision to allocate more money to cancer; that is a different issue altogether. It is about an alignment of processes and methodologies that we need to get sorted out, and the announcement last week provides us with the opportunity to do that.

Q25 Chair: In other words, you would like to see the cancer drugs fund brought in under NICE and for the political decision that money needs to go towards cancer treatment to be made by NICE.

Sir Andrew Dillon: Yes. There is no reason why we could not provide the basis for NHS England's decisions on cancer treatments, just as we do for all the other treatments that we look at for which they are the direct commissioner.

Professor Haslam: That is exactly what I was going to say. Long term, you are absolutely right. The aspiration is that there would be no need for these different methodologies and we could bring them together. I am optimistic that we will get there and we can work with the cancer drugs fund, NHS England and the DH to bring this together.

Q26 David Tredinnick: I want to ask you about some specific decisions you have made. Recently, you were much in the media with your decision not to approve Kadcyla as a treatment. Could you elaborate on your decision-making process?

Sir Andrew Dillon: Kadcyla is a treatment manufactured by Roche Pharmaceuticals for treating metastatic breast cancer. The simple reason for our inability to support it for routine use is its cost per quality-adjusted life year, which was in the region of £160,000. As we were discussing earlier on, even the extended range goes up only to £50,000. It was well beyond the advisory committees' ability to apply flexibility.

Q27 David Tredinnick: I have a slightly lower figure here. The company has produced the drug, it is effective and it has been knocked out of the frame on the ground of cost, which has been proved to be over double the parameters within which you work. Did you feel that the company could have helped themselves a bit more on this?

Sir Andrew Dillon: It is always in the gift of the company to make a proposal, generically described as a patient access scheme, which has the effect of discounting or reducing the price of the drug to the NHS. In this case, Roche did do that. On the basis of an agreement between the Government and the pharmaceutical industry, these discounts are confidential and so I cannot reveal it, but it did not make any significant progress towards enabling us to support the use of the drug.

Q28 David Tredinnick: Do you think that, looking at the drugs landscape, the costs are increasing, staying the same, or decreasing generally? This is a huge sum of money for a particular treatment. Is this representative of challenges that you are facing across the board?

Sir Andrew Dillon: I think Kadcyla is an outlier for the broad group of cancer treatments we are looking at. There are drugs that are very expensive but they are designed for very small groups of patients. Kadcyla is a particularly expensive treatment for that kind of patient population. Its headline list price, which is different from its quality adjusted life year, was about £90,000 per patient per year. It is certainly the case that the cancer treatments we have looked at recently are generally more expensive than treatments for other diseases and conditions. I guess this is a function of the companies' assessment of health systems' willingness to pay for drugs to treat cancer, but I do not think you can say it is a general trend that applies to all drug treatments.

Chair: We will move on to another area of controversy, and that is statins.

Q29 Robert Jenrick: Statins raise a concern about conflict of interest that has broader application than just statins. NICE's decision to issue revised guidance on statins in the prevention of CVD met with some concern, which you will be aware of. A number of

quite senior clinicians, including Sir Richard Thompson, president of the Royal College of Physicians, wrote to NICE and the Health Secretary raising issues about the way in which the decision was made. The issue that emerged from that was whether those involved in making the decision had wider conflicts of interest, such as involvement with pharmaceutical companies and so on. The issues in the media are whether the general public can have confidence that every decision made by NICE is 100% independent; what steps you are taking to ensure members on the panels are recruited for their independence; and how you are communicating that to the general public to raise confidence.

Professor Haslam: It is an extremely good and important question. You are right. I did receive a letter from a number of clinicians, including Sir Richard Thompson. I have to say that we were slightly surprised to receive this from Sir Richard Thompson, because the work that had been done on statins was housed in a collaborating centre in the Royal College of Physicians. Indeed, we had already had a full consultation response from that college which was broadly supportive of the work we had done. It gave us some very good suggestions and detailed amendments that we could make. The same applied to the Royal College of General Practitioners. Dr Clare Gerada was a signatory as well. The Royal College of GPs had written to us in a very supportive way, so the letter was a bit of a surprise from those two contributors. I went to see Sir Richard Thompson who stressed to me that he was writing in a personal capacity and not as president of the royal college. He has subsequently written to all fellows of the royal college to stress that is the case. The matter of conflicts of interest is hugely important to us.

So that's specific around the issue there there. The matter of conflicts of interest is hugely important to us, and—

Q30 Robert Jenrick: To go back to statins, many people do care about that. How can NICE assure people who are concerned about this that no members of the panel had any conflict of interest?

Professor Haslam: I was going to explain just how important conflicts of interest are to us, because, if we are not trusted, we might as well go home. It is as simple as that. We take it extremely seriously. Since the formation of NICE, we have had very tough conflict of interest policies. The board have been going through these recently in detail. We make it absolutely clear, for instance, that anyone who directly and personally receives finance from a pharmaceutical company would be excluded from this work. If you want me to, I can go through the full list of exclusions, but we are really tough on this.

There is a real difficulty here though, because university departments that do research into all manner of drugs will receive funding from the pharmaceutical industry; indeed, if they did not, the work would not be done, the drugs would not be developed and mankind would be worse off. I think there is a fundamental difference between a university department receiving funding to support research and an individual being paid by a company to be a spokesman for that company. Anyone who was a spokesman and received individual financial gain from working with a pharmaceutical company would be excluded from being part of our guidelines committees. We are really tough on this.

