Origins and Establishment of NICE (c. 1997 – 2002)

NICE, originally the National Institute for Clinical Excellence, is now the National Institute for Health and Care Excellence

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Introduction

The incoming Labour government of 1997 committed itself to open an institution called NICE in the White Paper on the future of the NHS which it rushed out in December of that year. There was little detail: essentially a paragraph, which said the goal was to further clinical and cost-effectiveness, drawing up new guidelines, and bringing together existing DH-funded guidelines programmes. NICE, it was claimed, would promote consistency and equity in access to services: Labour politicians emphasised how NICE would put an end to the 'postcode lottery'. But there was no mention of Health Technology Assessment or reference to the appraisal of drugs. This was to be fleshed out in publications over the next two years.

Just how the plans for NICE developed between May 1997 and the Institute's opening in April 1999 makes a fascinating study in policy development. We hope today's witness seminar will shed more light on the process. Some things are clear. Labour did not come to power with a blueprint for the NHS (let alone for NICE in particular). Simon Stevens (who had been adviser to Labour opposition health spokesman Chris Smith before becoming Frank Dobson's special adviser) certainly arrived with some ideas about the need to assess the cost-effectiveness of innovations but there is no sign (so far) that he was thinking of any particular institutional form to implement these.

Similarly, DH officials had already been working for the outgoing Conservative Ministers on initiatives such as an expert working group with academic health economists and the pharmaceutical industry on how the cost-effectiveness of drugs should be evaluated. This work is an example of the important role played in DH policy development at this time by the Economic Advisor's Office (under the late Clive Smee).

The roots of such work lie several years further back, in DH's constant concern about the mounting cost of the NHS and the need to find politically acceptable ways of getting it under control. Many options had been discussed during the 1990s, officially and otherwise: the approach which found most favour with Smee and his colleagues was to make use of the methods of health economics to prioritise spending on those activities which could be shown to deliver the most health gain. The Quality Adjusted Life Year (QALY), developed in the 1970s and 1980s, was by 1997 being seen by most health economists as the best available measure of this. The Health Technology Appraisal (HTA) Programme, established in 1993 and first operated as part of NHS R&D, was one concrete expression of this policy direction.

Any policy to constrain clinicians' freedom about what treatments they could select was of course controversial – much more so in the 1990s than today, when (thanks in part to NICE) guidelines are a more normal and accepted part of clinical life. Fear

of medical opposition meant that pre-1997 governments were highly circumspect about any steps beyond producing guidelines. The word ‘rationing’ came to be loosely applied to any such policy (although Rudolf Klein and colleagues argue that the word is best reserved for talking about allocations to individuals at the point of delivery). Rationing became a word which first Stephen Dorrell (Secretary of State 1995-97) and then Alan Milburn (Minister of State 1997-98 and Secretary of State 1999-2003) felt the need to avoid.

If NICE, its role and its methods were designed partly by Simon Stevens and partly by DH officials, another important part in defining NICE was certainly played by NICE itself. DH’s policy documents and NICE’s Establishment Order provided a skeleton: Mike Rawlins, Andrew Dillon and their tiny initial staff team also did a lot to put the flesh on it. Mike was appointed in September 1998: Andrew not until almost the moment NICE’s official existence began in April 1999 (he did not arrive on the payroll until July, along with NICE’s other initial employee, the Communications Director Anne-Toni Rodgers).

NICE brought together three related activities: publishing evidence-based clinical guidelines, promoting better – and more equal – access to new treatments (overcoming the ‘postcode lottery’), and controlling the cost of NHS care by preventing expenditure on treatments which appeared to offer poor value for money. What gave NICE its eventual character was the decision to combine them as the functions of a single body, and the precise ways they were combined.

NICE did not invent guidelines: indeed Martin Eccles has told us one of his roles was to reduce the number being produced (by stopping the low-quality ones). But guidelines informed by evidence about cost-effectiveness as well as (clinical) effectiveness were a relatively new departure and certainly not an intrinsic part of the evidence-based medicine movement, some of whom were actively opposed to this. NICE promoted a particular kind of methodological rigour in guideline production, and allowed those which met the standard to use the NHS branding which (and this is easily overlooked) had itself only been invented in 1997. We were told that Mike Rawlins always maintained that ‘it’s guidelines that NICE will be known for,’ and that Andrew Dillon, too, regarded them as even more important than the Technology Appraisals which attracted nearly all the headlines.

NICE would only improve access to new drugs if the NHS complied with its guidance that a new therapy ought to be adopted. This was not a foregone conclusion at first, but in January 2002 the funding direction, that NHS commissioners had to pay for treatments approved by NICE, made it more of a reality. Until then, the extra time spent getting a drug approved by NICE did not necessarily hasten its use in the NHS. As Evan Harris, the Liberal Democrat health spokesman, put it in 1999, the discussion paper about how NICE would work called ‘"Faster Access to Modern Treatment" … follows the trend of giving Government papers titles whose contents belie them’.

The third goal, that of saving the NHS money, was not as easy to present in an attractive light: it amounted to denying market access to drugs known to be effective, on the grounds that they had failed a ‘fourth hurdle’ (alongside safety, quality and

efficacy): the test of cost-effectiveness. Political opponents were not slow to point this out. In March 1999 Philip Hammond, then Conservative spokesman on health, told the Commons that NICE's 'prime purpose will be seen as providing a fig leaf for Government in rationing health care, while continuing to deny that such rationing exists.'

Starting work in April 1999 with a Board of twelve but no paid staff, empty premises and little else, NICE's first job was to create itself; to define its role, and, in Andrew Dillon's words, then 'to do what we say we are going to do.' Establishing the infant organisation's credibility with existing powerful players like Royal Colleges and drug companies, with the press, patient organisations and the public, was among the most important tasks. As Andrew described it, 'we … talked ourselves almost into the ground in order to explain what we are about.' NICE's Partners Council, on which all the major stakeholders came together, was one important forum for this, but there were very many discussions beyond it as well.

Taking over the existing DH funding of Royal Colleges for guideline production, NICE established six collaborating centres for guidelines. It took DH until November 1999 to approve NICE's programme of guidelines production. In April 2001 the first NICE guidelines, on prophylaxis for myocardial infarction and pressure ulcer risk assessment and prevention, were published. While most of NICE's early activities were about setting up and operating the systems to produce guidelines and Technology Appraisals, other work included the running of pre-existing programmes such as Confidential Enquiries (for example into perioperative deaths) and support for clinical audit.

Technology Appraisals were NICE's baptism of fire: the famous Relenza (zanamivir) appraisal, commissioned in July 1999 and published in October, was its first, and had to be conducted under a process that was still being designed – though the manufacturers, Glaxo Wellcome, gave their consent to this 'prototype' approach. Relenza, as is well known, immediately became a test of NICE's independence from government and its resolve to follow the evidence. It was a test NICE passed, standing up to Glaxo's and Richard Sykes' lobbying of the Prime Minister, threats of judicial review and relocation of manufacturing out of the UK. It could equally be said that the government passed a test of its willingness to let NICE make its own decisions. The Relenza decision was a one-off: the first 'full' Technology Appraisal, on the removal of wisdom teeth, emerged in March 2000. 20 more Technology Appraisals followed in NICE's second year of life, including hip prostheses, taxanes for breast cancer and drugs for Alzheimer's disease.

Contributors

Witnesses, with their connections to NICE:

Tony Culyer, Vice-Chair, NICE, Emeritus Professor of Economics, University of York (TC)

Andrew Dillon, Chief Executive, NICE (AD)

Mercy Jeyasingham, NICE Board, Partners Council and committees (MJ)

Trevor Jones, Director General, Association of the British Pharmaceutical Industry (TJ)

David Pink, Department of Health civil servant before 1999; later Head of Guidelines and Audit, NICE (DP)

Michael Rawlins, Chair, NICE (MR)

Andrew Stevens, Appraisal Committee Chair, NICE; Professor of Public Health, University of Birmingham (AS)

Chair:

Nick Timmins, King's Fund; Institute for Government; King's College London (NT)

Convenors:

Sally Sheard, Professor of Modern History, University of Liverpool (SS)

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Areas for discussion and seminar format

The aim of this witness seminar was to bring together those who were directly involved in the emergence of NICE or experienced it first hand, and re-examine this important moment in the history of the NHS. It was chaired by Nick Timmins, who invited selected participants to speak on the main areas of discussion outlined below. The discussion in each stage was then widened to take questions and comments from any participant.

Roots

In 1997-99, what did you think that NICE was for? (Producing better guidelines? Improving equity of access to medicines/ending the postcode lottery? Rationing/ensuring the NHS spent its resources where health gain was maximised? Something else?)

Whose thinking influenced you most at this time? (Either individuals or groups, e.g. 'health economists'?)

How important do you feel the health economists were, in particular? Who stands out among them, and for what?

Which politicians (if any) played a major role in shaping NICE? What was their contribution?

What did other interests hope to see happening in this field? (E.g. Royal Colleges, pharmaceutical manufacturers, patient groups?)

What influence did existing structures, like Colleges' guidelines teams, or the NHS Health Technology Assessment Programme, or Drug Evaluation Committees, have on the shape of NICE?

How would you assess the legacy of the pre-1997 Conservative governments in this area? How much did it influence subsequent developments?

First months: what did NICE want to become?

Which parts of the functions, and form, of NICE were laid down by DH and which did NICE design for itself?

What had Mike Rawlins already decided by the time the first NICE Board was appointed in April 1999?

How did the balance emerge in NICE's appraisal method between applying a health economics tool and reflecting social value judgments?

What went according to plan and what was unexpected?

First months: what did others want NICE to become?

What did the pharmaceutical industry want to happen in 1999 and immediately after? Were they trying to undermine NICE or to shape it? IF they were hoping to shape it, into what?

What did patients' and carers' organisations want? What did they think of NICE? Did they find it open to engagement with them?

Working at NICE in its early days

What was it like to work at NICE in 1999-2002? What was the atmosphere? What was a 'typical working day' like?

NICE attracted some impressive people, to both its Board and its staff. How? What made them come?

What adjectives best describe NICE's working style in these years?

Witness Seminar Transcript

NT: I'm going to reorder the questions marginally, let's start with this very broad one, which is, in the period 1997-1999, when NICE was being set up, what did you think NICE was for? Who would like to start on that?

MR: Shall I start off? Mike Rawlins here, well, it wasn't really conceived in the period of the Conservative government, and when it was conceived it was sort of laid out in *A First Class Service*, which had originally two functions, one was to look at the clinical economy and effectiveness of interventions, especially new interventions, and secondly to produce evidence-based clinical guidelines.[1]

[01:05] NT: Yes, there was a lot of talk at the time about rationing and postcode lotteries. [interruption]

[01:29] MR: Yes, they are two rather separate things actually, the postcode lottery was a problem of some hospitals were able, willing to provide particular treatments, particularly the beta interferon for multiple sclerosis, and others weren't, and it sort of depended on where you lived, which side of the street, which hospital was responsible for your care. That was a postcode lottery. Rationing was something rather different, and I always said at the time that NICE wasn't in the business of rationing, I remember rationing from my childhood, everyone got ten sweets per week, it didn't matter if you were fat or thin or whatever it was, you all got the same – that was rationing. Somewhere in a box somewhere I have still got my old ration book from the 1940s. It was rather different, and NICE was never into rationing, as I tried to explain right at the very beginning.

