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Origins of the National Institute for Health Research

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Introduction

There has been publicly-funded health research in the UK for just over 100 years, but the idea that the National Health Service needs to commission some of it is only a generation old. The focus of this seminar is how the present organisation of R&D in the English NHS, centred around the National Institute for Health Research, came about.

A good starting point is the seminal 1988 House of Lords Select Committee on Science and Technology report: *Priorities in Medical Research*. The Government response was the appointment in 1991of Michael Peckham as the first Director of NHS R&D, the publication of the first strategy, and the identification of a budget. The 1991Strategy was a broad vision of the need to 'introduce a sensible mechanism for handling within the NHS the output of basic and applied research and to apply research methods to examine the content and delivery of health care'. Peckham used this vision to secure a Ministerial commitment to build investment in R&D to 1.5% of the NHS budget. Among the ways this first strategy crystallised emerging ideas in health research – and set the tone for later strategies – was by embracing evidence-based medicine. The R&D Programme established the UK Cochrane Centre for the production of systematic reviews, and the Health Technology Assessment programme. Another element which caught the prevailing mood was the involvement of patients and the public in research design, a process which was to develop into the INVOLVE programme.

NHS R&D has not developed in a political vacuum. The backdrop to its early years was the implementation of NHS reforms creating the purchaser-provider split and the internal market. This made managers focus more on the direct and indirect costs of research, and many researchers were anxious about NHS support for research being withdrawn. On the positive side, this forced a clearer identification of where research money was spent, and a questioning of how it was deployed. Labour governments from 1997-2010 maintained the purchaser-provider split. When, after 2000, they invested growing amounts in the NHS, these rising budgets made structural changes to the distribution of research funds much more palatable for the potential losers than would otherwise have been the case.

The R&D programme's promise of delivering new evidence about effective health care appealed to New Labour politicians, whose programme emphasised 'investment for reform' and 'what works'. R&D outputs were used by NICE, the new National Institute for Clinical Excellence, and in new National Service Frameworks. This helped make a case for further investments in R&D, beginning in 2000 with a National Cancer Research Network, which in turn provided a template for clinical research networks in other fields. These networks provided local NHS support for research such as the infrastructure for clinical trials.

Policy decisions about the NHS also affected R&D in unintended ways. The first R&D programme had a strong regional component: the removal of Regional Health Authorities in 1996, and the abolition of any regional tier of management by 2003, removed the regional parts of the R&D infrastructure. The centre had little alternative but to run the essential programmes itself (though obliged by headcount ceilings to contract these out). This set the shape for the centralised research management which followed.

Government industrial policies also influenced NHS R&D. By 2000 the view was prevalent in Whitehall that R&D was an effective driver of growth and that, given the size of the pharmaceutical sector in the UK economy, measures to support its R&D would particularly benefit the UK economy. Britain's centralised NHS was seen as an opportunity to organise clinical trials more effectively, which had to be seized by initiatives to improve the NHS' support for trials. The cancer network showed how recruitment to trials could be greatly increased. Leaders of NHS R&D, from John Pattison onwards, not only saw the force of these arguments but also recognised that they gave

NHS R&D greater leverage in Whitehall and the promise of access to more funds. A turning point came in the 2004 Budget, which began a sustained increase in NHS R&D – and Medical Research Council – allocations. NHS R&D funding continued to grow in real terms even after 2008, despite austerity elsewhere.

This policy focus on industry drew attention to the question of the type of health research most needing support. Researchers had begun to distinguish between fundamental science; clinical science about how to deliver the most effective care; and translational research bridging the gap between the two. Mounting emphasis on support for trials, and the growth of a more managerial approach to research, prioritising measurable benefit, raised the issue of whether funding should be re-prioritised towards the translational and clinical parts of the research pipeline. This produced tensions between the MRC and the NHS R&D programme between 2004 and 2006.

One of the requirements of a well-functioning health research system is a career structure which retains and supports the best clinician scientists. In the 1980s and 1990s there was increasing concern that this was missing, as numbers began to drop. The Academy of Medical Sciences (established in 1998) was among those proposing remedies, above all in reports published in 2002 and 2003. The Wellcome Trust, and Mark Walport, were instrumental in securing improvement, for example by extending the range of Fellowships: in 2005 Walport led a review of NHS medical academic career structures. The creation and funding of a better career ladder for researchers was one of the key components of the NIHR's research strategy.

Many witnesses have told us that the single most important development in NHS R&D during the period was the centralisation of the budget and its management on new lines. Formerly, much NHS research expenditure was not separately identified, and quality control varied greatly from place to place. Central allocations were made on a historic basis which favoured a small number of hospitals, mainly in London, and neglected such fields as primary care and mental health. The 1994 Culyer Report laid down principles of accountability and transparency in funding, and led to major efforts to identify and quantify where research spending took place. In the following years, however, the Department of Health had other priorities than facing the political challenge of redistributing funds, and progress was slow.

The consensus among research leaders was that only incremental change would be politically possible. This consensus was broken by Sally Davies and Russell Hamilton, who became Director and Deputy Director of NHS R&D at the start of 2005. Their view, based for example on a Research and Development Directorate 'peer review' exercise in 2001-02, was that only a 'big bang' approach to redistribution could overcome the opposition of vested interests. The prize for success would be control over the large sums of identified NHS research spending, and the ability to deploy them in support of a strategy for the whole NHS research system.

This was set out in *Best Research for Best Health*, published for consultation in 2005 and in final form in January 2006. The strategy included extending Clinical Research Networks, new funding programmes, and more support for researchers' careers. Research funding, by the end of a three-year transition period, would be allocated competitively, following peer review. The higher profile central management needed for this would in future be badged as the National Institute for Health Research, an NHS organisation but managed as before from the Department of Health as a distributed virtual institute. This NIHR came into being in April 2006.

The Treasury, which had supported these developments, moved to cement the economic benefits by commissioning David Cooksey to review UK health research funding. Their particular concern was that NHS R&D and MRC research should interact smoothly, for example to secure as much high quality translational research as possible. In December 2006 Cooksey's report endorsed NIHR and made recommendations on support for commercial research, strengthening translational research

and greater co-ordination of funders in a new Office for the Strategic Co-ordination of Health Research (OSCHR), which was established soon afterwards under John Bell. Cooksey wanted translational and clinical research to expand, funded by new money rather than at the expense of the MRC's fundamental research: this hope was realised in the buoyant funding environment of the following years.

In the years immediately following, NIHR opened a range of funding programmes using the redistributed and new NHS research funds. The first Biomedical Research Centres were competitively selected in 2007. Much effort went into the quality of research management, for example standards of peer review, and this undoubtedly helped secure favourable funding settlements by convincing Treasury that the programmes gave good value for money. Working within and beyond OSCHR, the NIHR, MRC and the other key funders such as Wellcome developed more adaptable, fluid ways of working together. These successes have been neither complete nor easily-won, but the consensus among our witnesses and other commentators has been that NHS R&D is in a much healthier condition now than twenty or thirty years ago.

Contributors

Chair

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Witnesses, with their connections to the origins of NIHR

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Areas for Discussion

Origins

How did the evidence-based medicine movement make its breakthrough into significant influence on research policy makers in England?

Why, of all the present-day programmes, did Health Technology Assessment appear first? Did it just have effective advocates or was there a deeper reason?

Of the different discontents of health research in the 1980s, which ones influenced subsequent policies most?

What are the key parts of Michael Peckham's legacy – for instance the idea of a research strategy; stewardship of a research budget; features of content (such as the choice of priorities) and style (emphasis on regions, primary care, patients and public)?

How did the changing NHS context and government policy affect the development of NHS R&D after 1991?

How much difference did new policies under the 1997 Labour government make?

The emergence of the present NHS research system

'All the stars were aligned' – but what features of the circumstances of 2005 were essential/made the most difference?

The idea that there was one interconnected health research system was new – where did it come from? What impact did it have?

How did the Department of Health succeed in centralising R&D funding?

What models or forerunners shaped the way the post-2000 clinical research networks provided support for research in the NHS?

Why was NIHR given the particular organisational form it took in 2006? What have been the results of this choice?

Interactions with the wider world of health research

How has the MRC's interaction with NHS R&D developed since c.2000?

Do the post-2005 arrangements better support the translation of ideas from basic and clinical research into the development of new products and treatments? How?

How has the health care industries' ability to do research in the NHS developed since 2005?

What roles have the Wellcome Trust and the Academy of Medical Sciences played in the development of NHS R&D?

What are the best features of the present arrangements for co-operation between research funders, including charities, and how have they been arrived at? What part has the Office for the Strategic Co-Ordination of Health Research played?

Impact

[The first four questions look at the fields of activity selected in *Best Research for Best Health* in 2005]

How has the experience of doing NHS-commissioned research changed as a result of competition for NHS research funding, peer review and greater accountability?

What has the impact of the post-2005 changes like Biomedical Research Centres and the Research Facilities programme been on NHS research infrastructure and facilities?