Your final question was about how we make this clear. On our website, we have made it as clear as we can how important we regard this. I take the opportunity in every lecture and presentation I give to talk about this issue. When we are recruiting to all our committees and

so on, we make really clear the very tough conflicts policy that we hold. If we were to exclude everybody who had ever been near a university department that had ever received money from any pharmaceutical company, I do not know who we would recruit. There would not be any senior clinicians out there to recruit. If you want someone who is expert in, and has worked on, statins, the chances are that at some stage that work will have received funding from a company that developed statins. That is fundamentally different from having a personal financial conflict.

Q31 Robert Jenrick: Can I ask a related question about the data that pharmaceutical companies supply to you, which are not placed in the public domain? Campaigners have suggested that that adds to the secrecy behind decisions. You cannot see what the pharmaceutical companies are supplying to you and whether those data are accurate or could be contested by other bodies. Clearly, there are important commercial imperatives for the pharmaceutical companies, but is it appropriate that the data remain 100% confidential?

Professor Haslam: We were early signatories to the AllTrials.net campaign. We ask for a signature from the UK medical directors of pharmaceutical companies that we have all the data relevant to the drug we are considering. Again, it is an area that we take extremely seriously.

Q32 Robert Jenrick: You would not encourage the pharmaceutical companies to publish any of the data so more light is shone on your decision making.

Professor Haslam: My personal view is that I can see no reason whatsoever not to publish. I think there is a moral imperative from the point of view of the patients who have been part of the trials that their time and effort should not be ignored. I have always felt very strongly that everything should be in the public domain.

Q33 Chair: Do you not think that NICE could be a bit more muscular in their approach here? You allow the data to be evaluated by the Oxford Cholesterol Treatment Trialists' Collaboration, but there are calls to have other trusted bodies, such as Cochrane and so forth, to examine those data as well. Some concerns have been expressed about CTT's links with industry. You are in an extraordinarily powerful position to be recommending these treatments which, after all, will potentially medicalise millions more people. Given such a major step, do you not think you have a role to be more muscular in insisting that you have all the data, or that all the data are shared with other bodies as well?

Professor Haslam: I absolutely believe that all the data should be in the public domain, and I take your point. In terms of the medicalisation agenda, NICE made it clear that we are not saying we want millions more people taking statins. Fundamentally, we have said in the advice that it is really important that for patients who are at risk—we look at lifestyle issues such as weight, alcohol, smoking and exercise—we address all those issues, but, if it was felt by the patient and their doctor that statins were the right way forward, very straightforwardly, because the price of statins plummeted, the point at which they became cost-effective was significantly lower. There was a larger group of people for whom they might be cost-effective. In terms of medicalisation, the last thing I want to do is medicalise the British public.

Q34 Chair: You are just saying it is possible for them to prescribe it. You are not saying they should prescribe it.

Professor Haslam: Absolutely.

Q35 Chair: That is a very important difference. You are saying that it is available to them to prescribe, but you are not saying it should be standard medical practice, because the concern among some doctors is that they are going to feel under pressure to prescribe it or face the consequences.

Professor Haslam: You and I have both practised as general practitioners and know that the way forward is to explore with the patient their ideas, concerns and expectations about what they want, and what is appropriate for them. Some people will run a mile from taking statins; others will say, "Yes, please."

Q36 Chair: But the difference with NICE is that, if there is a perception they are saying that this is what they should be prescribing, you are quite clear today that you are not saying that. You are saying it should be available should that be deemed appropriate as part of the discussion about lifestyle and other measures and risks.

Professor Haslam: It is part of the menu. Because one third of deaths are from cardiovascular disease, despite the tremendous success in reducing coronary events, strokes and so on, there is still a huge number of people whose lives are turned upside down by this, and we owe it to them to present the information as to what can be done.

Q37 Chair: It is part of the menu, not a directive that it should be given.

Professor Haslam: Absolutely.

Q38 Chair: Thank you for clarifying that. Coming on to another aspect of statins, which is around the prevalence of side effects, section 4 of the letter referred to previously deals with industry bias—this comes back to the point Robert raised. It states: "Furthermore, industry sponsored trials include pre-randomisation run-in periods where those who fail to tolerate statins are excluded. RCT patients may therefore not represent the population that will actually take the drugs in the real world." That is a very important point. How would you respond to that? In other words, are you underestimating what would happen in the population to which you refer?

Professor Haslam: We can use only the evidence and data that we have; we cannot postulate about data that might be out there. There are widely differing prevalencies of side effects attributed to statins.

Q39 Chair: That is one of the controversies they raise.

Professor Haslam: I must say that most mornings when I wake up aching, I think that if I were taking statins, I would stop them now, but I am not. I am making a serious point.

Q40 Chair: But there is a serious point about the different levels in the various trials. There is a remarkable similarity between the placebo and the active treatment group in each of those and why those different levels occur in the different trials. If you have a run-in period where people are excluded if they have side effects, the people who have side effects are taken out, so are you underestimating the prevalence of side effects? I think that was an important point.

Professor Haslam: We do not want to ignore data that might help patients to know who should and should not take statins. To be very clear about that, we are not looking at selective data and ignoring other data.

Q41 Chair: But is that not what they are saying here? You are looking at selective data if people who have side effects are excluded. This is the point raised in point 4 of their letter to you about industry bias.

Professor Haslam: Let me just turn to that one.

Q42 Chair: There is reference to the true levels of adverse events, if the trials included mostly a pre-randomisation run-in where people who did not tolerate statins were excluded.

Professor Haslam: It would be extremely helpful, but we do not have those trials. We can look only at the data we have. I am not aware that the committee chose to look at one set of data and exclude other data.

Q43 Chair: But would you accept their criticism of the whole process? The reason they feel the prevalence of side effects may be underestimated is that, first, not all the data were put in the public domain by the drug industry, but, secondly, people who experienced side effects were taken out at an early stage.

Professor Haslam: I would be very keen for all data to be in the public domain and for NICE to have access to all of it. That is absolutely critical going forward.