[02:29] NT: Anybody want to comment on that?

[02:43] TC: Well I don't think I really ever changed my views about what I conceived NICE to be from the moment when Mike asked me to join him as vice-chair of the board. I had been involved in arguments about rationing and things like this for many years, I saw NICE as a great opportunity for rational decisions favouring population health… I had also been very much influenced by Archie Cochrane and

[1] Department of Health, *A First Class Service: Quality in the new NHS* (1998)

subsequently by the Canadians at McMaster, with the what was then called, some people still call it, the evidence-based medicine movement.[2] It seemed to me that if you do accept the basic premise of those epidemiologists and clinicians, that the object of health services is to improve the health of the population then it seems to me that… that leads very quickly to some notion of cost-effectiveness, criterion for deciding what in general is going to be made available for that population, and I admit that it immediately struck me that NICE could be developed into an instrument that was fit for that purpose.

That was what I conceive of NICE, what attracted me to it, was to make sure that as far as possible the economics was going to be respectable, to economists. Of course I could see that there were many people who would feel threatened by the existence of NICE, and although the economists in particular wouldn't feel threatened by it, but they would love to pounce on anything that was not correct, or was a misunderstanding, or an abuse of standard welfare economics. My concern then, was very much what Mike and I had as a recurring theme I think: it was about credibility, it became terribly important that as far as I was concerned, while other people would handle the epidemiology, I was there to monitor the credibility of the economics. Those are the two things that concerned me; NICE to be an instrument for a more efficient health service that had a better impact on the people's health for the resources that were available, and to make sure that the economics was right.

NT: Andrew?

[05:22] AS: In your question you've got 'rationing' and then 'forward slash' 'ensuring NHS spends its resources where health gain was maximised'. In other words, not wasting. And I always thought that that was at the centre of it, certainly with the health technology appraisals preceding guidelines on the whole. In the days, years rather, before NICE, in the eighties and nineties, something extraordinary happened to drug prices. So there were people researching this, how far it went and what the explanation was, but certainly during the seventies and early eighties, new drugs used to be priced not so very differently from other things you might buy from a chemist. It wasn't a problem. The problem certainly arose before NICE was established, which was why a whole number of regional Development and Evaluation Committees were set up, and their principle objective was to try and work whether new drugs were cost-effective.

[2] Archie Cochrane, first leading UK advocate of what was called 'evidence-based medicine'. David Sackett and Brian Haynes at McMaster University, Canada, were other important figures in this movement.

What they didn't have was the power to affect those prices, so if you get into the language of making sure that the NHS has got cost-effective interventions, one of the things you can do about them is not so much ration, as negotiate. Insofar as NICE was involved in these appraisals early on, there wasn't that much negotiation from the pharma industry, but we'll come back to that later, so there certainly was a big element of making sure the NHS spent its resources where health gain was maximised. The issue of 'what did anybody think NICE was for?' certainly for those of us who had come from the Regional Health Authorities and their attached institutes were familiar with what Development and Evaluation Committees did, there was certainly an expectation that NICE would do that nationally and with much more clout. And in fact that's sort of how it turned out.

[07:30] NT: Andrew are you saying that there was a change in the nature of drug pricing over the eighties and nineties? So, what was it?

[07:39] AS: I'm not a total expert on this, but in retrospect you can tell, A, from looking at the data, and B, from the experience that several of us had, with things like beta interferon, which although appraised by NICE had hit the decks a couple of years before, maybe even a couple of years before that.[3] And everybody was shocked that they were ten thousand pounds per patient, per year, before we had seen that sort of pricing with drugs for rare illnesses. Beta-interferon and one or two others – I've got a sort of folder of them somewhere – were a real shock, at what was the justification for this pricing? Insight into what goes on in pharmaceutical company boardrooms isn't mine, but I'm sure some sea-change took place.

[08:31] NT: Trevor, what's your view on that?

[08:34] TJ: Okay, so before NICE was, and actually in its early years, until recently, we had something called the PPRS, the pharmaceutical price regulation scheme. Those of you who are familiar with it, it meant that our industry could earn no more than the average profit of all the other industries, aerospace, mining, banking and so on – in other words we weren't given a favoured position, but we could make a profit, an average profit. What that meant was, if we invested heavily in R&D and manufacture in the UK, obviously you could offset that as part of your profit. Equally, by setting a price for a product you were going to export higher than you would have done in the UK and discounting it for cheap products in the UK, we were then able to

[3] Beta interferon, a drug licensed in the UK for multiple sclerosis in 1995.

get a very favourable balance of trade in pharmaceuticals, in the time of NICE it was £2.6 billion.

So here was an inventive scheme that the government and industry work hard on, to actually make sure that the industry was getting incentives to invest here, and the country was getting the benefit of balance of trade, and that is really important thing to remember when, at that time, the drugs bill accounted for twelve per cent of total NHS spend, very much lower than most services in the NHS, and the prices of pharmaceuticals then, as now, were much lower than they were in places like Germany, Italy and Spain.

[10:10] NT: David, you raised your hand?

[10:10] DP: Without wanting to disagree with anything that has been said, I think also it is worth commenting on the political circumstances of 1997. There were various people who wanted a body like NICE to exist, for reasons that are reflected in the way it was set up. But in 1997 you had the landslide Labour victory, and you had the prospect that the NHS was going to continue to be a painful headache for ministers and politicians, because there were blockbuster drugs, there was a rising interest in clinical cost-effectiveness, and there was postcode-prescribing, evidence-based medicine was not actually making the politicians' job any easier, it was making it worse, because decisions were being made in the NHS to not provide treatments, and ministers were being – people were trying to hold ministers accountable for what was going on.

So I think the political reasons were in some ways quite negative, issues of clinical cost-effectiveness and evidence-based medicine, which are two different things but with an overlap, could stop at NICE, and not go up to the minister's desk. Although the incoming Labour government did not have NICE within its manifesto, the NHS, or the concept of the NHS actually being valued and the quality of the NHS services becoming something the country could be proud of rather than ashamed of, was very much part of the Labour agenda.

[12:02] NT: I do remember when beta interferon first appeared, Gerry Malone's day, minster for health, just being shocked at the price, it felt enormous.[4]

[4] Gerry Malone was Minister of State for Health (second Minister in the Department of Health, 1994-97).

[12:17] TJ: When you have a big, blockbuster pharmaceutical in a big disease that is one thing, but many of the lessons we are seeing today, in personalised medicine and rare diseases, were true at the time of beta-interferon, which I also developed at Wellcome. For example, when I developed, with my team, AZT for the treatment of HIV/AIDS, we had no idea how many people would have the infection. We priced the drug to get a return out of our investment, as it turned out I think we got the price wrong, especially for the developing world, but you can't at that stage know what the potential revenue is going to be – so you tend to say 'how am I going to get a reasonable return on my investment at a reasonable price?' And then the willingness to pay of the payer.

[13:13] NT: I'm sure that is a point we will come back to. One of the things that the industry found helpful found helpful with NICE was that when it did make a recommendation, although it wasn't perfect, the NHS did tend to take the products up more swiftly…

[13:27] TJ: I do remember at the first conference, or second conference of NICE, that I was invited to on the platform with Michael, I asked him the question of 'what will you do then, now you have made these decisions, if they are not taken up by all the patients who are entitled to them in the National Health Service?' and Michael's reply was 'I will chase them to the ends of the lands'

[13:54] NT: We have slightly touched on this, but a shifting order of questions, how much – NICE was clearly Labour's creation, but how much was there a legacy from the previous Conservative government?

[14:13] MR: Very little, in fact. Very little indeed, and although, Gerry Malone did say to me once, some years after NICE had been established, that he never had the idea of NICE but he did recognise when he was a minister that something needed to be done, and it couldn't go on as it was, but they didn't really have anything to offer on it. It was really as a result of… also remember that when Labour came to power in 1997, they promised to use the same sort of budgets that had been previously set by Ken Clarke, they weren't increasing expenditure, so they had a problem.[5]

[15:13] NT: There was Gerry Malone's famous explosion at the end of the first beta-interferon episode, when he said to his civil servants 'this is not a decision that

[5] Kenneth Clarke, Chancellor of the Exchequer 1993-97. (He had been Secretary of State for Health, 1988-90).

should ever reach a minister's desk again' 'try and find me a mechanism that will avoid that.'

[15:30] MR: As he said to me, he reminded me that, he also said that I didn't actually have the idea of NICE.

[15:42] NT: I think that's true, it might be worth pointing out that Clive Smee, in 1996 had had an away study trip to Australia, New Zealand, Canada and I think the States, and had come back to say that we were off the pace in terms of doing cost-evaluations of new pharmaceuticals, and was putting papers around the department about that.[6] And Tony, ahead of Labour winning power, you were chairing this expert workshop on pharmaceutical guidelines and cost-effectiveness. These weren't NICE, but they were sort of steps towards it, is that fair?

[16:26] TC: We took it over, when we were developing NICE's methodology for technology appraisals, we really used that as a jumping-off point. I think a lot of our initial workshops were centred on the sort of recommendations that had been coming out of that working party. At the time, it was one of those great occasions where it seemed to be quite easy to reach consensus about the sort of principles that should be used. We had all four of the industry health economists in that group, and they were as keen as everybody else to get this right.

[17:14] NT: David, your hand was up?

[17:14] DP: I was going to say that, because I was working for the previous administration as well, I think NICE benefitted from programs that were funded by the previous government, some of which have been mentioned, from Clive Smee's work in particular, and the development of evaluation committees and there was a national clinical guidelines program. But under the previous administration, the notion that that should all come together in a national body was a complete non-starter, I say that as someone who was working for the previous administration and would have liked NICE to be created a lot earlier. But there was just no way a government body such as NICE was going to come into being, perhaps the government would have smiled on a professional body such as NICE coming into being, but that wasn't going to happen either, because the professional leaders were never going to set up such a body.

[6] Clive Smee, Chief Economic Adviser, Department of Health 1984-2002.

[18:15] NT: Yes, the concept of a national body was sort of antithetical to the nature of Conservatism at that time I think.

[18:22] DP: Yes, quite so.

TC: I think it was also antithetical to a majority, or clearly a substantial chunk of the clinical professions as well. It was seen – there was a lot of discussion in the late 90s, mostly in the rationing context, around limiting clinical freedom: what is clinical freedom? Is it clinical license to do anything? And of course the whole business of best practice, identifying best practice and using guidelines, guidance documents to help physicians to engage in effective healthcare. It was very much to the fore. It wasn't just a political thing, it is absolutely true that there was that, but the medical professions too, or some parts, probably the parts that are hard to reach, who hadn't discovered evidence-based medicine, were sceptical and saw NICE as a threat.

Which again raised the hugely important question of credibility, from the beginning we realised that in view of the fact that there might be opposition from a number of quarters, how do we make sure that what we create here is going to survive a possible change of government, how do we make sure that it does prove to be acceptable to clinicians, and in particular to clinical teachers in the medical schools, And how do we make sure that it is acceptable to the research community, who, after all, is the bunch of people who are going to be providing the evidence that we subsequently have to use in technology appraisals and to underpin guidelines.