What has been the contribution of NHS research systems [i.e. Research Governance Systems and Research Information Systems]?

What has the impact of establishing the NIHR Faculty been on research careers?

What has the payback been for the investment in the new NHS R&D system?

In the early 2000s the goal was to keep pharmaceutical trials in the UK by providing excellent trials infrastructure. What have we achieved?

How well have we used the results of NHS R&D?

- NICE
- other successes such as National Service Frameworks
- research on service delivery and organisation
- impact on commissioners and providers of care?

What difference have CLAHRCs[1], AHSCs[2], and AHSNs[3] made?

What explains NHS R&D's ability (and the MRC's) to secure better funding settlements since 2004 than most of the public sector?

What is your assessment of what has been achieved?

What lessons does experience since 2005 provide for research programme managers today?

What should NHS R&D be doing next?

[1] Centres for Leadership in Applied Health Research and Care
[2] Academic Health Science Centres
[3] Academic Health Science Networks

Paul Atkinson

I would like to begin by thanking everybody very sincerely for braving the weather. Some people have come a particularly long way and that has been hard for some [in the current weather conditions]. Thank you very much for being here. I am Paul Atkinson and I am a historian at the University of Liverpool.

I would like to welcome you to this witness seminar on the origins of the National Institute for Health Research, part of a programme of research on the history of medicine at the University of Liverpool, and the University is funding this project. A witness seminar, as some of you will know very well, is an event for gathering testimony about events from those who were present. Nick, our chairman, will be taking us through a series of topics and questions that we would like to discuss with you to hear your input, and that is all that the day is for.

The goal of the project is to try to get us to a deeper understanding of how it is that we got here, principally, perhaps, to help guide future policy on the support of research and development. There is one person who would have been here but is not and that is Walter Holland, the professor of clinical epidemiology and social medicine at St Thomas', who accepted our invitation but as most of you will know sadly died a couple of weeks ago. I had the pleasure of interviewing Walter and I know he would have been a lively contributor as well. That is all I need to say to get us started. I would like to just introduce Nick Timmins, who is a senior fellow at the Institute for Government and at the King's Fund, and formerly public policy editor at the *Financial Times*. I hand it over to you, Nick. Thank you.

Nick Timmins

It is lovely to see you here and congratulations for making it in the snow. I am very impressed. We are going to do NIHR. I have had the happy privilege of chairing a number of these witness seminars. The difference this time is that I know less about the subject and I know fewer of you so, when you want to speak, stick your hands up, wave and tell me who you are and what you want to contribute. We are doing four sessions: on the origins, the emergence of the present system, the interactions with the wider world and its impact since it was all created. There are people on the top table but that is just so there are people on the top table. It is not necessarily that they are more important at any point and we will move them around so it is very important that you all contribute.

Origins

To get going on origins, NIHR comes out of, in a sense, the evidence-based medicine movement and that began to emerge in the 1980s. How did it grow and how did it come to have an impact on policy? Would you like to start, Iain?

Iain Chalmers

Yes. I probably ought to start by challenging that perception. Basically, the NHS R&D programme from a long time previously had shown a respect for applied research to guide decisions within

health services and within clinical practice. Indeed, it is easy to point, for example, to Archie Cochrane's book published in 1972, which was 20 years before the term 'evidence-based medicine' was coined by Gordon Guyatt at McMaster University in 1992.

There was a tradition of applied research funded through the R&D programme of the Department of Health. I worked in a unit which was funded from a centrally commissioned programme called the National Perinatal Epidemiology Unit. In some senses, some of the things that were going on in other countries were not going on here, things that I think are relevant to this discussion. For example, the clinical epidemiology movement did not take hold in this country. I know that the Rockefeller Foundation tried to get British participation in INCLEN, but I think Southampton was probably the only medical school that did get involved in that movement. The same was the case with health technology assessment. There was not British participation in health technology assessment in a formal sense, despite the fact that there was plenty of health technology assessing going on, until the HTA programme was founded. There were these separate strands happening and indeed, when evidence-based medicine was, as it were, launched in this country as a term, it caused a lot of what is probably best described as 'backlash'.

Nick Timmins

What sort of date would you put that?

Iain Chalmers

It was about 1993 or 1994 – something like that. For example – I can relate this with some confidence because I have had it from the people who were involved – there was a *Lancet* editorial entitled 'Evidence-Based Medicine – In Its Place' and it was a very personal attack on David Sackett from McMaster and Brian Haynes from McMaster.[4] I know, from the editor of the *Lancet* who handled that, that the Regius Professor of Physic in Cambridge said to him, 'Good for you in putting the boot into these people who are implying that we have not been guided by evidence'.

Keith Peters

The Regius Processor of Physic in Cambridge, the aforesaid person, is me actually.

Iain Chalmers

Good to see you here, Keith. [Laughter]

Keith Peters

You might be interested to hear my perspective on my support for the then-editor of the *Lancet*. First, just to get it out of the way, Archie Cochrane of course was an MRC employee and the director of the MRC was in Cardiff, which was my medical school, and I knew him from my medical student days in the late 1950s. His support for evidence-based medicine, the use of the randomised control trial, was imbued into us as medical students, so the notion that this is a 1980s invention is, to say the least, somewhat exaggerated.

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[4] 'Evidence-based medicine, in its place.' *Lancet* (London, England), 0140-6736, 1995 Sep 23, Vol. 346, Issue 8978, p. 785.

The real reason behind my immediate antipathy to David Sackett arose from an event when I invited him to come to Cambridge to discuss cases at the Grand Round. He accepted the invitation but only on condition that certain diseases were actually presented, so the limits of evidence-based medicine in dealing with ordinary clinical practice, where the evidence of the kind that Sackett wanted did not exist and often does not exist to this day, was actually one of the reasons for putting it into perspective. We have, in the audience, Mike Rawlins, whose marvellous dissection of the limits of this kind of scientific approach to clinical decision-making, the gold standard of the randomised control trial as distinct from the problems of evaluating events in the real world and patients being individuals who do not fit the category that fell into the randomised control trial, was behind the sentiment that I evinced at the time, just to get it on the record.

Iain Chalmers

It is very good that it is on the record and I rather wish that Richard Horton was here so that he could give his account of it as well. We would maybe get a triangulation of what actually was said. I never claimed to be associated with the evidence-based medicine movement because I stopped being a proper doctor in 1973. I did not have to take decisions where I could find out the extent to which the principles of evidence-based medicine as set out by the group in McMaster in particular worked in practice. I was very clear that I was interested in the type of evidence that was available for people to take into account, but I did not have any credibility and should not have had any credibility in describing how well it worked in practice.

What I can say, though, is that there was a great deal of opposition: for example, the principle of trying to base decisions or in any way inform decisions, not just on a single study, but on systematic reviews of similar studies, was roundly rejected. Certainly I hope that there is someone here from the Wellcome Trust, because I can actually point to the data on this. It was roundly rejected as not important. I think that was a very bad mistake made by those people who opposed this. It is still a problem, in fact, that new research starts without adequate assessment of what is known already from existing evidence. That is a great shame because it wastes money as well as doing wrong research, and those were the sort of principles that went along with the idea of evidence-based medicine. It was not randomised trials. It was systematic reviews.

Keith Peters

When David Sackett came to Oxford systematic reviews had not started.[5]

Sally Davies

Well, hang on a minute. You are both going down a rabbit hole because – and John will be able to address this bit better than me – it was Lord Walton and the House of Lords that reviewed research in the NHS and it was not about evidence-based medicine as I remember it.[6] It was about the fact that if we invested so much in health services then we should have an intelligent commissioning arm that made sure we had research to address our needs, and arising out of that we got the NHS R&D programme and Michael Peckham was the first director.

[5] But see Iain Chalmers' comment on p. 15.

[6] The reference here is in fact to the 1988 Report of the House of Lords Select Committee on Science and Technology, '*Priorities in Medical Research*', when the committee was chaired by Lord Nelson of Stafford. Dame Sally has conflated this here with the Committee's 1995 report under Lord Walton, '*Medical Research and the NHS Reforms*'.

Nick Timmins

That is the Lords Select Committee in 1988 we are talking about.

Sally Davies

Yes.

Keith Peters

I was a special advisor to that committee.[7]

Nick Timmins

John, what is your take on this?

John Pattison

I can only agree with that. That is how I imagined that NHS R&D came into being: that you have a service that is based on science and technology and you cannot afford not to have an R&D programme that goes with that. I cannot really add very much else. There are others here who were there before I was but, by the time I got there, there had been two directors of NHS R&D: Michael Peckham and John Swales. Many programmes were in place so I feel rather inadequate in addressing the origins. For example, Chris had been there years before that.

Chris Henshall

I think a strand that is a key part of this is the management of the NHS and their requirement for knowledge, understanding and advice. I think the Lords were very much a customer-driven model. They said, 'We have this huge scientific-based enterprise, which is a customer for information and it should not expect to get everything it needs from the external providers of information because they have slightly different agendas. It needs its own R&D capacity.' I think the customer, implicit in the Lords report and explicit in Mike Peckham's early strategy, was both the clinician and the management. A range of customers were seen.