Sir Andrew Dillon: As an observation, selectivity in conducting clinical studies is not unique to statins; it is generally true of every clinical trial that is conducted for treatments where, in order to try to isolate the impact of the intervention, decisions are made about the nature of the patients accepted into the clinical study. Obviously, it would be ideal for every treatment, new or old, to be the subject of unrestricted studies in any sense so you are looking at real-world data collected for the use of interventions, but it is not, apparently, routinely the way clinical studies are constructed. In a sense, one either accepts it, works with that and uses statistical techniques and judgment in order to reach a conclusion about the weight and significance that can be attached to the outcome of clinical studies, with whatever deficits, as you might characterise them, they might have,

or you do not bother using them at all, in which case it is very difficult to make any kind of informed judgment about the use of the treatment.

Statins have been in use for many years. These are not new treatments. It seems to me that, beyond the clinical studies, if there was serious concern that would have caused a NICE appraisal committee to move to a very different recommendation about their use, that would be available through the systems in place, such as Pharmacovigilance, that would throw up information systematically about serious adverse effects. It is not to dismiss it; it is just the fact that we have to work with it; otherwise, we cannot reach a conclusion and make a recommendation. In the end, it is a judgment and balance of lots of things taken into account. Committees do their best to reach what they believe is a balance between the advantages and the risk with individual treatments.

Q44 Chair: To return to another point Robert touched on, did NICE make use of any non-industry-sponsored studies in developing the revised guidance? Could you clarify that for the Committee?

Sir Andrew Dillon: In both the original guideline and this update, we commissioned independent reviews of the evidence. Those systematic reviews would have inclusion and exclusion criteria which would not relate to sponsorship of the study but to the relevance, "generalisabilty" and quality of the clinical studies. I cannot confirm one way or the other whether or not non-industry-sponsored studies were included, but all the available English language clinical studies—relevant, appropriate and fitting the inclusion criteria—would have been part of the review.

Q45 David Tredinnick: I want to go back to an answer to a question that you gave the Chair just now. I thought you said that NICE had not said that statins should be available to a much wider group, as widely reported in the newspapers. You said that effectively the advice was that if you and your doctor thought it was a good idea, because they are now so cheap, you should have them. Is that an accurate representation of what you said?

Professor Haslam: I said that because of the falling price of statins, the threshold at which they were cost-effective had changed. What we certainly did not say was that we wanted doctors to go out there and put 5 million people on statins, as some newspapers reported. What we did say was that if doctors and patients, working together, having looked at things like lifestyle issues and all the other really important things, felt statins were appropriate, the point at which it was appropriate to prescribe them was different.

Q46 David Tredinnick: Is it not very strange that the media should have grasped this the way it did, and we have seen the representation in pretty much all the national newspapers that it is NICE's advice that statins should be much more widely used? How could there be such a public relations fiasco?

Sir Andrew Dillon: We have recommended them to an extended population. That is the nature of the guidance. The threshold that we are suggesting is appropriate for intervention should be lower, so inevitably there is a larger group of people who become potential users. It is not simply that once your risk is assessed as being within the frame we have

recommended you are automatically required to take a statin. Your risk is assessed and then there is a conversation about ways in which that risk can be reduced. If there are things that we could do as individuals through diet, exercise or other modifiers of lifestyle, that have the desired effect, we do not need to take statins. It may be there is nothing we can do and statins are the only option, and that is the advice the GP would give the patient, but it remains a decision for the patient.

Q47 David Tredinnick: Thank you for clarifying that. Moving to general attitudes to health, what is the role of NICE in educating the public about their responsibility for their own health?

Sir Andrew Dillon: It is largely through our public health programme. We are commissioned by the Department of Health to look at a wide range of topics since we took on that responsibility in 2005. The guidance we produce is intended largely to support the work of public health professionals in the NHS, as it was until recently. Now the lead role in public health is being taken by local government, much of our advice is directed to public health professionals and other colleagues working in local government.

Q48 David Tredinnick: Do you think that generally there is too much emphasis on putting new drugs out into the marketplace and not enough emphasis on people's lifestyles and healthy living? I have been told that the Department of Health spends about £100 million a year on healthy living advice, but one of the very large companies that produces hamburgers spends £2 billion. I was not able to establish whether that was this country. It probably covered a wider area. I think it is accepted that meat with a lot of fat in it can cause obesity, particularly if it is consumed late in the evening when the body is trying to shut down. Do you have a view on eating habits?

Professor Haslam: It is a fascinating question. There has been so much research done into the social determinants of health which are linked through poverty, education, diet, exercise and all these things. The bit of NICE that tends to make the headlines is the area where we deal with drugs and our technology appraisals, but our role now is right across the spectrum from assessing drugs for ultra-rare conditions all the way through to social care quality. As Andrew says, the public health guidance that we put out focuses very much on a lot of these issues and recommendations that can make a real difference. When it comes to drugs, part of our job is to look at them; it is not say whether those drugs should or should not exist as compared with more exercise, better schooling or whatever. It is a huge topic, as you rightly say.

Q49 Chair: Do you think there is a greater role NICE could play in explaining risk to the public? It strikes me that every time you open a newspaper there is a different story about statins and it is very confusing for the public to know whether they are a good or a bad thing. Are there better ways we could explain, using graphics, the key issues people want to know about? Are they likely to live longer if they take a statin? Are they likely to live healthier? It strikes me that the risks and benefits of taking them are poorly explained, and there is so much conflicting advice out there. Do you see NICE being able to take on how you communicate risk and benefit?

Professor Haslam: I absolutely agree with you that taking on and explaining risk is extraordinarily important, and it is an area of real interest. The way you explain risk to people has a fundamental effect on what their behaviours then are. You can explain it in different ways and get completely different human responses.