[20:27] NT: Which groups did you see as being most influential behind NICE, health economists, obviously?

[20:40] MR: Well it wasn't all health economists, and I'll share his blushes but it was Tony, Tony Culyer who was absolutely critical to the whole thing. It was extraordinary the way he… and it was really Tony who told us we should use QALYs.

[21:04] TC: Very nice of you to say that Mike, but the business of, I think the business at the time we were creating NICE, the business of persuading the then-opposition, the Tory opposition was very much Mike's doing, I had very little to do with that, but Mike was so diligent, it was very important, because it would be quite easy to imagine that NICE would be a Labour baby – there was a wonderful cartoon in the *BMJ* that had Tony Blair as a puppeteer manipulating NICE.

[21:47] MR: I've still got it on my wall

[21:52] TC: You've got it on your wall? Being only infinitely inferior to you, Mike, I have only a photocopy of it on my wall

[22:02] NT: In terms of what other influences… in the run up to NICE, Trevor, what was the industry's view of all this?'

[22:13] TJ: Well we had the situation of having in the UK an extremely well-respected and good regulation agency, the MHRA, still is the case.[7] Their job was to look at quality, safety and efficacy, and we feared that imposing another hurdle of cost-effectiveness would actually delay entry of these products to the patients, and delay return of investment. Around the patch, there were countries in Europe fixing prices, you had to negotiate a price on entry, and that process took about a year, at least, for most countries, sometimes more. From the time, in the UK, that you got MHRA approval you could go straight into the market and get patient benefit and return on investment.

The fear we had was that there would be a further delay of us to a year or more, that's not good for the patients or the industry, and furthermore, when do you really know the cost-effectiveness and value of a new product? Clinical trials in those days took place on a few hundreds, maybe a few thousands, at times, of patients, but they were all with massive exclusion criteria, so when you get to the real world and the real patient with other therapies, it is only after some time in that situation that you get to judge what the real benefit is and the value, and we were very concerned that that would, actually, again, get a false reading at the start of the activity. So the concern was delay – of access, delay of return on investment, and an imprecise judgement at the beginning of the life of the product as to its value.

[24:00] NT: Mercy, can you give us a view on - clearly it won't have been unanimous - but what the view of patient groups was, as this was coming over the horizon?

[24:10] MJ: Well I think, as I read *A First Class Service,* we had a lot of questions about what was the patient involvement? It did mention the patients, but it didn't have, obviously it was a White Paper, there was no detail, so we had lots of questions. Also, our pharmaceutical colleagues were talking about the fourth hurdle,

[7] MHRA: the Medicines and Healthcare Products Regulatory Agency

as well. I think there were concerns, at the same time we knew about postcode lottery and access to particular drugs, so certainly from my point of view and talking to other patients' groups at the time, it was just a series of questions; what was this body? What did they mean that they were going to be more involved with patients?

In fact, I remember when the paper first came out, and I had to give a talk at a seminar for the pharmaceutical companies, and Charles Dobson was one of the other speakers, he was obviously in the department, working on NICE, I think I just did a series of questions about actually what was the involvement of patients?[8] What did all this mean? I got a call from the Department of Health asking me to join the Partners Council. So I always think it was that seminar, my asking if patients were going to be involved in this, that I got involved with the board, and at that point I was just about leaving the National Eczema Society, I was about to take up my first CEO role in another charity, and I thought 'I can't represent the National Eczema Society, I'm about to leave' and what I was told was 'we want you as an individual, it doesn't matter who you are working for' and what I had found when I went on to the partners council, was that about a third, no a quarter, of the council was patient representatives, either organizations representing patients or, like me, three other individual patients reps, which was so unusual.

By then I had been working in health charities for quite some time, and it was very difficult to get a seat at the table, and suddenly we were on the advisory committee to this new organisation helping to shape what they were going to be, and what was quite impressive, being quite cynical at the time – having been round tables where nobody was listening – was that when we made suggestions they were actually acted upon, one of the first things that was suggested was there should be a patient representative on the appeals panels that had just been set up for technology appraisals. I remember Andrew you saying 'oh yes, I will take that to the lawyer' and before I knew it I was one of the patient reps on it. So I really found that we had loads of questions going in, but quite quickly NICE was showing it was more patient-focused, and our cynicism before … [27:36 unclear], so yes, that was my experience of it.

[27:40] NT: Can I ask, we have already talked about the medical profession in particular, and its varied attitude to this. Does anyone have a sense of whether the Royal Colleges were in favour of the creation of NICE, did they, David?

[8] Charles Dobson, DH civil servant, responsible in 1997 and after for aspects of medicines policy.

[28:00] MR: They were okay actually, it was slightly awkward because the government had very little money to give us, and most of the money that we had to start with was money that had previously been given to the colleges under the terms of clinical effectiveness research or something like that. It was given by the Thatcher government in order to buy the colleges off when there was some particular row going on, and the first thing, one of the first jobs I had to do was to tell the Royal Colleges that the clinical effectiveness research money that they used to have, they weren't going to get it any more, it was all coming to NICE. However, I bought them off by getting them to take a major role in developing the guidelines, so they in a sense had the money back, so it was okay. The BMA was okay.[9] The outfit who was not okay, and you will probably come onto it, was Richard Smith at the BMJ, he was quite heavily opposed to us and very critical for the first few years.[10]

[29:20] NT: Paul?

[29:26] PA: I was just going to throw in here that one of our interviewees, almost certainly David, who can comment on whether it really was him, said that NICE simply wasn't on most Colleges' radar until it was too late for them to work out what was happening, is that right David?

[29:38] DP: Yes, I mean, I was thinking that the period between the white paper, when NICE was a paragraph as I recall, and the legislation and the regulations and the birth of NICE, was characterised by not having a lot of formal inclusion mechanisms whatsoever. So it was quite remarkable that once NICE was created, having open methods of involvement and inclusion became the touchstone of the new organisation, because it wasn't the touchstone of how it was created. Once Mike was appointed he was a roving ambassador doing huge amounts of work in individual meetings that at least ensured that there was no organised opposition. I think the colleges were a bit taken aback, not just by the money side, but by the fact that the new Labour government had jumped onto a piece of turf that they might have considered theirs before.

But they were too late at organising themselves on that, there were some discussions that they would set up NICE themselves and it would be truly at arms-length from government because it wouldn't be a government institution. But I don't

[9] BMA: British Medical Association, representative and negotiating body for UK doctors.
[10] BMJ: *British Medical Journal*, scholarly journal

think that proposal came forward until we had actually got the full draft regulations and they were about to be laid before parliament, it was far too late.

[31:23] NT: Right, and that sort of leads into the next bit, which in the creation period – Labour government – which of the politicians do you see as being most influential in the creation of NICE?

[31:40] DP: Well, my recollection of the period was that the actual detailed work to do the creation was very technocratically driven by key civil servants, Clive Smee in particular and through Clive to his network of contacts. The political advisors were active, and from time to time Alan Milburn was and the Secretary of State was to a degree, but not in the design work really.[11] They were involved in the decision that such an institution should come into being, but not really in the boundary definitions of its work, and there was huge debate about the technology appraisal programme and the rationing questions, and the cost effectiveness questions, and there was political endorsement that that debate should happen, but not necessarily political drive and leadership saying 'and once you have had your debate the answer should be such and such'.

[32:50] NT: Right

[32:50] MR: That's about right, I mean one of the great things was when we were setting up NICE was that really they let us get on with the job and didn't interfere.

[33:02] NT: Right, that's jumping into the next section which we will get to in just a moment. At one level it seemed to me that quite a lot of ministers had a bit of a hand in this, because, Mike you have recalled that Margaret Jay at one point said to you could the Committee on the Safety of Medicines do cost effectiveness?[12]

[32:25] MR: That's right

[11] Alan Milburn, Minister of State for Health at this time (1997-98). The Secretary of State was Frank Dobson (1997-99). Milburn went on to hold that office in 1999-2003.
[12] (Baroness) Margaret Jay was also a Health Minister at the time. The Committee on the Safety of Medicines, a government advisory committee, was chaired by MR (1993-98).

[32:25] NT: Graham Winyard has this account of sitting in Milburn's office trying to set out what could be a departmental regulatory approach to quality and cost effectiveness, and what could be the professional bit, that was one of the bits from which NICE came.[13] Clive has recalled debates, as David has said, over all the cost effectiveness stuff, and saying when you ask questions like 'is this likely to increase the NHS drugs bill or decrease it?' the honest answer was 'we haven't got a clue – we think it will lead to more rational expenditure, but we don't know whether it will mean more expenditure or less expenditure'. So David's point that the technical design sat within the department and with the civil service is probably very valid isn't it?

[34:13] TJ: Just on that point about cost savings, I am looking at a quote here from Michael Rawlins in the *Times* from May 27th 1999, and he said 'anyone who believes that NICE will reduce NHS expenditure is whistling in the wind.' How right!

[34:32] NT: Indeed, indeed. Well, Paul, Sally, I was proposing to move onto the next bit, which is the first months of NICE, unless there is anything else you would like covered?

[34:49] SS: Yes, it's going really well, thank you everybody, we are getting some nuanced debate here about some things that we thought were quite straightforward.

[34:58] NT: So, let's move into the first months, the actual sort of making of NICE. How far did you feel that a lot of it had actually been laid down by the department, and how much did you feel that you were actually inventing this from scratch? Because there were bits in the white paper, in the regulation, like a Partners' Council for example, so it's a question of how much did you have to make it up, and how much was a blueprint there? I guess we should start with Mike and Andrew for that.

[35:34] MR: To start with, we just knew the programmes that we were expected to undertake, it was both health technology assessment [HTA] in terms of cost effectiveness, but also guidelines. Right from the very beginning I always thought the guidelines were critically important, and so the first board meeting we only had two items on the agenda; first was the appointment of the chief exec, the second was the appointment of the chairman of the appraisal committee.[14] It was slightly awkward

[13] Graham Winyard, Deputy Chief Medical Officer at DH
[14] NICE's Appraisal Committee (later plural) was responsible for Health Technology Assessment

because our statutory instrument, or whatever they were called then, indicated that although it was a board decision, the appointment of both those posts was to be agreed beforehand with the Secretary of State, and so we did that, we did that and there was no argument and at the meeting I remember saying that there really can't be that much discussion about this, went into how the appointment had been considered, and would we please appoint Andrew Dillon - we start tomorrow and without a chief exec we are in trouble, and they all did the decent thing and agreed, and Andrew came and joined the meeting. Remember that Andrew?

[37:14] AD: Yes I do, yes.

[37:18] NT: Andrew, what attracted you to the job? You were running St George's, a big teaching hospital and a very senior post, what was it that made you want to apply to join this entirely nascent body?

[37:34] AD: Well, by then I had been at St George's[15] for about eight years or so, and I had been thinking about what comes next: do I carry on for another eight years or some indefinite period or do something different? I had decided that I wasn't particularly interested in the commissioning side of how the NHS was organised at the time, so the obvious option would have been to move on to another trust chief executive role. So I suppose that was what I had been thinking, until the job at NICE was advertised. To go back to the earlier conversation, I had not heard about NICE until I saw the advert in the paper, and I don't think much of the debate about the need for a national body, or approaches to more forensic and objective ways of making decisions about new treatments and services, had filtered much into the management system in the NHS. Though it might have done, it may just have been that I just hadn't picked it up.