The tradition, as well as whatever we are going to call it – evidence-based medicine, clinical trials or whatever – that the NHS R&D programme was able to draw upon was the traditional operational research, which had been alive and well in the central Department of Health on behalf of the NHS. This includes, for example, work commissioned about the cost-effectiveness of heart transplantation which led to the establishment of quite a controversial, expensive programme. Regions were doing their own stuff. Regions were very powerful at that stage: decisions about development and siting of hospitals, purchasing of high-tech equipment, CT scans and things. These were being informed by economic and operations research by units such as the Centre for Health Economics at York working locally. A lot of these groups and universities set up their local units to support their local NHS. I think that was part of the foundation that was being drawn on.

[7] Sir Keith was specialist adviser on the 1995, not the 1988, Report.

Nick Timmins

What period are you talking about then? The issue I want to raise is the 1988 report, it's ahead of the purchase-provider split in the NHS but you are still talking about this as though the NHS should look at this as a customer.

Chris Henshall

I think that is what the Lords were saying in their own language. It does not require a purchaser-provider split to separate the purchaser: you have someone making decisions about service development, about allocation of money, development of what we now call the National Service Frameworks. We have people making decisions about clinical architecture, management architecture and infrastructure, whether or not you put them in a separate box and call them purchasers. In a way, the research function still needs to support those decisions. The customer-provider split was a useful way for Mike Peckham in the early strategy to play into a theme that was there which is, 'My goodness, we have created these commissioners. How on earth are they going to find out what to do? Where are they going to get advice from?'

Nick Timmins

Yes and this is one of the few bits that I do think I recall. When the purchaser-provider split happened a number of things broke down. Tell me if I am wrong, but there used to be arrangements in teaching hospitals known as 'knock for knock' where clinical academics would do NHS service work and would not get charged for it, and NHS consultants would do academic work and it was all 'knock for knock'. It was kind of assumed that it came out in the wash. One of the effects of the purchaser-provider split was that managers started saying, 'I am not sure how I am going to pay for that. It is part of my overhead', so that arrangement started to fall apart. Is that right? Yes. People are nodding their heads.

Sally Davies

There was still SIFTR in the system.

Keith Peters

It was a very arbitrary calculation indeed.

Sally Davies

Yes, historically.

Keith Peters

SIFT was based upon a basket of costs of teaching hospitals compared to other hospitals, and then the cost was attributed to the extra cost of teaching and research, but of course it was not due to that. It was often due to specialist services and a whole pile of other things. SIFTR was invented as a way of defending the R bit against the effects of the internal market and that was arbitrarily defined, as I recall, at 25% of the original SIFT, which itself was an arbitrary figure. The other thing, which I saw mentioned in the write-up, was the loss of the regions, which actually played a major part in sustaining the, if you like, research operation of the NHS generally with a lot of devolved budgeting. That, certainly in some parts of the world, was a major contributor to the

development of new services and medical schools etc. Once they disappeared, life got more complicated.

Nick Timmins

Right, but that was a bit later. The regions did not go for a while.

Sally Sheard

I just want to bring us a little bit further back in time. I know people are not comfortable going back beyond the last 20-odd years but I examined Stephen Davies' PhD thesis late last year, which focussed on the 1970s, Rothschild and the idea of the customer. I just thought it might be nice to have on record some reflection on how we got from Rothschild up to the point that people had been talking about so far. Stephen, could you just give us a couple of pithy comments on it?

Nick Timmins

Yes, just ten thousand words down to two hundred.

Stephen Davies

Well, in fact it went back to the 1960s so I would say that the real origins of a DH and NHS R&D were at the beginning of the 1960s. They were prompted by the need for evidence and knowledge which was, to quote the first chief scientist, Richard Cohen, of a precise and practical relevance to the NHS. The start of this was really all about operational research, as Chris Henshall has said, but it was always a multi-stranded project which included operational, service-orientated medical and social research. It is probably best characterised in the way it was at the time as being a programme of health and personal social services research. All that grew strongly in the 1960s from a very low base and the idea of the customer was actually already around before Rothschild, so the Department of Health invented the idea of the customer and identified the need to have internal customers for research as early as 1967.

Rothschild then came along with his own ideas of customers for research plus the very contentious proposal to move 25% of the MRC budget to the Department of Health to pay for the commissioning of biomedical research. At that point, the whole story gets overlaid with the politics of medical research, biomedical research, and gets a lot more complicated. However, I think it is completely wrong, given all of that, to say all this started even in 1988. It started in the 1960s. It was very successful. It was destabilised by the unintended consequences of the Rothschild reforms in the 1970s, and then the department continued with its programme of health and personal social services research in the 1980s, but in a much colder climate, financially and politically.

Nick Timmins

I have forgotten the date but the Department of Health appointed its first health economists a lot earlier than the 80s. Somewhere in the 70s.

Sally Sheard

1971.

Stephen Davies

Yes. The economic advisor's office and operational research were the internal resources but that was always separate from the commissioned programme of research, which was largely extramurally provided.

Chris Henshall

On the episode in the 70s and 80s, following the Rothschild movement of money, a chief scientist at the Department of Health, I think one Arthur Buller, made a decision as his staff was further reduced year on year that the Department of Health was not competent to manage the money it had been given under the Rothschild arrangement, so a proportion of it was returned to the MRC under the arrangement of the so-called concordat. Although that is a little bit of a detail of history, I think in terms of the ethos it is really important.

I joined the MRC as a young scientific secretary and my job was to manage the Health Services Research Committee, which was a kind of war zone, really, between the Department of Health and the MRC. The Department of Health says, 'You keep saying you do what we ask but you do not' and the MRC kept saying, 'You do not know what you ask for. You do not know what you want and you ask for silly things so we do sensible things'. This was the annual concordat meeting, put in polite language. Sally [Davies] and others later turned around something that really had quite a history of acrimony behind it, and I think that took a long time to turn around and you need to understand that bit of history to understand just what was achieved by the setting up of the NIHR and its really positive working relationship with the MRC, because I think there was a period of some considerable tension.

Nick Timmins

Yes. You are right. It triggers some memories, that. I remember almost public rows between the MRC and DH about what was being commissioned and not commissioned, and whether it was right or not.

Brian Edwards

I was at that time a manager. I have two things to say. This is about the National Institute for Health Research but, well before that, other organisations and regions in particular were investing in research and in the universities. I remember in Trent we put a lot of money into our three medical schools in order to get them to prepare the skills and the staff who could begin to answer our questions as well. I remember, when Michael Peckham first came to his meeting of regional general managers, the first question we asked was, 'Where is the evidence that small units are dangerous?' We were all in the business of then consolidating ophthalmology, ENT and all the rest of it.

To be fair to him, he said, 'I do not think there is any but we will go and have a look, and if there is not any we will go and commission some'. That changed the mood and the attitude, I think, amongst managers and researchers, because suddenly they were going to give us some answers which might turn out to be helpful.

I also have with me the minutes of a meeting of the NHS Policy Board in March 1991, so we have a precise date. This is Michael Peckham reporting to ministers, senior officials in the Department of Health, regional managers and others: 'We need a more thorough approach to bring new treatments into regular use. It is clear that the selection of treatments from those available was not based on an analysis of their effectiveness or their cost-effectiveness. There is a tendency for new treatments to

slip into practice without evaluation. There was a need for properly controlled trials'. He gave, as an example, the new use of lasers, to obviate the need for hysterectomy. This was a potentially beneficial procedure that carried with it serious risks. Now, this was 1991 and this was getting to be really interesting material. The managerial community welcomed it.

Nick Black

Going back to the House of Lords, the other factor that always struck me as really important was, as I understand it, the House of Lords Select Committee [enquiry] was set up because of concerns around largely what we might call clinical research and the state of clinical research, as opposed to the research the MRC was funding. The key thing was that the loudest voices on that committee were three or four ex-captains of industry who were shocked at how little information the NHS had about research on how to organise services and what was known, a bit like the examples that you gave, Brian, about size and so on. The report actually came out with something rather different. It did say, 'We need to strengthen clinical research in these ways' but we also need what I would now call health services research, research on how services should be delivered, as well. That was not expected and that was largely driven by people who had run large manufacturing companies such as Courtaulds, who were shocked to see how little money was invested in R&D by this huge enterprise, the NHS.