Q50 Chair: There are now very good graphics available about how many people would have to take a drug for how long for it to benefit how many people, and things like that.

Professor Haslam: Yes. We have been doing some work around that. We are very much interested in that. We have been working with members of the Royal College of GPs looking at some of these issues, particularly when it comes to the complex area of multi-morbidity and patients with multiple problems, particularly with poly-pharmacy. We had a wonderful session at NICE's May conference this year looking at the potential benefits and risks to patients of being on multiple drugs in, say, their 80s and trying to work out ways through this. I would hope this could become an increasingly important part of every doctor's work. I agree with you about NICE's role.

Q51 Chair: Is there also a role for NICE as a trusted resource for people to look at online?

Professor Haslam: It could be really important.

Q52 David Tredinnick: We have had evidence in this Committee and the Science and Technology Committee, on which I also sit, about the problems of poly-morbidity and poly-pharmacy and the whole issue of multiple quantities of drugs being prescribed. I think that in Scotland over half the population over a certain age are on more than five drugs. Does it worry you that there really is not a proper medical assessment of how drugs are used in multiple combinations? There may be assessments about how one or two react with one another, but is it not true that we have a large part of the population out there on many, many drugs all together and no one really has a clue of what the side effects are?

Professor Haslam: It worries me a great deal. NICE have been asked to develop a clinical practice guideline on multi-morbidity. The draft scope of that is currently out for consultation. It is an area that I think is extraordinarily important, and we are going to major on it because of the great benefits to patients from not being on multiple therapies, many of which may not be necessary, or the fact that the more drugs you are on the greater the risk of side effects. I think that, by the age of 65, 65% of the population have two or more long-term conditions and there are more people with two or more long-term conditions than there are with one long-term condition. So in other words, multi-morbidity is more common than single conditions, yet most of the NHS has been focused on single conditions: cardiology, respiratory medicine, urology or whatever. We are at a really interesting time when many people are beginning to look at this, but NICE are working very much on guidance around this.

Q53 David Tredinnick: One of the reasons I have supported complementary medicine—herbal medicine, acupuncture and homeopathy—for nearly 30 years here is that there are very few side effects. If you take homeopathy, you can take the entire box and it will not do any harm.

Professor Haslam: I cannot argue with you on that one.

Chair: No one speaks for it more than you, David. We are now going on to the next section, on guidance.

Q54 Rosie Cooper: Before I ask the questions I intended to ask about guidance, I understand your remit has expanded and that currently you review your clinical guidelines every three years, but you are not always in a position to update them. With this expanding remit, the big question for me is: are you adequately resourced for the job you are being asked to do?

Sir Andrew Dillon: We recently changed the arrangements for reviewing clinical guidelines because the elapsed time between the original guideline and the reviews that we were conducting had started to extend. The arrangement we have in place now is that guidelines are reviewed every two years, so the change in the underpinning evidence base is looked at. If there are elements of the guideline that require updating, we now have arrangements for looking at individual groups of recommendations and doing partial updates. We have restructured our capacity. We have a group of advisory committees whose job it is to do that on a routine basis. That is probably a reasonable balance, given that we do not have unlimited resources to devote to the clinical guidelines programme, between making sure the guidelines are kept up to date and not spending so much money on it that, in any circumstances that might cause us potentially to want to adjust something, the guidelines are looked at as soon as that happens.

On the question of resourcing, it would be lovely to have more money. We would be able to do more things; we would be able to do things more quickly in some circumstances, but the reality is that we have what we have, and it is reducing over the next couple of years. Therefore, we have to work hard to make it go as far as possible.

Q55 Rosie Cooper: I suppose the question is the one we asked of the CQC initially when they ran into all sorts of bother. Are you adequately resourced to do the job you are being asked to do? Do you think you have got the resources that will allow you to do the job you are required to do?

Sir Andrew Dillon: Yes.

Q56 Rosie Cooper: Great. My questions will be about whether you have begun the work of producing joint guidance for commissioners focused on integrated care, and, moving on from that, what you have done about developing guidance relating to co-morbidities, to which you made reference.

Professor Haslam: The whole way NICE are now organised is really an exemplar for integrated care. We no longer define our guidance as being clinical, public health or social care; we see it all as a spectrum. We are working very much in an integrated way. I think that is critically important. For instance, for a condition like Alzheimer's disease, we will be looking at drugs for that and the care of people with that disease in care homes, from the purely technical and pharmacological through to kindness. These things are hugely important to patients and service users. NICE are doing everything they can to try to work in an integrated way with organisations like NHS England, local authorities and so on, with all of whom they are building strong relationships, to try to ensure that our guidance is used across the system.

You asked specifically about multi-morbidities as well. The scope of that is currently out for consultation, and it will be a very significant piece of work.

Q57 Rosie Cooper: Leading on from that, my next question was going to be about how you are helping clinical commissioning groups establish the appropriate consistent application of those commissioning practices. This week, I have been looking at the report by the Royal College of Surgeons "Is Access to Surgery a Postcode Lottery?" They are very clear that clinical commissioning groups are applying whatever rules they want and are not adhering to your recommendations. You have given us a lot of assurance this afternoon about how you are trying to do the best thing possible; you want quality; you want to be trusted, but if you are producing all this stuff and clinical commissioning groups are ignoring you, what are we giving you the resources to do? How do you apply the glue?