When the NICE job was advertised I was attracted to it because although I hadn't thought about doing something radically different, it just seemed really interesting. In those days nobody talked about 'start-ups' in the way they do now, but I guess it had the feel of a start-up. It was so different, it was a completely new organisation. I do remember being intrigued by the idea, not so much about the drugs side of it, but just the general notion that this would be a national point of reference on decisions that as a hospital chief executive you would get embroiled in all the time. So much of that debate – in the time when I was a hospital chief executive – took place in the almost

[15] St George's Healthcare NHS Trust in south west London

total absence of objective information that both sides could share in order to reach a decision.

The idea that there could be some national point of reference on new things just felt good. I suppose the other thing was that having done twenty five years of my career in hospital management, which is a pretty stressful role, , and the idea that I could step out of that and do something different, but that was so connected into the world that I was familiar with, and something at a national level too, was intriguing.

[40:38] NT: Where did David Barnett come from?[16]

[40:45] MR: He applied to become chairman of the appraisal committee, when we started off we didn't think of having more than one, so he applied. There was another applicant but David, and I didn't know David, really at all, but I was particularly impressed that he was willing to forego being a Censor at the College of Physicians, which is sometimes a stepping stone to becoming president, to join us at NICE. I was impressed by that, and Frank Dobson agreed, and so we appointed him at the same board meeting that we appointed Andrew.

[41:22] NT: Right, so in a sense you have covered the next question, which was 'what had been decided by the first board meeting of NICE?' which was these two appointments had been made. Just to go back to how much did you have to invent question, it looks from the outside that the concept of the partners' council was already there, there was a lot of stuff you could draw on from the Health Technology Assessment Programme, the work of the DECs and what have you, the QALY was there as a tool.[17] Andrew has just talked about it being, effectively, a start-up. How much did you have to invent?

[42:13]: My recollection was that the script from the technology appraisal programme was reasonably clearly set out, so the methods and processes were sufficiently evolved to allow that programme to start quite quickly. That wasn't the case with the guideline programme. Mike mentioned earlier that there was the question of how that programme was going to be resourced, with money that had to be pulled back from the colleges and then reinvested, and that reinvestment required the creation of

[16] David Barnett, inaugural chair of the appraisal committee (1999-2009), consultant cardiologist
[17] HTA Programme, established by the NHS R&D programme in 1993. QALY: Quality Adjusted Life Year, leading measure for the measurement of the health impacts of clinical interventions

collaborating centres, which were going to form the principle resource for developing the guidelines. All of that took much longer, and it wasn't until really the back end of 1999 that I remember there was an ordered, organised approach to all that. David will remember, because of course David came in pretty early on to support the development of that programme along with Peter Littlejohns at the time.[18] The other thing of course was, it was one thing to have a theoretical approach to doing those things and producing those products, but we needed to recruit people and organise a team and have a structure and a way of working that both internally and also in terms of all the external engagement that would allow us to generate something that people can have a look at.

[43:45] NT: David, you have your hand up…

[43:45] DP: Yes, I was going to say, picking up those points from Andrew, I think the core technology, if I can call it that, of technology assessment, the methodological technology, and in fact to some extent the core technology of guidelines development, existed out there, but what didn't exist and was no part of what the department handed over, was the both governance in organisational terms, and the governance in terms of all the mechanisms for stakeholder engagement that were built on top of that. As Andrew says, they were working in partnership with the colleges to produce something which would at the end of the day be an official NHS guideline, rather than a guideline published by the Royal College of whatever. We had no track record to pick up on doing any of that, it all had to be invented, and I think it was invented. The department didn't hand over to Mike and Andrew any sort of blueprint for how to do the operations of the organisation, except that a couple of appointments had to be made and there had to be a partners' council. The rest was built, the actual organisation, really from when Andrew was actually starting or about to start, and operating via remote control from St George's.

[45:18] NT: Tony?

[45:18] TC: I don't think, I certainly didn't, realise until about 1999 the extent to which NICE was going to evolve in this sort of very open, multidisciplinary, multi-professional sort of way, which in fact, it came to involve a very large number of people who essentially gave their time. I think the only reward was, at least in the early days, a first class ticket, subsequently it was only standard. Of course the real reward was very exciting company to be mixing with, and particularly for the

[18] Peter Littlejohns, Professor of Public Health, King's College London, and founding Clinical and Public Health Director of NICE, 1999-2012.

academics - of which very large numbers were involved of course - particularly for the academics the idea that your participation was very close to policy. Most academics, unless they are political advisors or something, write stuff and it gathers dust, here was an opportunity for academics to get involved in the creation of and the implementation of policy, and I think that, I'm not quite sure how Andrew managed that, but it is something that as I say I don't think I quite anticipated in the early days, just how exactly we were going to be dependent on this army of volunteers. I don't think it is a mis-description to say that it was like an army of volunteers. Although that didn't emerge in 1999 it became an implication of nearly everything that we decided in those early days, the whole business of stakeholder collaboration.

[47:22] NT: Mercy?

[47:23] MJ: I was going to say, I remember being on the Partners' Council and a lot of the professional bodies, the presidents of the Royal Colleges, I remember that very soon the patient reps felt that we should get together and brief ourselves before meetings, because we felt out of our depth. Little did we know that all the Royal Colleges did as well, because when we talked to them individually, they weren't talking to each other, whereas the patient reps were talking to each other. In fact, in those early days at Long Acre, NICE gave us a room to meet, just the patient organizations, so that we could prepare ourselves for Partners' Council meetings, because we took them really, really seriously.[19]

We started to feel that we were shaping an organisation, that we did have a voice. So we wanted to prepare ourselves, so I found it really quite interesting to get an insight into the professional organizations, who weren't talking to each other, because I thought 'they all know what is going on, and we don't' but actually it was the other way around. Because we were briefing ourselves, preparing ourselves, getting our list of questions out there, and actually quite early on Andrew produced a paper on patient involvement that we all commented on, that was very early on. So already we were getting the feel that this was a listening organisation. So that was quite important, in those early days of the partners' council we really felt that we were shaping policy.

[49:10] AD: Just going back to Tony's point about the early and pretty extensive process of engaging with resources outside of NICE, and being open and collaborative. Some of that was just because we didn't have enough money to do it

[19] Long Acre: London address where NICE's office was situated at one time.

any other way. We had so little money at the time, we had to move quickly, and we weren't confident that we could recruit people even if we did have the money. NICE was so new and the sort of people who had all the really strong technical skills might be rather hesitant about coming to a completely new organisation from wherever they might already feel secure, in the NHS or academia or industry. So being able to go out to a community of willing collaborators, whether it was people in your community Tony, in health economics, or the huge array of other experts, who we needed in increasingly large numbers in order to produce what we were doing, was really important.

Mike, I know, particularly, from the start, was absolutely convinced that the only way we were going to be credible with all those communities, would be to draw them into the development of our recommendations so that there would be a shared ownership of the things that we would be producing.

[50:49]: Andrew, do you have a view on that? Andrew Stevens?

[50:55] AS: I was very impressed with how Mike and Andrew got everybody involved, both from the moneymaking and the moneysaving, and also for getting people to feel that there was an ownership of it, that was a great success. My view of the whole thing comes as from an early committee member, either Mike or David Barnett asked me to become vice chair, which I was very privileged in sort of getting into the inside, as regards to the earlier question of whether people felt out of their depth, I have to say that the health economists did not feel out of their depth, Martin Buxton and Karl Claxton and the others, were very comfortable with what they did, and probably the more numerate physicians too, they felt very at home.[20]

[51:50]: NT: Right. Trevor, how did this look from the industry's perspective? They were on the partners' council, did they feel it helped?

[51:49] TJ: Let me first say, without sycophancy, that NICE has done an incredibly great job, for the last fifteen or more years. It has led the way in the world, and it has taught the industry actually that it has to get data, real-world data, to justify prices and so on, and in no small measure Tony, Andrew and Mike have led that. I just want to say that that's where we are. But in those days, those uncertainties I mentioned earlier about delays, there was this fear that actually there would be

[20] Martin Buxton, Professor of Health Economics, Brunel University 1980-2014; Karl Claxton, Professor of Health Economics, University of York

leaks, and there were leaks, about what was going on, and provisional information was going out there, and that could really scare the horses in the marketplace and companies were saying ‘my share price is being affected’ because of uncertainty. What that led to was a lot of international chief executives saying ‘I’m not going to bother coming to Britain for a while, I’m going to get my product launched elsewhere while you sort this out’ and that meant that the patients weren’t getting the access to the new medicines.

Indeed, and I quote here from the paper at the time, one of the big chief executives from one of our own companies, said, and this was over the uncertainty over beta-interferon, that if you block that ‘we would certainly think about moving our headquarters operations out of England, and certainly we will consider investing far more overseas, and there is no overriding reason that we should be in the UK’. My concern as the director-general, with the chief executives of these companies, was ‘we are producing an unstable area at a time when we are doing some really big advances in medical science’ the issue of the taxanes, women with breast cancer not getting the treatment here that they were getting in Europe, the fiasco over whether Relenza was cost-effective, how many communities, led us to this very unstable period.[21]

Fortunately, by good discussion with Andrew, Michael and so on, the industry got out of that. I have to say that one of the sequalae of that was that the cost of bringing a drug to market almost doubled, because we realised that in order to get the right comparators in the right countries, you know, whatever was the benchmark in Germany might not be the same benchmark in the UK, then you have to do more and more patient comparisons, and you weren’t doing that to get more efficacy data or more safety data, but to get more data to put into the HTA appraisals, and that is just a fact of life. So those early days were very uncertain over whether we were going to lose the industry investment here, and hence the fruits of the research of our academic community, as well as whether patients were still going to get delays. That took a bit of time, but fortunately it got resolved by good discussion, and we have seen the fruits of it.

[55:05] NT: Mike, Andrew, Tony, would you like to comment on that?

[21] Taxanes: class of chemicals forming active ingredient of some cancer drugs, such as Taxol, subject of NICE appraisals from c. 2001. Relenza: drug licensed in the UK for influenza, 1999, but not at first judged cost-effective by NICE (see pp. 22-23).

[55:10] MR: Not on that, but I just want to make a comment, back to the guidelines actually. The person who was extraordinarily helpful was Martin Eccles, and for a time we did actually have a guidelines advisory committee which perused each guideline as they were developed to ensure their validity.[22] Martin was extremely helpful, and we should acknowledge that, and the value he was to us.

[55:41]: AD: Yes, absolutely.

[55:45] TC: The impression, I think, Nick that you seem to be getting is that there are huge amounts of uncertainty on both sides. From the industry's perspective of course that was what it was, the professions or the clinical professions felt huge uncertainty as to what this meant. At NICE we didn't know if it was going to work, nearly everything that we did, nearly all the things that we did have become topics of considerable interest in academic circles since, mostly health circles but not exclusively so, the whole business about deliberative processes, for example, more process-y type things that NICE essentially invented on the hoof. None of us were professionals on any of this, I don't think we knew any professionals who could really advise us, the thing was tremendously risky from every perspective, people were taking different risks.