Iain Chalmers

I just wondered if I could get a perspective on Sally's question, because I was the grateful recipient of funds over that period, the transition that you are referring to, so that, for example, as someone who worked in the National Perinatal Epidemiology Unit, I had it from the centrally-commissioned programme. It was founded in 1978, but during the 1980s we developed, as part of the programme, the programme and systematic reviews, which ended in being referred to by Michael Peckham in his 1991 article in the *Lancet* saying what he would like to see happen.[8] The reason that he came to know about it, almost certainly, was that he is married to Catherine Peckham and Catherine Peckham was an external assessor on one of the external assessments of the National Perinatal Epidemiology Unit, and in fact in its 1989 one, where we actually had these big books and the electronic publication available.[9]

He obviously – I am pretty certain it is fair to say 'obviously' – saw this as something that was cost-effective: find out what is known already before commissioning new work. Not only did he give support to the idea of the UK Cochrane Centre, which was not going to do reviews itself; it was going to try to promote the preparation and use of systematic reviews, which happened, but also he established – Chris will I am sure confirm this – the NHS Centre for Reviews and Dissemination in York, seeing that this was an important trend that should be encouraged. I think that carry over from the 1980s for those trends into something that grew quite a lot during the 1990s was a nice bit of continuity. Things had been, in some senses, piloted during the 1980s.

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[8] Michael Peckham, 'Research and Development for the National Health Service.', *Lancet* 338, no. 8763 (1991): 367.

[9] Chalmers I, Enkin M, Keirse MJNC, eds. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989; Chalmers I. The Oxford Database of Perinatal Trials. Oxford: Oxford University Press, 1989-1992: (Contents subsequently transferred to and maintained in The Cochrane Database of Systematic Reviews. Cochrane Collaboration and Update Software. 1992, ongoing).

Nick Timmins

We get to Peckham being there and Peckham's day, and Peckham getting the NHS to commit to 1.5% resource going into R&D, which was clearly an important moment.

Sally Davies

I thought he had got a commitment to 2%. I always used to tell the politicians that is what they had committed to.

Chris Henshall

The politicians never committed to anything.

Sally Davies

I was told that they had.

Chris Henshall

Michael was not prevented from putting a 1.5% figure in one of his announcements and papers, but I do not think he ever got ministerial approval for it.

Sally Davies

I told them they had committed to it.

Nick Timmins

That is known as power and influence I think. Out of this, we get the Cochrane Centre, the Centre for Reviews and Disseminations and we get the Health Technology Assessment programme, which corrals a lot of the stuff that we have been talking about. Can you talk a bit about that, John? Was there a particular logic that led to those, in a sense, being the first three initiatives?

John Pattison

I cannot answer that. I think others who were there at the time of its creation might be able to.

Tom Walley

Maybe I can. The common feature across all of these was the systematic review: the systematic reviews from York, from the Cochrane Centre, and, initially when it was set up, the HTA programme largely delivered systematic reviews. It was doing that in part to address the need of commissioners for research and it was identifying what it thought were the needs of commissioners with their help, with all of the difficulties that brings, and then trying to deliver a product back to commissioners.

However, it became quickly clear that you can only go so far with systematic reviews because there were lots of areas where there was no data to synthesise, and therefore the HTA programme started to get into the business of generating data as well as analysing other people's data. Where it really kicked off most strongly was probably around prostatic cancer, where there was a strong push to

have a national screening programme for prostate cancer, and there had been an attempt to do a trial in prostate cancer, which had been unsuccessful, led by the MRC. The clinicians simply could not get patients to randomise into the trial. The HTA programme adopted a very pragmatic approach and first of all commissioned a couple of systematic reviews – two economic evaluations, and fortunately they both came out with the same answer – and then commissioned work around evaluating how to approach patients, get them to participate in the trial, and then ultimately into our first big trial, which was the ProtecT study, which has reported only last year.[10] Therefore, the HTA programme moved from a core of systematic reviews, which still pertains today, into doing more and more original data-generation using various designs but most commonly the randomised control trial.

Nick Timmins

Right, and it also started putting money directly into places like Southampton, or into universities, to do HTA.

Tom Walley

That really came later.

John Pattison

It was outsourcing of the management of the HTA.

Tom Walley

Yes. Southampton managed the programme, but in terms of doing the systematic reviews and so forth – the HTA programme initially – that was all done on a tender basis, but then as NICE developed and the work of NICE developed, we took over the role previously held by the regional development and evaluation committees (DEC). There were four or five of those around the country and they were rolled into what became the HTA's systematic review programme, which mainly fed into NICE. We are now talking 1997 and 1998, so a bit further on.

Nick Black

As a supplement to Tom's point, the other thing looking back which I would say was one of the greatest contributions of those early Peckham years was not systematic reviews of treatments but very detailed reviews of methods, and that went round the world and it has been used for the following 20 years. For the first time, people looked at anything from randomised trial design right through to qualitative methods, and came up with absolutely seminal technical reports, books really, which laid out the whole methodological basis for what has gone on ever since.

Nick Timmins

How to do it.

[10] Hamdy, F.C., et al., '10-Year Outcomes after Monitoring, Surgery, or Radiotherapy for Localized Prostate Cancer', *New England Journal of Medicine* 2016; 375:1415-1424.

Nick Black

How to do it, yes.

Sally Davies

Of course all of those reports were open access on the web, so we were pioneers in open access and people around the world can get them free of charge.

Nick Black

Yes, in the tens of thousands. It has been absolutely massive.

Keith Peters

I think one other feature of those early years, which is worth mentioning, is that medicine for the first time was starting to get very expensive, and some of the gadgets that were needed and the costs of running them, from early CT scans, early MRIs, could only be afforded in a limited number of places. That transition in medicine from being a relatively cheap discipline to one that we now know of as very expensive obviously started in some areas before that – cardiac surgery was mentioned as a good example – but I think the realisation that things were going to cost a great deal of money and needed to be used intelligently was another force behind the development of the assessment of the value of the technology that was expensive. [38'53]

Nick Timmins

That is great. There is a hand up at the back.

Marc Taylor

Before I became involved in developing the NIHR I did central finance work for the Department of Health. I wanted to add that although the tendency of this discussion is to focus on, if you like, scientific concerns around the assessment of evidence in medicine, it is worth remembering that Michael Peckham had a following wind because of the general dissatisfaction about measuring all sorts of things. For example, in those days there was an allocation to regions through a formula in which a population was weighted for mortality, and every year there was a lively debate about whether any of this was appropriate given some of the changes that we have just been talking about and the general lack of evidence about joining one end of health services to any other end. The focus on and worry about testing the quality and bringing together the evidence was not just to do with medicine but to do with understanding how to deliver appropriate health services fairly.

Brian Edwards

I have just one final example. I remember Michael stunned a regional general managers' meeting by saying, 'Gentleman and ladies' – because there were one or two ladies there – 'please always distinguish between clinical opinion and clinical evidence, and always check that clinical opinion has some evidence behind it. You usually will not find it but always ask for it'. The final point was: the real bombshell for me was when Ken Calman was pushing for cancer centres and somebody asked the question, 'Where is the evidence that cancer centres would produce better results?' and Michael Peckham said, 'There is not any that I know of but I will go and have a look'. That was pretty brave.

Nick Timmins

Yes. We come to the mid-1990s now and the Culyer report.

Chris Henshall

I would just like to provide a very quick footnote. I think part of the philosophy and the politics behind the early structure of Mike Peckham's programme was that we had better get some early results. Research takes a long time so there was not just a kind of scientific logic to the idea of funding reviews. There was a kind of political reality. Ministers, having been bounced into supposedly agreeing to 1.5%, then started to say, 'What am I getting for this, Michael?' and Michael said, 'I will get back to you on that one' and we went off to Brunel and commissioned Martin Buxton to produce what has now become the payback research framework and programme.

However, there was quite a bit of pressure to deliver. The early structure of the programme had priority research programmes that were trying to focus on what the management and their clinicians most needed to know, and there were various topic-based programmes, but then we kind of thought, 'We can carry on doing topics for ever and just keep going round in a circle. Why do we not have something more generic like health technology assessment, which is basically trying to find out what works?'

The first lasting programme was focused very much back to the customer thinking. The idea of using today's information was enshrined in the first version of the strategy in something that was called the 'information systems strategy' which was about systems to marshal the existing information we have to feed into the system, and the Cochrane Centre was a key part of that. That was felt to be provider-driven. Cochrane was saying, in our characterisation of it, 'What have all those guys doing trials been doing? Let's go and find out what they found out' and that was complemented by the Centre for Reviews and Dissemination, which was customer-driven.

We would rally the questions that the managers and the clinicians were asking and we would go to Trevor Sheldon and Alan Maynard at York and say, 'People want to know the answer to incontinence. There is probably not much in the trial literature but you can liaise with Iain and the UK Cochrane Centre and find out, but we need some answers on the best treatment for incontinence so go and look beyond the trials'. The idea of the information systems strategy was 'jam today as well as jam tomorrow', and we will have a twofold strategy, science-driven and customer-driven, and get them to work together. That was the kind of thinking behind it. [44'00]

Nick Timmins

That's exactly right.