Professor Haslam: In a number of important ways. It is a really good point. The last thing we want to do is produce what we believe is world-class information for to sit on shelves or computer files. It is pointless. You are absolutely right. It is worth doing only if it is implemented, which is why we have an implementation team that is making as many links as possible with CCGs. It is early days. We have had very considerable change in the health service since April of last year, as you will appreciate, but we are beginning to make links there. Regulators—the chief inspectors of hospitals and general practice—are relevant to this as well. The general view of NICE guidance is that it should be followed unless there is good reason not to. Good reasons include things like patient autonomy. I would not want our guidance to be seen as mandatory. That is not good for personal caring medicine.

Q58 Rosie Cooper: Nobody is suggesting that. The Royal College of Surgeons are not suggesting that. They are saying that mainstream there are CCGs who are disregarding your recommendations and guidelines. What happens in those cases?

Professor Haslam: We have a committee commissioning guidelines—I have forgotten what CCG stands for. We have a committee that is looking specifically at the impact of commissioning. Commissioners can use this to see what impact they are having, for instance, on the trusts that they commission care from. We are trying to work on that side of it; we have the regulator side; and our implementation team is meeting up with CCGs as much as possible. Andrew is going to give me about two others.

Sir Andrew Dillon: CCGs act like PCTs. Primary care trusts, as they were, had a duty to take account of the guidance that NICE produces, but they were not under a duty, always and immediately in every circumstance, to apply it. There has always been discretion in the NHS to take a look at any piece of NICE guidance and exercise a judgment locally about its application. It is not the case that CCGs ignore NICE guidance. There may be individual circumstances. I have not looked at the particular report you are referring to from the Royal College of Surgeons. I do not know whether David has seen it.

Q59 Rosie Cooper: I have read it, and I re-read it this morning. The last time I referred to a report, I was caught out by not having read the whole damned lot—forgive me. This time I made sure I did. It is very clear that there are CCGs that are automatically excluding the elderly, for whatever reason, and not adhering to your guidelines. If it is not going to be mandatory, which I would not want, how do you improve adherence? You have got adequate resources. Now we want you to join all of it together, but if the clinical commissioning group decide they do not have enough money, they are going to ignore you, so why are we pouring money into you and not putting it there to replace it and get the job done?

Sir Andrew Dillon: You could decide not to put any money into NICE and then nobody knows what would represent good practice, but the fact is that because you put money into NICE, the entire NHS have the ability to recognise what constitutes good care. Significant proportions of the NHS will recognise that and apply the guidance NICE produce.

You can take any particular recommendation of NICE and find variation in its application. You will find some variation in its application in the NHS. Our response is that that is very disappointing. We are realistic about the fact that, given the size of the NHS and the challenges facing it, the distance between concordance with any particular NICE recommendation, which may be very considerable in one location and negligible in another, will inevitably influence the priority that that particular local health community gives to implementing any particular piece of guidance that comes out of NICE.

We would love it if the whole system immediately dropped everything every month when we publish our recommendations and did nothing but implement what we do. It is certainly the case that the NHS over time would be a better service as a result of that, but it is not going to happen. What we have provided over 15 years is a rich source of advice for the service on the right thing to do for patients, and the things that are most likely to get the best outcomes for them. We do the best with the resources that we have to encourage them to do that. Our critical role is awareness. We need to make sure, as a minimum, that CCGs, providers and everybody else who needs to know, knows that we have published a recommendation in a particular area. Beyond that, our influence is largely indirect. We need to work with professional associations and directly with clinical commissioning groups as best we can, with our huge field team of seven people working in the NHS. Critically and most importantly, we now have to work with NHS England as the sponsor of those clinical commissioning groups. The most powerful signal about the implementation of NICE guidance comes from the signal that NHS England send about its importance to clinical commissioning groups. The stronger and more direct that signal is, the more likely it will influence those CCGs that are, for one reason or another, reluctant to take up our recommendations.

Professor Haslam: There is another player in this who is extraordinarily important: patients and the public. Publishing our information in accessible forms for patients so they know what good care looks like puts them in a position to raise the issue with their local organisations and say, "How come I'm not receiving this?"

Rosie Cooper: It takes the Royal College of Surgeons to show very clearly that that is in existence. You have written some more questions for Simon Stevens when he gets here next.

Q60 Chair: I assume there is also a role for CQC.

Professor Haslam: For me, you could have a system in which over-simplistically NICE tell you what good looks like and NHS England and CCGs help you do it, and CQC see if you did not. That works fairly seamlessly for me as a model.

Q61 David Tredinnick: Are you satisfied with the progress you have made in combining the quality standards set that will underpin NHS commissioning boards' outcomes framework?

Sir Andrew Dillon: Their quality standards programme is aligned directly to our clinical guidelines and public health guidelines programme, so every clinical and public health guideline will eventually have a quality standard associated with it. It started off by publishing those quality standards on guidelines that had been recently published, so we can be confident about the evidence base for it. We produce a quality standard after we publish each new clinical guideline and we review quality standards that have been published when the underpinning guideline is updated for one reason or another. Inevitably, it is going to take us time completely to finish the quality standard catalogue, and then there will be a maintenance programme to make sure that they are kept up to date, but given the resources that we have, we are making as good progress as we can reasonably expect to make in putting together that library of quality standards.

Q62 David Tredinnick: Do you think you will meet your commitment to have 150 standards completed by July 2015?

Sir Andrew Dillon: I'm afraid that I don't have with me the detail of where the programme is or its ambition by that date, but I can provide the Chair with that information, if that would be helpful.

David Tredinnick: Thank you very much.

Q63 Rosie Cooper: Do you intend to take into account the work being done by other professional bodies as another source of evidence in developing quality standards, particularly those for social care, not relying just on your own good offices for that? How wide do you go?

Sir Andrew Dillon: The core is the underpinning NICE guideline, but the advisory committees that put the quality standards together have the ability to draw on wider sources than simply the underpinning NICE guideline.

Q64 Rosie Cooper: How do you think the social care element, which is completely different, will fit in?