I think that is another reason [for] the strategy of openness, stakeholder involvement, being honest about what we don't know, what we need to know, how we are going to do things, having a system that enabled appeals to take place, to have a system that was reasonably transparent so that we could see what was going on, it was all… it all had a big snag of course which was that it was dreadfully slow, and that was a very difficult one that we tackled subsequently, but not in 1999 or 2000.

[57:47] AD: Triggered partly by what Tony has just been saying, this a sort of contextual point. What I remember is just how chummy everybody seemed to be. I had just stepped into a world of which I had absolutely no knowledge. I didn't know anyone in the industry particularly, drugs were just another troublesome budget line if you are a hospital chief executive, I didn't know anyone in the HTA world, at all. I had some knowledge of and a little bit of contact with people in the colleges, but in general this was a world I was unfamiliar with. Two things struck me; one was just how pleasant and polite people seemed to be generally with each other, and if you have been a hospital chief executive that is not necessarily an emotional

[22] Martin Eccles, chair of the Guidelines Advisory Committee, NICE; Emeritus Professor of Clinical Effectiveness, University of Newcastle

environment that you are familiar with. So that was a big tick in the box for me, and the other thing I remember was just how much everybody liked Mike.

I remember, Tony, those early meetings you chaired with the health economists and the clinicians who had knowledge of the evaluative methodology for looking at new drugs. I also remember meetings with college presidents or other college representatives at which and while everyone seemed to know Mike. Nobody knew me at all. For a short period I felt as if I was just observing a team, rather than being part of it. I remember that quite vividly, and being hugely impressed, and actually quite relieved that there was someone (Mike) who had the right connections and who had a profile in all these communities that I knew were going to be so important to the early stages of building NICE and ultimately for its success.

[59:54] MR: [Inaudible]… the College of Physicians, George Alberti was the president, and he was an old friend from Newcastle so that helped a lot.

[1:00:06] MJ: Even the appeals committees were non adversarial, so those early days, when actually we were quite a small room anyway, so that differentiation between the panel and those presenting, there wasn't, it was quite a, I suppose even though we were following process and things like that, I remember at the end of the digital hearing aids appeal, we were asking the person who was using them to demonstrate a bit, it was just more chummy. The big change was when I did the beta interferon appeal, when you had four barristers from all these different appellants, and things, this huge room, and it completely changed, it was much more adversarial. But I remember those early days when it was, you know, non adversarial, we were just trying to make sure people followed process, things like that. And then it kind of really changed over the years, that was one of the things, that kind of friendliness, getting on, even when actually you were on opposite sides of the table, then changed over the years.

[01:01:27] AD: You're right Mercy, I remember the first appeal was for the original decision on Relenza, and that was so friendly that when we had a break for lunch everyone just piled into the same room to eat sandwiches. And so there were people from Glaxo Wellcome there, people from NICE, and obviously other members of the appeal committee.[23] Everyone was just sort of chatting happily about the events of the morning, 'how do you think it's going to go?' and 'do you think we're going to win?' It was really quite a collegiate sort of atmosphere. As you say, it was very different from appeals as they eventually became, particularly after the lawyers

[23] Glaxo Wellcome were the manufacturers of Relenza

appeared, when the whole thing became highly structured, often very tense. Definitely lots of degrees of separation between participants at any break. It really was a very different atmosphere in those very early days.

[01:02:37] NT: Trevor, in terms of relationship with the industry, I mean – Mike must have been known to the industry up to a point, because he had been with the [Committee on the Safety of Medicines], a long background in medicines regulation. I think you had known him for a long time. In terms of the chief executives of Glaxo and others, what was their view?

[1:03:04] TJ: Well it wasn't about the personalities. People knew Mike very well, and respected him, and of course his Newcastle days, a lot of us gave lectures and whatever. It was really the issue of what we called 'NICE blight'. Despite all the good attempts and so on, whilst all these provisional information leaflets, the PADs were going out, people just put away their prescribing pens, and internationally people were saying 'whoah, wait a minute – if there is going to be a problem, maybe we don't do that'.[24] And that wasn't helped by, you know, definite leaks that occurred in that first year, particularly, about whether or not this was going to get approval. So it wasn't about the personalities, it was about the process, which got tightened up.

[1:03:56] NT: We have sort of touched on this a bit, but there is a question here: 'what went according to plan, and what was unexpected?'

[1:04:00] PA: Which is a good place for me to ask if we could just talk a little bit more about those leaks? I've heard how important they were to the pharmaceutical industry.

[1:04:11] NT: Were you aware of them, Andrew Dillon?

[1:04:15] AD: Leaks? About individual appraisals, you mean? I have a recollection of the first one.You probably remember this as well Mike, I can't remember what the topic was now, but it was in the days when the consultation documents were confidential to the stakeholders.and there was a leak. I think it must have been the first time that it happened, because it seemed to be quite dramatic.There were all

[24] PAD: NICE's Provisional Appraisal Decision, issued while the Appraisal Committee's initial decision was out for consultation

sorts of concerns about what impact this might have on the commercial prospects of the company involved and so on.

I remember the Department of Health became very concerned about it. Simon Stevens made it clear, that it was necessary to conduct a formal investigation to find out who had been responsible for the leak.[25] I don't know if you can Mike, but I can't remember what the outcome was but I don't think the culprit was identified. I was very impressed by the idea that you could get people in to work out who had spilled the beans, though.

[01:06:23] MR: There was an inquiry. But I think they came to the conclusion that they didn't know quite how it worked, but the other thing about leaks was, in the days which, as you say Andrew, the papers were confidential, was the problem of the extent to which releasing these documents was share-price sensitive. I actually went to see the chairman of the Stock Exchange, I forget who it was now, and I explained the problem and he said 'you have got to be public, I can't force you to be, but you have got to put them in the public domain, so that the stock exchange, stockbrokers, investors, can all have, in theory, access at the same time, rather than confidential.' And that was I think, Andrew, when we stopped making them confidential.

[1:07:13] AD: I think that's right.

[1:07:15] MR: I think it also stopped the problem of leaks! Because, you know, who wants to leak a non-confidential document!

[1:07:24] TJ: I think it is useful to have that clarification. I am reading from an article in *Chemistry in Britain* from August 2000, where the leak, this was over the multiple-sclerosis and beta-interferon glatiramer, 'the leak came after NICE circulated its PAD to interested parties, patient groups, medical professionals and the manufacturers in mid-June. In a statement released shortly afterwards NICE blamed one of these groups for the leak.' Then it goes on to talk about the need for transparency, which of course frightened us again about what information was going to go out there, and as Mike says would that be share price sensitive. I think all that was a really important lesson, and it all got tightened up, or we became less secretive, and that has worked very well.

[25] Simon Stevens, at this time Special Adviser at DH (1997-2001); Prime Minister's Health Adviser, 10 Downing St Policy Unit, 2001–04; Chief Executive, NHS England, since 2014

[1:08:09] MJ: I remember when it came to the Patient Council [sic – Partners Council], the person and, Andrew said, 'we should publish this and go open with it', the only people that objected were the industry, the rest of the Partners' Council were quite happy with that suggestion. Though I actually think that the leak came from a patient organisation, I am not completely sure but I think it was, who went to the papers with it, so yes.

[1:08:44] NT: I bet the leak inquiry got nowhere, having been involved in a few of those and they don't very often find out what happened. Are you happy with that Paul, can I move on? In a sense, we have almost touched on this – but what went according to plan, and what was unexpected, is the question here. I suppose one answer to that might be, in the first instance, Relenza, which was kind of both!

[1:09:18] MR: Relenza was, of course, to start with Andrew's baby, because he chaired, what did we call it at that stage?, the committee that did that, and then I chaired the appeal. That was in the summer of, we published I think in September or October, Glaxo was absolutely incandescent, particularly, Richard Sykes.[26] Stormed into Downing Street and Tony Blair backed us, and said 'I have set up NICE to make these difficult decisions and I am not going to interfere'. That was a very important lesson actually, that there wasn't going to be political interference in our decisions. Andrew, you will remember it very well.

[1:10:19] AD: I certainly remember it and it strikes me now that one of the more bizarre aspects of the early days of NICE was that I was asked to chair an appraisal committee. Looking back on it, and it was you Mike that said 'you're the chief executive so you should do it', and I am thinking, well I have absolutely no idea how to chair a scientific advisory committee. And it was in the end a one-off, because after I had done it I can remember you saying 'it is really important that you never do this again.' I think at the time I interpreted that as meaning that I had more important things to do with my time, as opposed to the fact that it had been such a disastrous experience that it was necessary never to put me in a position of doing it again! It was odd, but curiously very enjoyable, I remember the people who were on that committee, Andrew you were on that committee, weren't you? The first rapid appraisal committee?

AS: Yes

[26] Richard Sykes: then Chairman of Glaxo Wellcome

AD: Anyway, the people on it were just extraordinary minds, and made it really easy, We had Rod Taylor, who was briefly the director of the appraisal programme, who was just very good at summarising evidence and drawing conclusions, or drawing people together in a conversation to reach conclusions.

[1:12:00] NT: Andrew Stevens?

[1:12:02] AS: Well, I can remember the details of the Relenza appraisal, Andrew chaired it very well, so it must have been that he was too busy, rather than that he had failed on that particular task. It exposed a lot of things; as I remember Glaxo/ GSK had put forward three big trials, all of which specifically excluded anybody at risk, and the appraisal was about the at-risk groups, it seemed almost sort of bizarre to the committee that anybody should have thought it would go otherwise, as we in effect had no data on the question in front of us.

[1:12:44] NT: Anybody want to add to that?

[1:12:48] MR: No, and I think Paul you have seen it, but we got support from the *Times* in a leading article.

[1:13:02] PA: Not to mention *Private Eye*

[1:13:05] MR: (Laughs) And *Private Eye*, yes

[1:13:09] TJ: The initial decision, as I understood it, was ‘no’, and then eventually there was a further decision about selective groups, elderly people and so on.

[1:13:20] MR: That’s absolutely right. A year later Glaxo came up with data showing its benefits in elderly people.

[1:13:30] NT: Yes, in a sense that was NICE process working as it should, wasn’t it? [general assent]

[1:13:35] AD: Then the appraisal committee was chaired by David Barnett, and that positive decision, the change from the initial negative decision to the positive decision was as a result of David's casting vote at the appraisal committee.

[1:13:57] NT: Gosh

[1:13:59] TJ: The difficulty is that obviously it is very nice to have a large population, well phenotyped and genotyped, to look at the benefit and risks and so on and efficacy of a product. We are seeing with the current COVID19 pandemic, that you have to take decisions with limited data, that may actually turn out not to be the right ones later. Somebody said last week in the press about the use of some of these early interventions, as yet not subject to major placebo/control studies, well nobody ever did a placebo/control study on parachutes! This is the difficulty, isn't it, for regulators and for health technology appraisers, that where there is a real need for a product or a treatment, we mustn't forget that NICE was much more than medicines, very, very importantly about different therapies. But where there is a need and there's not enough data, then those difficult decisions have to be taken without having all the facts that you would really like to have.