Iain Chalmers

Trevor Sheldon and I co-authored a paper for *Health Economics* which said at greater length what Chris has just summarised.[11]

[11] Sheldon T, Chalmers I. The UK Cochrane Centre and the NHS Centre for Reviews and Dissemination: respective roles within the Information Systems Strategy of the NHS R&D Programme, coordination and principles underlying collaboration. *Health Economics* 1994; 3:201-203.

Sally Sheard

The political imperative is something that we need to try to pull out as we go through and it is there but it is intermittent. Getting the quick wins was critical for Peckham. It made me think about a parallel, which was the resource management initiative that came out alongside Griffiths in the mid-1980s. Apparently when they went to sell it to Margaret Thatcher and she said, 'How long is this going to take to implement?', clinical budgeting and all of the stuff that Chantler was doing, somebody said to her, 'It is probably going to take about five to six years'. Her classic response was, 'That is longer than the Second World War'. The political imperative is important and I would like to get the sense of that as we go through.

Nick Timmins

That was the time of the NHS review when Ian Mills and that lot were taking it, and she said, 'That is longer than it took them to win the Second World War'.

Kieran Walshe

I just have an observation, Nick, which you might reflect on, given your past role. This discussion that we are having and hearing about in this room was taking place, I think, in parallel to but quite separate from the debate about how to organise and manage health services in this country. I am really struck that, in the discussion up until now, things like the introduction of NHS Trusts, the various reforms and mergers which Brian will be all too familiar with through the late 80s and 90s, the introduction of the purchaser-provider split and all those profoundly important policy concerns which drove really big changes in the way that we organised health services were taking place in a room over here. The debate I am hearing in this room was taking place somewhere else and quite separate.

Nick Timmins

Some of it interacts here because the DECs were developed partly in response to the purchaser-provider split because the purchasers, the health authorities and the GPs wanted advice on what they should buy so they actually got bigger and stronger. Is that right? The DECs emerged out of that so it is bit more of a Venn diagram. I think your point is absolutely valid.

Brian Edwards

Yes. You cannot envisage intelligent commissioning without clear, scientifically evidenced guidelines on what should be done. That all sounds so easy, but the fact is we sat in this room a few months ago looking at commissioning; it still has not happened.[12] We still cannot really do intelligent commissioning apart from in a few very specific areas of healthcare, because the evidence is not there. The systemic reviews were intended to produce guidelines from NICE and others, I agree with you Kieran, it was fairly tenuous and in abstract rather than in reality.

Kieran Walshe

There was quite a bit of rhetoric in Michael Peckham's early documents about an evidence-based, knowledge-led, healthcare system, etc, but the reality in those days was that there was not a lot of

[12] The University of Liverpool witness seminar on the 1991 NHS internal market.

connection. I guess the question we will come back to is how much more connection there has been.

Sally Davies

Did Clive Smee not fill that hole?

Chris Henshall

In part, he did, yes. [47'56]

Kieran Walshe

One man.

Sally Davies

He was very important in straddling the worlds as the chief economist and advising the ministers on a lot of that. Clive's pivotal role, I would argue, was not recognised. He was very influential.

Nick Timmins

Particularly around cost effectiveness questions.

Keith Peters

Michael Peckham, whom I admire greatly and I knew very well, exaggerated for effect, on the one hand, the lack of, as it were, real understanding by doctors of what they did. The fact of the matter is a great deal of medicine is very well done in the absence of robust evidence and to say to managers, 'They do not really know what they are doing' was quite a nice move, as it were, but to exaggerate the ignorance of medicine, on the one hand, and the power of a scientific technology that did not exist, on the other, left him somewhat exposed to criticism. You might say, 'Well, they would say that, would they not?' but remember that people have to face the reality of doing medicine day by day, seeing patients, making the best decisions they can and people coming along and telling the managers, 'They do not know what they are doing' is seriously unhelpful.

Brian Edwards

Do we know who appointed Michael Peckham?

John Pattison

It was a Department of Health appointment.

Brian Edwards

Duncan Nichol was present, I think, as the chief exec of the NHS.

John Pattison

Yes, he would have been.

Sally Sheard

John, you had something about this in your memoir.

John Pattison

Only my own appointment. I can tell you who was there then and it was the Chief Executive of the NHS, the Permanent Secretary, the Chief Scientist and the CMO.

Nick Black

Was it advertised?

John Pattison

Yes.

Sally Davies

Yes. There were head hunters.

Nick Black

No, but going back to Mike?

Chris Henshall

Yes, the first director was advertised. I was working at MRC at the time and MRC was asked to suggest people who might be encouraged to apply. In fact, the folklore was that Mike Peckham's name was put into people's thoughts by someone senior at the MRC. He was not much on the map of all the things we have been talking about up to now. He was brought in from outside operational research, evidence, whatever we are going to call reviews.

Nick Black

He was head of BPMF, so he was not in the wilderness.[13]

Keith Peters

He was a clinical oncologist. One of his great contributions was the introduction of platinum therapy in cancer.

Nick Timmins

I want to keep moving, because I thought this would be a short section and instead there is loads of interesting stuff pouring out of it, so we need to keep going. Let us pick up a few more events and see if people think they are important. There is the Culyer report.

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[13] The British Postgraduate Medical Federation, one of the postgraduate medical schools of the University of London from 1947-1996.

Sally Davies

Essential.

Nick Timmins

It was essential, yes.

Sally Davies

Yes, we could never have set up NIHR without the Culyer report.

Nick Timmins

Unfortunately, Tony is not well and cannot be here, so, Sally, do it for him.

Sally Davies

Chris always does all this better than me, but the money was getting lost and by doing the Culyer review we got a visible budget. It was not a real budget, as we all know, but it was a visible budget, so then you could start to think about where is the budget and what is it doing.

Nick Timmins

What is the difference between a visible and a real budget?

Sally Davies

A real budget is when you can spend it. A visible budget is said to be spent, but it is very difficult to track whether it is.

Chris Henshall

There were two key steps. The Culyer review set out a number of principles about NHS R&D funding, but what it is remembered for, probably, is proposing that the research expenditure should somehow be identified and made accountable. That was an exhortation and a principle and we then ran almost a two-year exercise across what was still then a regional structure. Indeed, I do not think it would have worked without a regional structure, with all the regional directors of finance and all the power, influence and knowledge in the regional office to run what we called 'the declaration of R&D expenditure'. We said that we have to find this money and the only people who know where it is are the people in the Trusts, because that is where it is, not that they knew where it was, but we encouraged them to go and look, to a set of very simple accounting principles that we agreed with the regional directors of finance. That allowed us to say, 'Here is a notional budget' and then we made it a real notional budget, still not moveable, by doing a zero-based cost movement exercise. Hospitals said, 'I am spending £10 million a year on R&D'. Up until that point, they were getting that £10 million through their purchaser contracts, because that is the only way they got money or at least that bit of money. We said, 'Okay, from now on, that money is going to come to you centrally from an R&D budget and we are going to take it from the purchasers and put it into the R&D budget'. A massive matrix was drawn up of 450 Trusts versus 14 or eight regions or whatever it was and all of the purchasers, and all of the declarations in the Trusts were mapped across the purchasers they interacted with. On day zero of the beginning of a financial year, we reduced all

those purchasers' budgets by the amount that had been mapped to them and we created the central R&D budget. As Sally said, it did not mean you could do anything with it, because that money was all being spent, it just had a different label on it when it arrived at the Trust. None of that was in the Culyer report; that was what we did to try to turn the theoretical principle in the Culyer report into something that was beginning to be a reality, as it were, but it took Sally to figure out how to move that money.

Stephen Davies

At that time, I was a mid-level finance manager in a teaching hospital and Trust and I can assure you that we did not know that the money was being spent; that the declaration, which I personally looked after, was an exercise in backward mapping to arrive back at the number that one first started with, i.e. the SIFTR allocation. In that sense, the origins of the budget are in the historical artifice of SIFT and SIFTR.

Chris Henshall

That was not true of all institutions, some of whom had much more money going in. There was a political game that institutions played, basically who was your money safest with. The people who had huge research expenditures in reality and who thought that the purchasers were an easier win than the R&D centrally would be under-declared, so they kept getting the money from the purchasers. The people who thought that the purchasers were going to get tough with them and that central R&D would be a safe place to have their money coming from, declared something closer to what they were spending. There was huge political game playing going on.

Brian Edwards

It was called gaming the system.

Sally Davies

In the regions, it was led by the regional director supported by the finance one and I remember going to a number of Trusts and saying, 'I do not believe your declaration, I think you spend more' or, 'I think you spend less' and we came to an accommodation.

Nick Timmins

That is an interesting word.

Marc Taylor

I was the secretary of the Culyer review and it was a very interesting process because what it brought together was people interested in R&D and the financial function and the Chief Medical Officer.[14] It was a kind of plot between them to produce a convincing report and it was not at all clear that ministers would act on the principles of it. In fact, there was a tipping point. The decision needed to be taken to go ahead and do what Sally said; Brian Mawhinney, the minister at the time, was extremely stubborn and a statistician who, once he understood what was going on, was offended by it, as anybody in the finance function was also. That was what gave it the force to

[14] Refers to Liam Donaldson, who was in fact Regional General Manager of Northern RHA at that point, and CMO later.

overcome the enormous political resistance, which you must have gathered from what Chris was describing, because lots of people hated it bitterly and went on hating it even well into the time when Sally started –

Sally Davies

Taking it away. That is why they hated it.