Sir Andrew Dillon: The quality standards will be based on the underpinning social care guideline, which itself will be a product of a careful review of all of the evidence. It will be a guideline written by people working in social care, so they understand the culture and language and the nature of the evidence, which in some respects is different from the evidence we look for in relation to clinical practice for public health, for example. It is good quality work and the quality standards will draw on that.

Professor Haslam: Almost everything done by NICE is done in partnership with the professionals, patients and service users from the relevant sector.

Q65 Rosie Cooper: In terms of social care, who would you include in that case?

Sir Andrew Dillon: In the development of the original guideline, the people recruited to the group would be practitioners: those responsible for delivering social care, for commissioning it and for managing services, domiciliary and residential care, depending on the nature of the topic, and users of the service. They come together to form the group that looks at the evidence which we will have commissioned independently as a systematic review. Then, they have the ability to draw on other experts, if they feel they need advice, and then we go to public consultation. Therefore, the broad community of providers and users of social care then have the opportunity to comment on it.

Q66 Rosie Cooper: Without drawing that out almost for ever, could you write to us and tell us how you chose the people you brought into the social care model you have just described, and who they are?

Sir Andrew Dillon: We will do that.

Q67 Rosie Cooper: It is quite interesting, because even social workers feel that they ought to have an input.

Sir Andrew Dillon: We will certainly provide that information, but the actual groups who develop the guidance are all recruited through advertisement. We will set out a specification. We need a group of people—three doing this, two doing that and one doing this. We have a spec for the group, and then we advertise and recruit on that basis. We do that as a way of avoiding bias in recruitment of the individuals and to make the opportunity available as widely as possible.

Q68 Valerie Vaz: We sit in these rooms and talk to each other and use acronyms, but for members of the public, a quality standard is—what? How would you define that? How would you define clinical guidance, just so it is on the record and people out there can understand what it is? When you talk about putting it in a library, is that in an accessible form for members of the public?

Sir Andrew Dillon: For the purpose of this conversation, a clinical guideline—it could be a clinical guideline, social care or public health—is like a map. What is the problem? What are the solutions available to us? What are the options at important decision points in the sequence of treatment or care that somebody needs to get the best possible outcome for whatever problem they have, whether it is a disease or condition, or an assessment for social care needs? It can be a very big piece of work depending on the complexity of the topic.

The quality standard synthesises and extracts from that the critical sentinel markers of good practice that need to be in place in order for the provider of care and user of care to be confident that the service in total is in place to give them the best outcomes. It also identifies and points out two things. One is interventions and things that need to be done where we know there is very significant variation, for whatever reason. Therefore, we are signalling that this is something people really need to pay attention to.

As a result of the Robert Francis report into Mid Staffs, we are putting what are described as developmental recommendations in those quality standards, which act to identify excellent practice. Therefore, it is the very best that the NHS could be doing, so it is a way of encouraging the service to move towards really good things. The quality standard bores into the guideline and gives a quick look. It can be used by providers of care; it can be used by the users of care to look at and say, "Here's the basis of a conversation I can have with those who are delivering care." It is a really good, useful piece of work for lots of people.

Q69 Valerie Vaz: My colleague talked about resources, and you said you had enough. Now is your chance. I will ask you again. Do you have enough resources for your new remit?

Sir Andrew Dillon: It depends on what answer you want to that question.

Q70 Valerie Vaz: I want it to be your answer. What do you need?

Sir Andrew Dillon: We are not falling over. We have a set of functions and we are able to do them with the money we have got. If you would like to give us more money, we will use it really productively and do more.

Q71 Valerie Vaz: I wish we could. You have just touched on management. Do you feel you might need to change your management and governance structures as a result of your new remit?

Professor Haslam: Governance is fundamentally the responsibility of the board. The board now has representatives. For instance, like all our committees and boards, we have

patient representatives, social care representatives and people from the medical profession, nursing profession, health economists and so on. It is across the board, and we have a good group to keep an eye on that. I do not think there is any sense that there is a concern about governance issues with the changing remit. We have managed to recruit the right people to address that.

You asked an interesting question earlier about what we do being comprehensible to the public. One of the things we have done is to put all our guidance and information on everything we do on our website in things called NICE pathways. For a given condition—say, hypertension—it will run all the way through almost from pre-diagnosis to the complex drugs, but it is a very simple flow diagram which is very accessible. It looks very simple. It is only when you click and go further in that you get all the detail, which we hope is much more usable for everybody.

Q72 Chair: Before we leave the issue of quality standards and outcomes frameworks, are you addressing some of the inconsistencies that have arisen? For example, quality standards suggested a 12-month review of chronic obstructive pulmonary disease, but the quality outcome framework indicated that it was 15 months. These kinds of things arise. Do you have thoughts on how you are going to deal with those when they arrive, where there is duplication and inconsistency?

Sir Andrew Dillon: We do. There are circumstances in which, as we update a clinical guideline—for example, in the case of the GP QOF—we have the opportunity to update the recommendations as we do that. We look in every case to check whether the read-across to the quality and outcomes framework and the indicators is there. Where there is, we let the negotiators of the QOF know that that is the case. It is not our responsibility. We cannot require the change to take place, so inevitably there is some lag between the updated guidance being available and changes taking place in the QOF. Obviously we would like that to be minimised, but in a sense our job ends at the point at which we advise the QOF negotiators of the need to make that change, and then we are in their hands in terms of how quickly that happens.

Q73 Chair: But you expect them to respond. Your guidance should take precedence.

Sir Andrew Dillon: We encourage them to take it into account; we cannot require it.