[1:15:10] AS: There is very good data on parachutes, it may not be an RCT, but the data is very good, and NICE would have passed them at the drop of a hat.

[1:15:19] NT: Indeed, indeed. I wanted to go back slightly, and inject something which, from my point of view – I was a journalist covering this at the time – talking about the early days of NICE, talking about stakeholder engagement, I thought the handling of the media was exemplary. I would like to think that I understood what NICE was about from the beginning, because I covered the evidence-based medicine movement and what have you, but for a lot of my colleagues this was just terribly strange territory. This was the 'rationing body' and of course the *Daily Mail* still calls it the 'rationing body', but there was a huge amount of effort that went into trying to explain, via the media, what it was all about, and I think that was impressively successful, from my point of view, that's just an observation. Two other things, I'll move on in a second, David, at one point you said when we were talking about the involvement of ministers in the department, you said that the special advisers did get engaged, I presume that was Simon Stevens, is that right?

[1:16:34] DP: Yes, I think, though I was talking about the stages before NICE came into being, there. I think the extent to which the department was involved or not involved after NICE was created was interesting as well. From the period when NICE

came into being until NICE's independence being backed on the Relenza decision, I am not sure the department really wanted to let go. I particularly remember it because it was quite awkward for me, I had been in charge of the project to set up the organisation, and then I was sent out on loan to NICE, and I would be subject to phone calls from old colleagues who thought they needed to keep a grip on what was going on inside NICE, but I think eventually most civil servants realised that not being involved in NICE decision-making was what they needed, that was why it had been set up in the first place: to put a distance between the political machine of government and the decisions made on clinical cost-effectiveness. But I think even the department struggled with that up until, and probably beyond Relenza. And then there were the cancer drugs of course, which illustrated the department's unwillingness to let go again, but that was later.

[1:18:14] NT: And this is a really, really trivial point, that jumps back, Andrew Dillon, when you were appointed did you just apply to an ad or were there headhunters involved?

[1:18:28] AD: I wasn't contacted by headhunters – I found out about the job through an ad in the paper, but the application process initially was handled by headhunters. Just a thought on what David was just saying about the department, I must admit that I didn't feel at all that the department was sitting on NICE in any kind of unreasonable way in those early stages. I recognised that given it was a completely new entity in a pretty controversial high-profile area, that the department inevitably was going to take a close interest in how the organisation was going. But I certainly never felt that we were being unreasonably constrained or prevented from doing the things that we thought were necessary in order to keep the organisation going. If I reflect back over twenty years, I would say that the department was more actively engaged, if I can put it in those terms, in the operation of NICE, at the end of that twenty-year period, than they were at the beginning.

[1:20:04] MR: The other person who was in the department who was very helpful, not critical – but helpful, was Simon Stevens. Both when he was at the department of health and when he went into No. 10. Nick and I were at some of those roundtable meetings with Tony Blair, do you remember Nick?

[1:20:26] NT: Vaguely, yes. Vaguely.

[1:20:29] MR: There were only two journalists there, you and Niall [Dixon], from the BBC

[1:20:35] NT: Right. And of course it was Simon who was instrumental in the funding directive, wasn't he – when that came.[27]

[1:20:45] SS: I wondered, you may have already talked about this, whether the permanent secretary had any direct interest or influence over NICE. This comes up because you talk about that period around 2000 when you have a change in perm sec. you had Chris Kelly in there from 1997-2000, and then Nigel Crisp comes in in 2000, and is there until 2006 I think. Nigel has had a mixed press in terms of his capacities, and his oversight of what was happening in the various bits within the department, but what I am interested in is those external relations. Maybe we could have some reflection on Chris Kelly and Nigel Crisp, and their attitude, or is that beyond this group to speak to?

[1:21:52] AD: Well I don't really remember either of them taking much interest, although that is probably the wrong way of putting it – I am sure they were both interested – but neither of them engaged particularly with NICE, either strategically or operationally.

[1:22:13] MR: I agree – neither of them.

[1:22:16] AD: As you probably remember, Mike, and probably David as well, was just how closely involved the ministers were - the secretary of state, and Tony Blair as well, personally, in NICE. So the contact we had with the department wasn't really with officials at all, other than the sponsor team, the NICE handling team, on a day-to-day basis. Beyond that all the contact for the really big issues and the strategic issues we were facing was with the special advisers and the ministers, direct.

[1:22:52] MR: I completely agree Andrew.

[1:22:58] PA: You have both referred to special advisers, plural. So there is Simon Stevens, surely not Joe McCrea, or was it?

[1:23:08] AD: I can't remember

[27] Funding Directive: Ministerial Direction to the NHS in 2002 that when a NICE appraisal found an intervention to be cost-effective, NHS organisations were to fund its use

[1:23:08] MR: There was a special adviser at Downing Street

[1:23:10] PA: Robert Hill?

[1:23:13] MR: Robert Hill, that's right. So we had some discussions with him, yes. But mainly with Simon.

[1:23:24] AD: And somebody called Chris Ham, I've got a vague recollection of, no idea what happened to him [laughter][28]

[1:23:32] PA: What about Robert Hill, can you recall anything about specific subjects you might have talked to him about?

[1:23:37] MR: I can't, no. Can you remember Andrew?

[1:23:39] AD: No, I've got a much clearer recollection of the kinds of issues that Simon Stevens was involved in. For example, the decision that Simon took, or somebody took in the department but it came through him, to take away the responsibility that we had had originally for managing the national confidential enquiries, which were then transferred to the National Patient Safety Agency. Something that, Mike, that you might remember we really objected to at the time, I think we both felt strongly that it was a better fit with NICE, but they were, in those days, looking for functions to give the NPSA to do.

[1:24:22] MR: Yes, we were disappointed when they moved it away. But in those first two or three years we also got John Grimley Evans to do a review of the confidential enquiry.[29]

[1:24:34] AD: Yes, absolutely – I had forgotten that, so we handed them over in good shape.

[28] Chris Ham: Professor of Health Policy and Management, University of Birmingham; DH Strategy Unit 2000-2004
[29] John Grimley Evans: Professor of Clinical Geratology, University of Oxford; medical adviser to DH

[1:24:43] NT: Can I pause for a moment and ask Sally and Paul a question – if you look at the rest of the questions that are on your outline sheet, we have pretty much touched on all of them already, like 'what it was like to work in the early days of NICE' we have talked about the collegiate atmosphere and all that sort of stuff, purely personally I would be interested in some questions about some of the later period, but do you not want me to go there?

[1:25:09] PA: No objection to you going there, if the participants will play along, please do.

[1:25:16] NT: One bit that particularly interests me…

[1:25:20] PA: I should say that we are going to have more witness seminars later, which will cover later times, but that's fine

[1:25:25] MR: The thing about the early days, Nick, was the antagonism between us and Richard Smith, who was the editor of the *BMJ.* Antagonistic pieces, 'time for a new NICE' was one of his headlines, or something like that.

[1:25:48] NT: Yes, Richard was a key movement in the Rationing Agenda Group, he was deeply into 'cut the cloth'.[30]

[1:25:55] MR: Five years later he wrote another article, 'Britain's great gifts to the world; Newtonian physics…' I can't remember the other one, '… and NICE'

[1:26:04] NT: Yes, 'the Beatles, Teletubbies and…' I can't remember, something else

[1:26:07] MR: That's right, 'the Teletubbies…' and NICE. And of course since then the *BMJ* has published summaries of our guidelines. Well, NICE's guidelines, sorry – not our guidelines.

[30] Rationing Agenda Group: 1990s lobbying group, regarded rationing of health services as inevitable in the UK and promoted debate on how to undertake it. See Bill New, ed., *Rationing: Talk and Action in Health Care* (London: Wiley/King's Fund, 1997).

[1:26:25] PA: It would be good to explore this a little bit more. Richard is a person who hasn't agreed to be interviewed, so if anybody can shed light on why he felt the way he did, even second-hand, then that would be quite helpful.

[1:26:38] MR: Why won't he… is he embarrassed by his initial antagonism? Hostility to NICE?

[1:26:45] NT: My view would be, you know, you have to remember end of the 1990s there was a real debate about rationing. And we have discussed what we mean, I share Mike's view, rationing is giving everybody the same amount, but there was this debate about rationing. And some very, very senior, otherwise level-headed people were saying that the NHS would have to be restricted in some way. Chris Ham sat on a pharmaceutical-industry funded working party that Duncan Nichol, the ex-NHS chief executive chaired, of which Patricia Hewitt was the secretary, which was talking about how you might have to restrict the nature of the service in one way or another.[31] Richard Smith was very involved in that, very involved in the Rationing Agenda Group, and looking back it was a very, very widespread view that we might have to constrain what the service did, in sort of serious ways. Richard was part of that, and if my memory of his very hostile early leaders in the *BMJ* were actually that this was actually quite a good idea but it won't work. And it was a good idea because he thought it ought to be rationing services, and he didn't think that would work.

[1:28:14] MR: There was a group called the Rationing something Group [NT: Rationing Agenda Group], that's right.

[1:28:22] NT: There were quite level-headed serious people involved in that.

[1:28:28] TJ: I remember having that conversation with Richard around that time, and he was concerned very much about the overall spend of the nation on the NHS. And that is reflected of course in his editorial of March 27th, 1999, in which he says 'centralised direction is a poor way of solving the NHS' bigger problem: the amount of money available to spend.' That was his mission.

[31] The group was called Healthcare 2000. Patricia Hewitt, then prominent in the Institute for Public Policy Research and the Labour Party, went on to serve as Secretary of State for Health, 2005-2007

[1:28:55] DP: I was just going to say that I think this applies to Richard, but some others who were around at the time as well, that there were commentators who were very keen and supportive of the fact that the agenda that NICE was tackling [what] needed tackling, in terms of our publicly funded health services, but by character and inclination, were not the kind of people who were comfortable about what NICE became, which was, inevitably, a large guidelines factory, a rather corporate beast, for all it might be open and inclusive, making singular decisions on behalf of society as a whole. These were very individualistic people, I found, in general, who were sounding off about these things. And there was no way we could ever do right by some of them. However elaborate and open our processes, because they weren't in favour of there being a national guidelines factory that made decisions that they knew better about.

[1:30:00] MR: Yes, that's right. People would be embarrassed nowadays, but this business about 'clinical freedom' was tossed around quite often, and nowadays I don't think people would dare talk about clinical freedom in that sort of way.

[1:30:20] NT: Tony?

[1:30:20]: TC Maybe not here, but what about the States? Mike, tell us some of your recollections of being mauled by the libertarians in the US

[1:30:34] MR: Yes, particularly happened during the later stages of NICE, when on a number of occasions, a fair number of occasions, I travelled with minsters, initially with Norman Warner, who was very badly behaved, but that's another story. I was brought along, in large part because NICE was controversial and he was trying to persuade American pharmaceutical companies, in particular, to invest in the UK. So I was brought along to explain what NICE was up to, what we were trying to do. Norman Warner was the first one I went with, he actually said on one occasion, 'the real reason you are here, Mike, is you are my personal physician' so I did make sure I had a few drugs with me, but that's another story altogether really, my travels with ministers.