Nick Timmins

You have the regional structure that allows you to do this and then the regions get abolished. Did that have an impact? Keith, you made the point earlier that it did, but in terms of where we go next with this story?

Sally Davies

We had a stage before that, where we ran a competition for the Culyer money, though it was all pretend money, and all the Trusts had to bid in dreadfully long documents. We then had a very interesting process with all the regional directors there and 53% of the money was in whatever region I was doing at the time, North Thames, and the rest was across eight other regions.[15] They thought this was unfair and wanted to move it. Then started one of my long-standing phrases, which is: if you can show me it will be better spent somewhere else, you may move it. They could not show it would be better spent, so we never moved it, but because I used that everywhere, I was then able to use it in NIHR, 'I can spend it better not with you but over there', so I was able to move it. However, we did have that exercise and I think £10 million moved.

Nick Timmins

That is £10 million out of how much?

Chris Henshall

Five hundred million.

John Pattison

We were still wrestling with that in a meeting that I had with you and Nigel Crisp; Nigel was regional director and you were the regional director of R&D. At the time, we were only thinking of moving something like £10 million out of a budget of £400-and-something million and you were very concerned to know that Bart's and UCH would not be disadvantaged by that. That process, it is quite right, we are all poachers turned gamekeepers, are we not, depending which side of the fence we are on. What was the date that you are talking about finding out from each of your Trusts that 53% was in north London? Was that 1998?

Sally Davies

It was as soon as we had done the Culyer declaration.

[15] The other seven regions.

Chris Henshall

The Culyer declaration was done and the money was moved, but then the first set of allocations within this new budget was a year or two later, because a lot of preparation had to be done, Trusts had to be told that they now had to bid. Sally has put her finger on it; the first attempt – and maybe we could have done it better, but you learn as you go –

Sally Davies

No, I would never have let you move it.

Chris Henshall

No, but what we learned was that there were people who were going to mount very strong, and good, arguments, exactly as Sally said: what evidence do you have it will do better somewhere else? I had moved on by that point, but what was learned by the system was if you are going to start moving serious sums of money like this, you had better have a proper system for doing it. You had better have a system of quality assurance that is robust and fit for purpose and that is what was then set up.

John Pattison

Meanwhile, people like Keith in Cambridge were saying, 'We get so little by comparison and yet our research effort is comparable in size and in quality'. We had many conversations about that.

Keith Peters

I had moved from the Hammersmith, which had a huge research budget, to Cambridge, which had virtually none. I am talking about in the health service.

Sally Davies

I thought it was £4 million.

Keith Peters

I am not sure, Sally. It is very important to consider these things against the economic background of the health service. It is one thing to move money when money is going into the health service; it is another thing to move money when the health service, like it is now, is absolutely static and facing increasing costs. Throughout most of the period that we are talking about, of course, the health service was under severe pressure.

Nick Timmins

At the end of the 1990s, money was very tight.

Keith Peters

It only returned in 1997, 1998 when Gordon Brown loosened his grip on things as more money was coming in.[16] It is under those circumstances that it was much more practical to – remember, most of the money we are talking about was paying salaries and looking at the real cost of looking after patients in hospital. It was not a budget that you could easily move and that is one reason why the defence against moving was so powerful: you are asking me to sack people. In Cambridge, though, when eventually money started to be more proportionate to research activity we got a lot more and it was wonderful.

John Pattison

Keith makes a very good point that R&D is alongside long-term maintenance; that when the going gets tough then that tends to suffer. When I arrived, in 1999, for that reason and a number of others, one of which was 'well, show us what the payback is', the standing of NHS R&D was going down. If that trend had continued, we would have been in serious trouble over the next four or five years. Fortunately, things turned around.

Nick Timmins

That standing in whose eyes? Ministers' eyes?

John Pattison

Yes.

Sally Davies

This is global. There was quite an interesting move about four years ago by OECD and they relabelled R&D funding not as revenue but as investment, as R&D capital. It is quite interesting that it is a global issue, this stealing of R&D money and not recognising the long-term role.

Chris Henshall

On what John has said, I then moved to the Department of Trade and Industry and worked on the science and innovation budget in general and that dynamic, which Sally harnessed by the time she had become a – the health people were beginning to say, 'Well, this could be spent on replacing hips and we have a queue for those, so why are we spending this money?' That was always there and John is right, it was getting stronger, but Gordon Brown, with the white heat of revolution, the 2004 10-year spending review for science and technology, the future of the country's economy is in pumping money into R&D. That was influencing a reluctant Minister of Health and so whilst the Minister of Health's excitement may have been dampening after a launch in 1991 and 'well, what have we got for it?', that was countered by the Gordon Brown Treasury – and David [Cooksey] was very much involved in this – push on 'this is an investment in the future, this is fundamental to our economy'. Various other things happened, including the Cooksey report, which was to try to line up the Department's view of research and development with the national view that this was an investment and had a major economic component as well as efficiency and quality for the health service. Bringing those two things together was absolutely key politically.

[16] The 1997 government delayed substantial real-terms increases in NHS spending until 2000/01.

Paul Atkinson

By the time we get to the 10-year investment strategy we are talking about 2004.

John Pattison

Just to illustrate the situation, Frank Dobson was the secretary of state when I was appointed, but he was then persuaded to stand as London mayor, much against his better judgement – as it turned out, he was right – and Alan Milburn was appointed. Shortly after Alan Milburn arrived, Simon Stevens came to see me. He was then special advisor to Alan Milburn and he said to me, 'John, you have a long way to go to capture the hearts and minds of ministers'. We were at a bit of a low ebb at that stage.

Nick Timmins

I find that very interesting, because my impression was that throughout the 1990s, which we have been talking about a lot, as the money was getting tighter and tighter and tighter after a big spending increase in 1991, people like Alan Langlands, Ken Calman, Clive Smee were determined to keep a quality, evidence-based medicine research agenda going in the face of this as best they could and with not a lot of interest from ministers.

Chris Henshall

Yes.

John Pattison

Yes.

Nick Timmins

That was happening and when Labour arrived they did create NICE. Labour's political positioning ahead of 1997 was just all over the place. They did not have a policy other than the fact that they were interested in evidence-based medicine and what became NICE. Are you drawing a distinction here between a willingness to create NICE, which is an absolute use of cost effectiveness stuff and scepticism about returns from the broader R&D programme?

Chris Henshall

The incoming Labour government had huge scepticism about the good faith of the civil service. There was an enormous suspicion of existing institutions – because they had been working so long for the other side they must be suspect – so the Department's own work on something like NICE was left on the shelf. Simon Stephens' blueprint for NICE influenced what was created and Graham Winyard and people in the healthcare directorate had been working on something similar for ages. It ended up very similar, but that was not what drove NICE, that was Labour's political advisors. There was a big suspicion, when Labour came in, of the R&D programme, just like there was a big suspicion of a lot of things.

Michael Rawlins

It was more complicated than that, Chris. During the middle to late-1990s, there was the whole postcode prescribing of beta interferon; there was the business of the incoming Labour government wanting to incorporate elements of cost effectiveness. In fact, in early 1998, when I was chairman of the Committee on Safety of Medicines, Baroness Jay summoned me to her office on my own – Keith Jones, who ran the MCA, was horrified that Rawlins was going to see a minister without a minder. Baroness Jay said to me, 'We are interested in incorporating elements of cost effectiveness for new drugs. Would your committee, having given advice on quality, safety and efficacy, be prepared to then consider cost effectiveness, to separate out the decisions?' I said, 'I would not advise it. I know committee behaviour. If you know, in 30 minutes' time, you have a rotten cost effectiveness decision, you will fudge the first one. You can always find something wrong with the quality. The pharmacists can be guaranteed; the clinical trials, you can always find something wrong' and all the rest of it. I said, 'No' and I am sure I was completely right, but afterwards I wrote her a memo, which I have lost; an FOI request could probably dig it out, but I am slightly shy of doing an FOI request on my own memo. [1h09'47]

Nick Timmins

That is alright, Mike, I will do it for you. [laughter]

John Pattison

Your point, Nick, is that an incoming government wants to do all sorts of things. Money has to be found to do those all sorts of things and, as Keith described, in a situation where money is staying level, in real terms, at best and diminishing, in real terms, at worst, you have to take money from somewhere that exists in order to do something new. It was not just NICE, I am not getting at NICE at all, it was a question of is it going to stay in R&D in DH or is the DTI somehow, with David's help, not that he was on the DTI side, but when industry, which is another stream of the changes, was coming along DTI made a strong play for the extra investment to be given to the DTI as opposed to the DH in supporting bioscience, which was going to support some of the recommendations in your report, David. You had to re-establish or promote the ability and the trust that was based in NHS and DH R&D; otherwise the new money was going to go somewhere else if you were not careful.