Q74 Barbara Keeley: Going back to guidelines, particularly the new role in evaluating social care interventions, the Royal College of Physicians raised concerns about how you will do that evaluation. They feel that outcomes in social care interventions are likely to be descriptive and vary from locality to locality. Can you say how you will carry out evaluation of social care interventions? Do you have a timetable for developing an evaluation framework?

Sir Andrew Dillon: We already have a framework in place. We have a methodology for developing social care guidelines. We developed that and have consulted on that with people in social care and others who have an interest in it. It recognises the difference between social care and anything else we have done previously and the nature of the

evidence base of social care. Though in clinical practice what we want as individual patients is critically important, the nature of the relationship between the needs and expectations of individuals and what is available is different in social care than in health. We recognise that as well. All of that is captured in the methodology that we prepared. Based on the response we have got from people working in social care, we think that is a good fix. It will evolve over time as our experience of producing guidance in social care increases; and, as with all the other methodologies we have got, we will update it and check that it still represents the right approach to take.

As David was pointing out a few minutes ago, one of the great strengths of NICE is its willingness and ability to listen to the personal experience of providers and users of social care and how that relates to the evidence we are looking at and the way that evidence has been interpreted. It is a very powerful input because it plays to the discretion that our advisory committees have to take an evidence base, interpret it and look at how that is going to work for individuals or groups, whether in the NHS or in social care, and take advice from those who are providing those services and those using them before the final guidance is drafted.

Q75 Barbara Keeley: Another set of issues is related to your guidelines on staffing levels. That is an incredibly variable standard at the moment. My colleague Andrew George—who is not here at the moment—and I have asked questions about it repeatedly. Many people hold the view that we should be moving to a safe staffing level. If I may say so, there was a bit of confusion about what you were saying, and perhaps there is a question as to why you could not be clearer about that, on the part of all those who believe in safe staffing levels as the right level of excellent practice, or the level of practice that we should be moving to in every case. My local hospital, Salford Royal, does adhere to safe staffing guidelines. Would you like to comment on that? What was the difficulty, and how do you see moving forward on that? There is a level of dissatisfaction with the current situation.

Sir Andrew Dillon: Some people hold the view that for adult acute wards there ought to be one nurse for every eight patients. If you have got one nurse for every eight patients, you are fine, and that is your concerns about safe staffing resolved. The fact is that that is not the case. You can have a ratio of one to eight and it can be absolutely right for the patients you are looking after, or it may not be adequate at all.

Q76 Barbara Keeley: My colleague is here now and can speak for himself. That is not the answer I am advocating. Clearly, it is different. At Salford Royal, they have a toolkit and it depends on the patient mix they have and the situation. That is understood, but we seem to be in a situation where in certain areas of hospital life—for example, children—you can say this ratio has to apply, and yet there is a constant shying away from a commitment to an adequate and safe staffing level. Andrew can speak for himself now that he is here. My view is that if some places can do it, other places could do it too. Why shy away from what Robert Francis has moved towards, which is to use toolkits to work out what the safe staffing level is? The one to eight guidance is not a bad starting point, so just move to that.

Professor Haslam: We would support 100% what you have said about the importance of a commitment to safe staffing levels. There is no doubt about that. It is how you reach that

and what are the unintended consequences of saying that one in eight is the answer. As Andrew was saying, sometimes one in eight may not be enough.

Q77 Barbara Keeley: That is understood.

Professor Haslam: There is also the anxiety that sometimes one in eight might be too much, and then where do those staff come from?

Q78 Barbara Keeley: From what we talk about in debates here—I have raised this time and time again—I hear from people who talk about one to 22, or two to 28.

Professor Haslam: Which is unacceptable.

Q79 Barbara Keeley: That is why we need to be clearer. The more that organisations like yours putting out guidance cannot be as clear as they could be about this, the more it is letting people off the hook. There are too many hospitals up and down the country that seemingly are prepared to accept staffing levels that are nothing like safe. As Members of Parliament, we hear repeatedly from people. I have had direct messages back from people that say this is the dominant issue in their working lives as nurses.

Sir Andrew Dillon: I am struggling a little. What was not clear in the guideline that you think should have been clearer?

Barbara Keeley: I am asking this question for Andrew. I do not know whether he wants to deal with it.

Q80 Andrew George: I apologise; I was unavoidably detained. The reason I wanted to pursue this line of questioning—I am sure that Barbara has done an excellent job in pursuing it—is that Professor Haslam was saying there might be circumstances where, for example, one to eight was too much. The clinical guidance on this, certainly from those clinicians who have offered advice and the evidence you have had to assess, suggests that in an acute setting there are never any circumstances where one registered nurse to eight patients, taking into account that the nurse in charge is supernumerary, is ever too many. It should never fall above that particular ratio; it is unsafe. Indeed, the one-to-eight ratio, for reasons you have already explained, is simply a floor below which you never fall. That is the advice. It would be helpful to have NICE say a little more clearly that that should be the case and that is the floor. I am extremely troubled to hear you express the view that it may be too many, unless you can write to the Committee and provide examples of where one to eight may be too many.

Professor Haslam: The point I am trying to make is that what really mattered to the committee was safety. If there were situations in which patients were not safe, we talked about red flags and points at which it should be absolutely prioritised that more staff are required on a given unit. We are absolutely with you about the importance of this being addressed correctly. The concern related first to the absolute evidence around one in eight being always critical and what the unintended consequences might be of saying that had to

be the answer. Will there be units where, for instance, it is said, "We've got one in eight now, so we're okay," when they are not?

Q81 Andrew George: I do not think that really applies. Your guidance is reasonable on that. I think all of the discourse around it makes quite clear that it is not a target; it is a floor below which you never fall. I would find it very helpful if you could provide any evidence or suggestions about circumstances where it is acceptable to have a ratio greater than one to eight. It would be genuinely helpful to have an explanation as to where, as you put it, it may be too much, because no one has ever suggested that so far.