[1:31:38] NT: If you are going to do more seminars on the later years

[1:31:50] PA: I wouldn't want to stop you, carry on

[1:31:50] NT: Can I just pick up one thing that Andrew Dillon said just now, about relations with the department and how, in a sense, they have got more intrusive later, in the later years. Is that relations with the department or relations with NHS England?[32]

[1:32:08] AD: Well they are connected, I think. The creation of NHS England changed NICE's external relationships really quite fundamentally. Before NHS England the proxy for our understanding of what the NHS wanted from our guidance and its ability to action it , was informed in part by our contacts in the NHS but mainly it came through the Department of Health. With the creation of NHS England that changed completely. Not only did we have a new source for the NHS view on everything, but NHS England became the primary customer, or rather the single customer, for the majority of the appraisal programme, though not the guidelines programme.

That changed the nature of the relationship that NICE had with the department in a couple of ways. To some extent it allowed the department to pull back a bit, because they didn't need to do the things that NHS England was going to do, including commissioning some aspects of NICE's work, and in relation to some of the practical issues around, for example the resource impact of the recommendations that we were producing. However, I think they quickly became conscious that they needed to be careful not to cede everything to NHS England, particularly in terms of the core methods that NICE was operating to, especially but not exclusively in the technology appraisal programme. This is because changes in NICE's methods have both policy and fiscal consequences, in which the department has an interest and because, ultimately, NICE is still accountable to the Department, for the delivery of its mandate. So they needed to maintain their influence and ultimately, their control.

I think there was a process of letting go and then pulling back of some of those influences, against the backdrop of the more complex dynamic between the department and NHS England.. NICE sits sometimes uncomfortably between the Department and NHS England. I don't mean it as a criticism, but the way that the department structures its relationship with NHS England can make NICE's task more or less complicated. This results from the tension between what the department is responsible for and has to account for and what NHS England is responsible for, and what it sees as its accountability to parliament and the public should be. NICE,

[32] NHS England, created in 2012, was the more arm's-length successor to the NHS Executive, charged with the central direction of NHS activity

because of the significance of the relationship it has with NHS England and the department has to carefully triangulate its relationship with both organisations.

Most recently, for the last couple of years or so that I was at NICE, that tension seemed to be heightened, partly because of the growing impact of extremely expensive new technologies being introduced into the NHS, partly as a consequence of the NHS' growing capacity to undertake what it refers to as 'commercial negotiations'. It was also partly because of the importance to the government of the country's relationship with the pharmaceutical industry, as one of the 'engines of the economy' and because of Brexit and the immense nervousness around what is going to happen to the life sciences industry as the UK leaves the European Union. It's a complex situation and NICE is right in the middle of it. I think that explains the growing attention to some of the methodological detail of NICE's work on the part of the department, in recent years, compared to the more relaxed approach it was taking in the early and middle years of NICE.

[1:37:18] PA: Could I ask what sort of forms that takes, that attention to the methodology?

[1:37:22] AD: It's almost always entirely constructive.

[1:37:28] PA: I mean, topics for instance – is it the Highly Specialised Technologies programme, or is it XYZ?

[1:37:35] AD: It's almost exclusively in relation to the technology appraisal programmes, not just the HST programme. But also some other aspects of what we do too, including , the work NICE has started to do on evaluating digital health technologies, together with some aspects of the guidelines programme, because of their resource consequences for the NHS. The department felt that it was its responsibility to help the NHS manage the financial consequences of some of the guidance that NICE produced. It wouldn't suggest that the NHS shouldn't do what NICE was recommending, but it was clear that it was acutely aware that in individual cases NICE was recommending the NHS to do things that it was conscious would stress the NHS budget in circumstances in which that budget, more generally, was under huge pressure.

[1:38:45] NT: Andrew, specifically can I ask, I'm going to get the name for it wrong, but the relatively recent budget [impact] cap decision, 'if a drug is going to cost more

than so much over the first three years, NHS England can ask NICE to recommend…' was that, did that initiative, and the agreement around that come solely from NHS England or was the department involved as well?

[1:39:09] AD: I don't know whether the department was that involved in the early evolution of that concept. Clearly they became involved in it because ultimately they had to be a partner to the process that was eventually put into place, but its origins were in concerns that were being expressed by NHS England about some of the highly specialised technology decisions that were, by then, being taken. Both NICE and NHS England were also conscious of the need to avoid some of the difficult conversations that had started to emerge in the end stages of some appraisals. I felt the need to find a consistent approach to resolving those issues. Although each appraisal is unique, many of the end stage issues are sufficiently similar for there to be a protocol so that the people working in both organizations had a frame of reference to reach conclusions on them, rather than creating solutions from scratch on a case by case basis. The budget impact cap was the result of a conversation I had with Simon Stevens in the margins of a meeting, where we talked about the need for it and had an initial discussion about what the amount should be.

[1:41:19] NT: Now, I have pulled this twenty years forward, which was probably slightly naughty of me, we did say we would have a break, but Paul, Sally, it seems to me that we have covered everything that was on your set of questions.

[1:41:34] PA: Yes

[1:41:36] NT: So, in that sense we could begin to wind up, before I do, I thought we would go round and ask anybody if they have anything they wish to say about these earlier days, that has not been said and that we should have addressed. Tony, we can start with you.

[1:41:55] TC: One of the things we haven't actually raised was research. Obviously one of the things that NICE's processes were going to generate, was identify areas where more research needed to be done in order that future decisions would be better. We had a research director, I can't remember whether we had one at the very beginning, we also had a research committee, and I think we also had an effective working relationship, although I wasn't intimately involve with this at all, with the NHS R&D programme, where our priorities for research could be fed in and so on, I used to chair the research committee, which had a lot of very distinguished people on,

people like Iain Chalmers and a whole bunch of household names in the modern medicine, modern research.[33]

There was a lot of pressure, I seem to recall, from that committee, that NICE ought to have a research strategy, and I don't think we ever did have a research strategy in any overall sense, perhaps we got one after I had gone, but it seemed to me to be an area that was pragmatically resolved, probably reasonably satisfactorily, but not fully satisfactorily until the other national institute was created in which I gather NICE interests are well - I don't know whether this is a correct impression- are well-represented. However, in those early days it seemed to me that we struggled a bit with the idea of where, what our role in research priorities, research funding even, should be. I don't know whether Mike or Andrew, you have got some reflections on that? It seemed to me to be a slightly messy area.

[1:44:04] AD: I always think that there were two aspects to the research NICE should engage in; one was 'how do we connect the uncertainties that arise in the production of individual pieces of guidance, with research funders - whether that was the publicly-resourced research funders or industry in individual cases?' The other was 'what role does NICE have in conducting research relevant to its methods and processes?': how do we do better at gathering and interpreting evidence and turning it into something useful for the system?

Initially I think in both cases they were part of Peter Littlejohn's remit, Peter was appointed as the clinical director of NICE, and I confess I don't think it engaged much with me, at first, in terms of being an important part of the management agenda. I don't think that we focused a lot on making sure that we had effective relationships with the MRC, with the NHS R&D system or with other research funders, I just assumed that that happened, that it was part of the process. As it turned out, and Mike probably may be able to talk about this, it didn't seem that we were doing particularly well in that respect for quite a long time. The research questions that I had assumed were forming an important part of the agendas for research funders, weren't really being picked up.

Partly, I think this was simply because we weren't formulating the questions in a way that those funders could take into account , in the way they applied their criteria to judgements about how to apply their funding. In relation to our own methods and processes, I'm not sure how active we were in promoting things that were puzzling

[33] Iain Chalmers: Director, 1992–2002, UK Cochrane Centre, which publishes evidence reviews on effectiveness of treatments

us. I wonder if partly that was because so many of the methodologists that were practising and researching in the areas that were of interest in the evolution of our processes and methods, were already involved in NICE. were themselves taking the initiative, through their own arrangements for seeking research funding, to address the sort of questions that we would have wanted to have answered anyway.

[1:47:05] MJ: I remember being on the subcommittee with Peter Littlejohns, myself, Ruth Carlyle, and Richard [surname unknown]…who's a very-well known researcher, can't remember who he was.[34] But I can't even remember what we were discussing, it was a research advisory- kind of group, but there were only about four of us on it, but that was early days, that was before I even joined the board. I also remember those recommendations we used to make at appeals, because I was on the hip appeal, and I remember even that, that was twenty years ago, saying that there should be, one of our recommendations was a hip registry, so that was one of them – but I don't think there was any follow-up, I wasn't aware of any.

[1:47:58] TC: It might be worth your while to do a little bit of follow-up conversation with Peter Littlejohns, it is an important area. I think it did get resolved in the end.

[1:48:15] AD: I think it did, yes.

[1:48:16] PA: We have certainly talked to Peter, a couple of times now, and this was one of the things that he wanted to talk about. He made one interesting point, which was that the NHS R&D programme were rather hostile to any other NHS body having its own budget for research, which it controlled itself. They felt, under Sally Davies, that they should be making all the strategic decisions about research investment.[35]

[1:48:40] TC: Yes. There's an interesting story to be told there, I think.

[1:48:51] NT: Before I round up, can I just raise one more thing; almost inevitably when it comes to NICE we end up talking about health technology assessment, and there is a huge guidelines programme. One of the things I found very mildly entertaining at the very beginning was that the first decision was Relenza, and there

[34] Ruth Carlyle: Head of NHS Library and Knowledge Services, East of England and the Midlands for Health Education England
[35] Sally Davies: Director of NHS R&D, 2005-15; Chief Medical Officer 2011-19

was this almighty row, and then NICE produces its first guideline, and it's on 'impacted wisdom teeth', it was like one extreme to the other.

[1:49:25] MR: That was a technology appraisal, not a guideline

[1:49:26] NT: …and it might save five million pounds a year, it was mildly entertaining.

[1:49:37] PA: Everybody is complaining that you have got this wrong, Nick

[1:49:42] MR: The wisdom teeth was the first proper appraisal, it wasn't a guideline

[1:49:48] NT: Oh right, sorry – my apologies.

[1:49:50] MR: The first guideline was actually on schizophrenia.

[1:49:54] NT: Right, and again I don't know how far you want to go into this, Sally and Paul, but relatively early on, 2000/2002 we are back into beta interferon and the decision not to recommend it. My memory may be at fault, but there was a huge row about that, and direct action by patients so that, I think for the first time, NICE found its offices being picketed, members of the appraisals committee were bombarded with views and information, and I remember when I was doing the short history, some of the members from that said that the hostility kind of left scars, was that the first time, we have talked about how good early relations were with all the various stakeholders at the beginning, but beta interferon was a change of tone, was it not?

[1:51:02] AD: Yes, I think you're right, Nick. There were all sorts of things going on with protests outside the board meetings. I seem to remember we had to send Mike out with cups of tea at one point to placate groups of protesting patients. The other thing I remember is was that the rather collegiate, friendly, respectful atmosphere that connected NICE to its stakeholder groups, did change a little. For the first time I remember difficult exchanges with a patient group, the MS Society. And also a rather hostile discussion with a manufacturer of one of the beta-interferons. So you are right, it was a moment when it was brought home to us we realised that these were extraordinarily important decisions with big impacts, and that the nature of

those impacts could generate a rather different atmosphere and response to what we had been used to up to that point.