David Cooksey

One of the things that really worried Gordon Brown was the fact that the pharmaceutical industry was emigrating its R&D from this country, mainly because the university infrastructure was totally insufficient at that time. I persuaded the Wellcome Trust (I was a governor at the time) to work with the government, with the Joint Infrastructure Fund (JIF) programme and Gordon picked that up immediately and it made a very substantial difference to his attitude, particularly from the feedback he got from that programme. It was what primed him for what came later.

Nick Timmins

Are we now talking about 2000?

David Cooksey

No, that was in 1998.

Nick Timmins

Right, so he was interested then. It seems to me that NICE gets set up and there is a bit of a lacuna until we hit 2000 when, suddenly, Tony Blair makes his spending pledge and the taps do not open instantly, but they start to open and there is a lot more money around suddenly.

Sally Davies

Then you have to look at the predecessor of John, who found the job, I would argue, rather difficult.[17] I remember we had a board and he told us (the regional directors) that £10 million was being taken out of the budget. At which point, I went off to see Ron Oxburgh and said, 'What do I do about this?' and he said, 'I am going to introduce you to Bob May, who is the Chief Scientific Advisor'. When I told him the story, he said, 'I will sort that'. At the next board I went to, John's predecessor said, 'Someone has leaked it and they are for the sack if they find out' and I sat there, smiled sweetly and said, 'I would be fascinated to know who leaked it'. He did not battle for it, though, and if people do not battle for things they are not valued.

Keith Peters

There is one other bit of mood music that is worth saying. Now it seems so obvious, but the mindset in the 1990s, as I perceived it, at the centre of government and Treasury and so on, was that the NHS and medicine was a black hole into which you poured money, which was spent in ways that many people thought was unaccountable and unproductive, etc. The best thing for the country to do was to limit, as it were, the 'waste' of money on healthcare and keep the money that you had left over for education, research, industry, etc. The idea that the healthcare system was part of a wealth-generating system was really quite alien then. It is not alien now and I am not sure, looking back, when that transition occurred.

Sally Davies

Bioscience Innovation and Growth Team (BIGT), then Cooksey's report.[18]

Keith Peters

David's report helped, but reports always reflect the attitudes of the people who are in them. Somewhere around 2000, there was a starting to realise that the healthcare system was an asset.

The other thing is, which David referred to, it was already clear that the NHS had an important relationship with the pharmaceutical industry, often fraught, but in fact the pharmaceutical industry was retreating from the UK and has continued to do so. However, it might have retreated a damn sight faster if some of the things that David did through BIGT, etc, had not happened.

Nick Timmins

I would endorse a bit of that, because there was a hell of a lot of right-wing hostility to the whole idea of the NHS from the mid-1990s onwards.

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[17] Professor John Swales.

[18] Biosciences Innovation and Growth Team, *Bioscience 2015: Improving National Health, Increasing National Wealth* (London: Bioindustry Association, DH, DTI, 2003).

Louise Wood

I was just about to pick up on that point. In 1999, the then PM met with the chief execs of AstraZeneca, Glaxo Wellcome and SmithKline Beecham and that led to the establishment of the Pharmaceutical Industry Competitiveness Task Force (PICTF). That was the first time that there was a strategic relationship between government and the pharmaceutical industry and it was not just between the Department of Health and the industry, it also involved Treasury, No 10, the Business Department and the Education Department. That signalled a big change that followed a whole series of reports.

Nick Timmins

That is a great point at which to break and we will jump off from there in the next session.

Emergence of the Present NHS Research System

Nick Timmins

We have reached the stage where we need to do two things one after the other, but slightly in parallel. We have reached the PICTF and all that bit and, over tea, Sally said to me that what John was up to immediately after this period (2000-2006) was really important as part of laying the ground for NIHR, so do you want to start with that?[19] [1h38'36]

John Pattison

We have already begun to identify some of the general themes that, to my mind, happily, all took us in the same direction towards, ultimately, NIHR. We reversed the standing of NHS DH R&D in the view of ministers, including, importantly, the Prime Minister and the Chancellor of the Exchequer. There was a time when it seemed clear that much of the policies had moved across Whitehall to No 10 and 11 rather than on the fourth floor of Richmond House.[20]

Secondly, Sally and Chris, we established that NHS R&D could be helpful and deliver and that is always important. The best example was prostate cancer, probably. It was an embarrassment, at the time. It was and still is one of the major causes of morbidity and mortality in men and NHS R&D was spending the princely total of £90,000 per annum on it. Ministers recognised that there was public clamour and also recognised, on numerous occasions, that when you do not know what to do about an issue, to sponsor an R&D programme is about as good a response as you can give. They did that and we helped them with it, I think successfully, though we still do not have a number of the answers to key questions.

Thirdly, there was the reorganisation of the Department of Health and the administration of the National Health Service with the disappearance of the regions, etc, which seemed, to me, to lay the ground for the centralisation of much of the decision making and the potential to run NHS R&D from the centre as opposed to the very distributed system with regional directors, 10,000 projects,

[19] John Pattison's term as Director of NHS R&D was 2000-2004.
[20] Richmond House, Whitehall, was the headquarters of the Department of Health.

13 R&D units, the major programmes of HTA, the Cochrane Collaboration, SDO, which I found when I first got there, in 1999.

The other stream, which David can talk much more insightfully about, is the whole business of the espousal of the fact that a science-based and particularly a bioscience-based economy is probably one of our best bets for the future as a country. The relationship between Sir David and Gordon Brown was absolutely key in taking things forward in that respect.

Nick Timmins

Right. The greater Prime Ministerial and Chancellor interest in this presumably came with the big announcement of the money. Once Blair has said, 'We are going to get it up to European spending levels' and Gordon has said, 'You have stolen my fucking budget', but came up with the cash, it was clear that there was a very central interest in getting something back from all this, yes?

John Pattison

I have to say that, sitting in the Department, I was absolutely astonished at that settlement, completely surprised. It just felt as if Gordon Brown was saying to the NHS and to the Department of Health and its relationship with the NHS, 'I have taken care of the money, now you show us what you can do'.

Sally Davies

Before we go to David, you have forgotten some bits, John, which you played a role in. We moved from petty baronies of the R&D directors – I am a petty baron, reformed, of course – into a much more centralised system. You set up the Cancer Research Network, which delivered. You set up the Experimental Medicine for Cancer Network and then you chaired the Research for Patient Benefit Working Party. All of those were key foundational things that you did that delivered. There are probably more, I just cannot remember them.

John Pattison

We were given tasks, we worked at them and delivered something useful. That did our standing quite a lot of good and it achieved things. PICTF is an interesting one. Philip Hunt was put in charge of it as the minister. It worked. There was a certain amount of tension to start with, but by the end there was quite good relationships between all the parties who were gathered around the table. Interestingly, though, I am not sure what it achieved in concrete terms, except that it showed the pharmaceutical industry that the government was prepared to collaborate with the pharmaceutical industry. Whether anything concrete came out of it I have no idea. I was always suspicious that something was agreed behind closed doors that we did not ever talk about in open committee, but there we are.

Keith Peters

There is one other thing to say about you, John. When you took the job, you had been dean of a very large medical school and you understood the breadth and complexity of medical research in a way that neither of your predecessors had done. You brought a different sort of credibility to the table and that is worth recording as well.

John Pattison

Thank you. You are embarrassing me.

Chris Henshall

To pick up John's point about PICTF, obviously I agree with the previous point. I had been in the Department of Health for nearly 10 years when PICTF was set up and what had changed was the Blair kind of centralised government, government from No 10, saying to the Department of Health, in very clear terms that it had never heard before, 'You are part of a government that has a bigger agenda and you need to be part of that agenda'. For most of my 10 years in the Department of Health up to that point, frankly, a lot of people saw industry as the problem. Here it was producing all this expensive stuff that we could not afford and the solution to this problem was health technology assessment to keep it out. That is obviously a ridiculous oversimplification, but the idea that industry was a key part of the national economy and that we had to find a way of working together was kickstarted by PICTF. The fact was that the two departments of state were made to work together and Blair and Brown basically said, 'You will sort this problem'. By the time I left the Department, a year later, there had been a real change in attitude across the Department and perhaps, to some extent, in the NHS, perhaps less so, to the idea that industry was a key part of the national strategy.

Nick Timmins

When you say the 'two departments' do you mean Health and DTI?

Chris Henshall

Yes. That was my take on the culture.

David Cooksey

That certainly feeds into what I would say. I came to this as being the founder of the first true venture capital firm in the UK and even before Blair and Brown came to power they were both in touch with me about trying to improve the success rate of technology innovation in this country and its commercialisation. That is how I came into this. I mentioned earlier the JIF programme, but that had followed the establishment of seed venture capital funds on all the university campuses, which I did with Gordon in his first budget and he came back to me in the second budget and asked for ideas, which ended up with JIF.