Professor Haslam: I am not saying I would like a different ratio from that but that safety is critical, and it is the focus on that, rather than automatically defaulting to the number, which concerns me.

Q82 Barbara Keeley: But in other situations, we do; we do it in paediatrics and intensive care, so the notion that you cannot accept and apply a ratio seems strange. Admittedly, I tend to know only about my local hospital. I have spent a lot of time visiting others and talking about others. We included their practice, which I think is good practice, of having a toolkit and balancing out the cases they have got in any situation, and also publicising it—there are two sides to this—saying both what we should have on this ward and what we have got on the ward. I think it is possible to point it out, but I keep hearing from people in nursing that at certain times during the day they are left in a very precarious position.

Professor Haslam: And that should not happen.

Q83 Barbara Keeley: Indeed, but we all keep saying that. The more people prevaricate about saying one to eight is the floor, including yourselves, the more the whole thing becomes arguable. We do argue it in our debate here. I agree with my colleague Andrew George that the time for that is over. If you care about safety, why not be as clear as you could be and say that this is the floor? Obviously, in certain situations with a certain mix of patients, it might be different from that, but if we know this and accept this for certain wards in hospitals why do we shy away from it? We shy away from it because it is not the case in too many hospitals in the country. Ministers are running away from saying it. I am not running away from saying it. I think it is important.

Sir Andrew Dillon: What we have been asked to do is write to explain the basis of the decision of the advisory group, consisting of practising nurses in whose judgment we have confidence, using the evidence, including all of that accumulated around the figure of one in eight, and how that was brought together with a recommendation that did not produce clear, unequivocal and never-to-be-breached advice that there should always be eight patients for every nurse on the ward. It was not the opinion of the advisory committee that that was the way to reassure patients that an individual unit is safely staffed.

Q84 Barbara Keeley: Have you looked at hospitals that are doing this? You talked earlier about different ways in which you look at excellent practice. There are examples. I have quoted one to you. I am sure that my local hospital is not the only one. Have you looked at those and talked to people?

Sir Andrew Dillon: The people round the table are responsible for ward staffing all the time. The people at NICE who were supporting their work visited hospitals in different parts of the country to look at the approach.

Q85 Barbara Keeley: That is not a very direct answer. Given that this is a very controversial matter and is at the heart of a set of issues that the Francis report drew out, if there is confusion and a perception that you are not being clear about it, it allows for a bit of backsliding because other people can say, "We're not insisting on this."

Sir Andrew Dillon: It allows people to exercise judgment, which in the end is what is going to matter to individual patients in a safe area, but there was not the evidence to support an unequivocal never-to-be-breached position which said there must never be fewer than one to eight patients on a ward. If that had been the view of people round the table with operational day-to-day responsibility, that would have been reflected in the guidance. We cannot force something into a recommendation that is not supported by the evidence or the judgment of those people whose advice we are taking.

Professor Haslam: And indeed, the response from the Royal College of Nursing to our report was entirely supportive. We could not be more with you in wanting—

Q86 Barbara Keeley: I have read many responses that were not supported, and I think there was a degree of confusion. As a final point—maybe Andrew has another—when we know there are unsafe situations still in existence with unacceptable ratios of one to 22, or two to 28, to me, not to insist on a safe level does support a degree of backsliding.

Professor Haslam: I hear what you say. We absolutely do insist on a certain safe level. The one thing we say is that patient safety is absolutely paramount.

Q87 Barbara Keeley: But you are not clear what that consists of.

Professor Haslam: We are also an entirely evidence-based organisation. If there is evidence that we have not been clear, we would listen to that.

Q88 Andrew George: I appreciate your answers. The problem in the past and the discourse we have had with the chief nursing officer and others is that, when we have raised the issue of safe ratios, we have been taken down the route of management baffle—that is the only way I can describe it—talking in terms of leadership and culture and moving away from hard evidence of any rational basis of judging what is actually safe in terms of registered nurse staffing levels on acute wards. What has become clear to many of us, having studied this and looked at the evidence as well, is that it is enormously helpful to have a guidance figure there, particularly if it becomes a benchmark or floor below which staffing levels should not fall. First, where is the evidence to suggest that a staffing ratio greater than one to

eight is safe? Indeed, you were suggesting it was too much, which suggests it might be unsafe for it to be lower than that. Secondly, if this is guidance, it would be helpful to know what weight NICE guidance has in the hospital setting, because clearly it is not a mandatory situation. They are not totally obliged to follow it, but it would be helpful to know how significant that is, and why it might be relevant that NICE have produced guidance on this.

Sir Andrew Dillon: We will do both of those things. We will set out what we have said about one in eight. We have not ignored it. We have set out a view about its significance to those who are ultimately exercising a judgment about what the right level should be at any one point in time on any shift for any given group of patients. We can talk about the impact of the guidance. Its status, as we have previously discussed at this meeting, is that the expectation of the Department of Health and the NHS is that it is taken into account in the judgments being made. I am confident that, given the demand for a national point of reference for nurse staffing from nurses themselves, from hospitals with responsibility for running services and employing nurses, from the Department of Health and the Royal College of Nursing, this guidance will be read and used. I am very happy to write and confirm the basis on which we have formulated the recommendation.

Q89 Barbara Keeley: Could you include which hospitals gave evidence on that? You said you had not been involved in that, but individuals had been. I asked about which hospitals you had visited or taken evidence from. It is quite important to see what you are drawing from.

Sir Andrew Dillon: We will set out precisely who was on the group, where they work, what hospitals we visited and who commented in consultation.

Chair: Thank you very much for coming to give evidence to the Committee today.