[1:52:29] SS: Can I just follow up on that, Andrew, and ask whether there was a conscious revision of comms strategy, when you got that reaction to beta interferon?

[1:52:40] AD: No, I don't think so, no. There were changes through the years in NICE's approach to comms. Nick was very charitable in his remarks about NICE's approach to the media, and we certainly tried to be as open as possible, but we were cagey in other circumstances, and we were also a little bit on the back foot when we put consultation documents out in the early years. We wouldn't do any proactive comms at all, because we thought that would be inappropriate because we would be somehow constraining the freedom of stakeholders to reflect on what we were saying and to send their comments back to us. I think that was unlikely actually, and so it has turned out to be. But I'm aware that it was very frustrating for the media, because they weren't able to talk to the organisation that was putting out the communications, relying on the press announcements that we made at consultation. So most of messages that they were getting were coming from our stakeholders, and that was clearly something that we had to fix. That happened much further down the track. I don't think that the beta interferon experience particularly changed our approach to comms.

[1:54:04] NT: I would agree with what you have just said about the changing nature of the relationship with the media, something definitely changed. Sally, Paul, do you think you have what you were hoping to get from this first session, and if you are happy, I will just go round and say does anybody want to raise anything we have not covered, add anything, and at that point we will wind up, does that makes sense? [General agreement].

[1:54:32] SS: That sounds like a good idea from my perspective, but Paul is the one who is driving this, so I will leave Paul to give the substantial comment.

[1:54:38] PA: I think that we have got what we wanted, and a lot more – thank you everybody.

[1:54:43] NT: Okay, so let's go round. Trevor, you had your hand up?

[1:54:46] TJ: Yes, I would like to know from Mike whether it was fortuitous that NICE was created on All Fools' Day in 1999? [Laughter]

[1:54:59] MR: It wasn't a planned date, it just happened

[1:55:03] PA: David knows about this, it's a civil service thing, it's the start of the year, isn't it?

[1:55:09] DP: Yes, it was a planned date actually. It was the date all the strands of work flowing from the Labour white paper were meant to deliver. In fact, NICE was I think the only one that delivered from that date. But yes, it was an interesting date and I remember, I think we met that evening in the basement at Covent Garden, and we had got these empty premises hadn't we, and a board that had been appointed, a chief executive that was still working elsewhere for the next couple of months, and it all felt quite, it was All Fools' Day, and it felt quite unreal.[36]

[1:55:58] NT: Yes, I can't remember which one it was but I know there is one NHS body that when it was set up insisted that it started on April 5th rather than April 1st so it didn't fall on All Fools Day

[1:56:10] MJ: I went to our first partners' council meeting on the first of April as well, I remember meeting Andrew and finding out that he was the chief exec of my local hospital, which I was quite impressed with.

[1:56:22] NT: So, Mercy is there anything you would like to raise or add that we haven't covered?

[1:56:26] MJ: No, I think we have covered most of the things

[1:56:29] NT: Tony?

[1:56:29]: No, nothing more really.

[36] Covent Garden: NICE's first office premises

[1:56:32] NT: Andrew? Andrew Stevens?

[1:56:38] DP: There was one thing I wanted to say about the guidelines programme, which has been mentioned a few times, and I think much of our discussion has been as relevant to the guideline programme as the technology appraisals, though technology appraisals have tended to be the more memorable examples. I think one of the most surprising things about NICE is that the definitive statement on the management of patients with schizophrenia, or asthma or whatever, NICE has usurped the leadership of the medical royal colleges, albeit binding them into the process, but nevertheless taking away their independence on the best practice in the management of the major medical conditions that drive the health service and health in the country. That seems to have gone almost unremarked, which I think is astonishing. I could say it is just because there weren't such big cash figures so obviously attached, but surely it represented quite a fundamental change in public policy in our society. It's happened, and I am pleased it has happened, I am just surprised it happened so easily. Not a single guideline was publicly opposed by a royal college.

[1:58:12] MR: Well of course the colleges are instrumental in producing them – have been and still are. But the problem with the guidelines when NICE was set up was that it wasn't just the royal colleges who were producing them, all sorts of organizations were producing them, and many of them were complete rubbish. That was really the reason why NICE took over the responsibility of doing guidelines.

[1:58:42] NT: Yes, and I would make the observation that although colleges were doing guidelines ahead of NICE, they were, different colleges took it with different degrees of seriousness, and ability, quality. I mean, some of them were not very good, even though the had the royal college imprimatur. Andrew Stevens, sorry you were muted when I came back to you last time

[1:59:07] AS: Yes, and my unmute button is a very weak one. A couple of things, perhaps this is off centre, if you don't want me to go into it, one on roots, you asked about the Conservatives, and of course institutionally they had little to do with it, with NICE, at the beginning, but the whole atmosphere of the need for evaluation, the need for there to be better value for money, and above all with the purchaser provider split, all had its origins in their day, so because of the purchaser provider split there were a lot of people in the NHS and in universities who became much more interested in the NHS being cost effective than they would have been without that. So their hand was there in a sort of diffuse way.

The other thing I just wanted to chip in, I was out of the room for a bit, one of the questions you asked was about the balance between a health economics tool and social value judgements, and my impression was that sort of emerged from the committee structure. There was thirty-odd committee members ranging from die-hard health economists, to people who had none of it. A lot of people in the middle, and sort of the balance mostly reflected that a group of that number of people couldn't come to a consensus without a bit of laxity, that was then rationalised into social value judgements, which then of course made their way into the NICE system as an official document. So I think it was sort of learning on the hoof, also a combination of the types of people who were on the committees in the first place.

[2:00:44] NT: That reminds me of something we should have talked about, which is the Citizens' Council[37]

[2:00:51] PA: Except that I want to have a whole witness seminar about that, the public. But can I follow up that fascinating comment that Andrew has just made, because this is one of my real sort of research interests, and I wonder what Tony makes of Andrew Stevens' comments that it is happenstance, the balance of who is in the committee.

[2:01:12] TC: I don't know, I don't doubt that what he said was right. I tend to see it, I think there were several converging lines of thought. The board had certainly been thinking about this sort of thing, the board had a presentation, we had one of the 'not for public' meetings, internal seminars, when I talked explicitly about the nature of the ethical value judgements that our activities were necessarily involving, and so we had quite a long discussion of the nature of these social value judgements, the construction of the QALY for example, and the board had a reasonably good grasp of these sorts of issues, I can't actually remember exactly how the citizens' council got defined and created, I will have to rack my memory, and you are going to help us do that anyway, in the near future.

[2:02:27] MR: Also Tony, remember that you and I wrote the paper for the *BMJ* on 'NICE and its social value judgements'.[38]

[37] Citizens Council: a group established by NICE to advise it on the social values which should inform its work

[38] A J Culyer, M Rawlins, "NICE and its value judgments", *British Medical Journal*, 2004, 329: 7459.

[2:02:32] TC: We did. We did, and I think there were several things that were bubbling away that eventually led to both the idea of social value judgements and being explicit about that, and the creation of the citizens' council, they had a common political philosophy almost. Necessarily much more than just health technology appraisal, much more than just medicine, so it took us into a much broader field and started involving a broader field of external people as well, that we… Peter Littlejohns certainly pursued this very thoroughly subsequently, and there is still an active couple of groups of which he is a – if not 'the' – member. I myself have taken a continuing interest in it as well. I look forward to having that discussion.

[2:03:44] PA: Can I come back to Andrew Stevens, and ask you which committee in particular you were thinking about when you talked about balance?

[2:03:50] AS: Happenstance was too strong a word – and I know that the board was having these discussions. I also wrote a paper, with Mike Rawlins, which was on our deviation from the threshold, and we, Mike and I, constructed that into a post-hoc rationale of why we were not strict adherents to the threshold in every case. I have to say, actually, in practice the threshold and the incremental cost effectiveness ratio in the appraisal committees was the sort of starting point and the strongest determinant of decisions. As to the 'which committee?' there was only one appraisal committee to start with, then we had two, and I was on the one, and I was also on the two when there were two. So it was all before it became four.

These things had sort of hardened, and they had hardened both into the papers that we wrote for publication, and in the sort of methods guide, and there was, obviously, it wasn't a thought-free zone, it wasn't happenstance in that sense, it was just that the tension between wanting to ever prevent, to ever have an untenable opportunity cost, but also to not appear unreasonable with patient groups who get a hard deal. That tension evolved, you know, in a fairly rational way, into the sort of flexibility, founded on health economics in the first place, though, that evolved, but early committees more than the later ones, because obviously that is when the thinking had had the biggest hole to fill.

[2:05:42] TC: These are still active issues, both the notion of a threshold, or multiple thresholds, is something under tremendous international discussion still today, and is of critical importance to countries trying to set up universal health coverage by public insurance. And similarly the notion that cost effectiveness may be necessary but it is hardly a sufficient criterion for determining what is going to go into a publicly insured package, so there is quite a good book coming out by Richard Cookson, towards the end of this year, which is a really serious attempt to integrate the equity concern that

lots of people have, including our own government, in economic appraisals, so it is still very active stuff.[39] I think NICE, one of the things that NICE has undoubtedly done, not only nationally but internationally, is to raise these as issues that need to be discussed, and they are, actively, still.

[2:06:56] AD: I agree with that, I was just going to say, listening to Andrew, the two enduring questions that people have put to me in my time at NICE, are firstly, 'why is the cost effectiveness threshold twenty to thirty thousand pounds?' and secondly 'why hasn't it changed?' The first of those two questions I have been asked almost for the entire twenty years, and the second for about the last fifteen years. I look forward to Richard Cookson's book.

[2:07:36] PA: I look forward to interviewing Andrew Dillon and Andrew Stevens, who are on the list but we haven't had one-to-one interviews with yet.

[2:07:45] NT: David, David Pink, do you have anything to add on these early years that we have not covered, that we should have covered?

[2:07:57] DP: No I don't think so, I think we have covered it quite well. I think the most astonishing thing about the early years was that we survived them.

[2:08:11] NT: Andrew, same question to you – anything we should have talked about in the early years that we haven't talked about?

[2:08:20] AD: Not really, only – just an observation, which isn't so much about the early years, but the totality of NICE, that is that so much of the culture that NICE developed and indeed many of the principles that still endure in the way it goes about running its current array of programmes, were formed in those very early days. They are a product of the people who were around then, the way they thought, and you can sort of trace some of the ways in which NICE sets up new programmes now back to decisions that were taken in the early days about the right way to go about bringing evidence together, interpreting it and producing something useful from it.

[39] R Cookson, S Griffin, O F Norheim, A J Culyer (eds.), *Distributional Cost-Effectiveness Analysis: Quantifying Health Equity Impacts and Trade- Offs,* (Oxford: Oxford University Press, Handbooks in Health Economic Evaluation Series, 2020).

[2:09:19] NT: Mike, anything we should have raised about the early years that we haven't?

[2:09:23] MR: No, I think we have covered most of the ground.

[2:09:30] NT: Well in that case if Paul and Sally are happy, I will draw this to a close. It has been absolutely fabulous to see you all, and it will be even better when we can all have a drink at some point.

[2:09:45] SS: We owe you all a big one, thank you very much

[2:09:47] NT: Thank you very much indeed for your time, hope you felt it's worthwhile.