What was interesting to me then, just moving forward a couple of years, was the setting up of the BIGT, which produced this report in 2003, *Bioscience 2015*, which was trying to pave the way forward.[21]

It drew a lot of attention to the lack of collaboration between the health service and the pharmaceutical industry, particularly the biotech industry. I foresaw that if there were good collaboration, you could get drugs to market much more quickly.

The BIGT used the 1.5% research budget number. We were in a spending review period which ended in 2006 but we were in 2003 and the budget had dropped from an objective of 1.5% to 0.9%

[21] Biosciences Innovation and Growth Team, *Bioscience 2015: Improving National Health, Increasing National Wealth*.

and by 2006 the allocation was due to drop to 0.52%. When we dug deeper into the numbers it was clear that 80% of the research budget was being spent on service delivery – in other words, operational research and so on – and only 20% of it was being spent on clinical research. That was the trigger that got Gordon Brown interested.

An interesting item to note about this report was that it had two editions, one with an introduction by Tony Blair and one with an introduction by Gordon Brown. It was the first time that I witnessed the fight between them but the fact that they were fighting over the credit for writing the introduction meant that they were both engaged and wanted to make it happen. The BIGT report was jointly sponsored by the DTI, the Department of Health and the BioIndustry Association. When, as far as Gordon was concerned, there was not a fast enough response, he ring-fenced the budget for health research and paved the way for NIHR. I think Sally will agree. He then came back to me within a year and said, 'I want a much more fundamental review of funding for the whole health research function'..

Nick Timmins

Can you date those two events?

David Cooksey

This was 2003.

Nick Timmins

Therefore, he came back to you in 2004.

David Cooksey

No, he came back in 2005 and my Review was published in 2006. I strayed way outside my brief in that review proposing a change to the approach to licensing to what I called 'conditional licensing' but is now called 'adaptive licensing'. The whole objective of the report was to engage the pharmaceutical industry much more and to have a responsive National Health Service for delivering clinical research, clinical trials and so on. Sally should speak about this because she made sure that we got the Clinical Trials Networks going as soon as possible after that.

Nick Timmins

I was quite intrigued by your comment about what PICTF really did apart from change the climate. I remember trying to find out what PICTF was up to and never could, in terms of what it had done, other than people were talking about each other in much warmer terms than they had been in the past.

Chris Henshall

I do not think you would have had initiatives on information on the trials networks and things. A number of things happened in response to PICTF that would not have happened if people had not been shaken and told to go in a room and come out with some solutions.

John Pattison

In a sense, the Research for Patient Benefit Working Party came out of PICTF. Ministers wanted something to follow on from that, putting it crudely, in helping the pharmaceutical industry stay in the UK. We could not have a working party called 'Helping the Pharmaceutical Industry Stay in the UK', so we called it Research for Patient Benefit Working Party.

David Cooksey

One thing that may not have come directly from PICTF but certainly came from that initiative was the Patent Box, which was definitely part of keeping the industry in the UK.[22]

Keith Peters

That was much later, was it not, David?

David Cooksey

Yes, it was much later.

Kieran Walshe

I just wanted to sound a slightly more sceptical note about PICTF. What did the NHS get out of PICTF? As I listened to the discussion, did you get into the discussion with the pharmaceutical companies about how they spent the £4 billion a year or so that they spent on research, and how that fitted with the needs of the NHS? [1h53'40]

John Pattison

No.

Kieran Walshe

Was that a missed opportunity?

Chris Henshall

PICTF was a bit of a one-way street. The agenda was the country needs the industry, the industry is telling us it is a nightmare dealing with the NHS, please sort that. That was basically the agenda and that is what people discussed. It led to a number of initiatives and the patient benefit side of it, which John has, quite rightly, picked up was where the win-win was. When we said, 'Okay, what are we now going to do about implementing this?' the idea that cancer networks would not just facilitate the setting up of industry trials but would work for patients to get faster access to treatment and things, came in the implementation. The agenda for PICTF was very much No 10 and No 11 telling the health service to start getting real about being friendly within their remit, as it were, to an industry that was finding them pretty unfriendly.

[22] The Patent Box enables a company to apply a lower rate of Corporation Tax to profits earned after 1 April 2013 from its patented inventions.

Louise Wood

One of the legacies of PICTF was that there was a Clinical Research Working Group, which continued to meet after PICTF, which Sally and Vincent Lawton chaired. There were a number of practical things that came out of that, which included a partnership agreement with the NHS that articulated essentially the principles to which the parties could hold each other together. There was also the model Clinical Trials Agreement, which was aimed at speeding up the initiation of trials and saving the NHS the cost of legal reviews of individual trials contracts. PICTF, as a whole, produced competitiveness indicators, which were published year after year afterwards. It is the first time there are public metrics where people could track progress, including of clinical trial numbers, which had a nadir and then increased.

Kay Pattison

Chris is right to say that at the same time there was an expansion in budget. We went from a £10 million HTA budget to a £40 million HTA budget or more. All the things Louise has just described in terms of getting research into the NHS quickly and therefore getting results more quickly were impactful across all of our budgets, so the fact that we were spending more on patient-driven research as well; we have not covered that very much. We involved patients and prioritised research programmes across the NIHR, including through the HTA programme, for all programmes. That research, too, was happening more quickly because of the reforms that came through PICTF.

John Pattison

What we are doing is emphasising that it was the start of something that subsequently delivered quite a bit. One thing that I really felt personally a complete failure in was to take forward to an appropriate point the whole difficulty around research ethics committees. Subsequently, that has all been sorted out.

Sally Davies

It started under you. We did sort it fully, but it started under you. You laid the foundations for a lot more than you are taking credit for.

John Pattison

Is this early dementia do you think? [1h57'10]

Sally Davies

No, it is your gentle nature.

Keith Peters

Just to get all the praise for John out of the way, there is one other thing. I can recall that on the Research for Patient Benefit Working Party we were very conscious of the success of the Cancer Network and you said to me, 'I think we might be able to do this for maybe one or two more subjects, what do you think?' and I think I said something about stroke and so on. Then you went ahead and created a much more full on system of networks, about a dozen, which altered the whole dynamic of clinical research. It means there is not just a few fancy doctors in a specialist unit doing

research but making the whole system research conscious. That came from that particular Working Party and you were in charge of it at the time and drove it.

Nick Timmins

In this period of 2000-2005, there are a couple of Academy of Medical Sciences reports.[23] Did they play a significant part?

Sally Davies

John Savill's on clinical scientists was important and Sir John [Pattison] responded. Mark Walport's, which came later, on the failures of academic training and the need to put that right was also useful, but that would have been irrelevant if it had not been for David's 2006 report, which gave me £56 million, transferred from the NHS and NIHR set it up and everything. Mark wrote the report, but my team in NIHR and another, contracted out, centre in Leeds delivered that with the money that David delivered.

Keith Peters

I was president of the Academy in 2002-2006 and, as you know, the Academy was set up in 1998 with Peter Lachmann as the first president. The Academy's mission was to address, if you like, the crevasse between, on the one hand, the very powerful base of biomedical science in this country and everything else, which formerly had been the responsibility of the royal colleges but they were not delivering on. [1h59'50] The translational gap, which is what all this is about, was the Academy's prime mission and the Academy, of course, had strong representation from industry and does to this very day, and so the industrial plank was one element of it.

The other thing that had bothered people from the mid-1980s onwards, but particularly with the loss of regions, which were sponsoring the careers, through local funds, of clinical research workers, not just medics but the variety, that disappeared with the regions and there was deep concern about the lack of clinical research workers. John Savill did the first report on that and it was followed by Mark putting the flesh on it, as you say, and then of course John Bell's *Strengthening Clinical Research* was the immediate predecessor of your Working Party on Research for Patient Benefit.[24] That covered more than just research training; it is a pretty accurate analysis of the major problems that existed around about 2002, 2003 and 2004. Then the Academy was extremely involved with you, David, in your review in 2006. We spent hours on it and, in fact, the Royal Society was involved as well, but of course the Royal Society had played virtually no part in the discussions and deliberations about the problems of medical research in the context that we are discussing it. There were hardly any fellows of the Royal Society who were interested in it. I remember going to one meeting and trying to raise it and it disappeared, a bit like Czechoslovakia, a far off country, they do things differently there. The Academy played a pretty vital part in the culture out of which these things grew and certainly the dialogue with you, David, was very powerful. [2h01'56]

Nick Timmins

Colin Blakemore, what did this look like from the MRC at this point?

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[23] *Clinical academic medicine in jeopardy: recommendations for change* (Academy of Medical Sciences, London: 2002); *Strengthening Clinical Research* (Academy of Medical Sciences, London: 2003).
[24] *Strengthening Clinical Research* (Academy of Medical Sciences, London: 2003).

Colin Blakemore

I would pick up particularly on one of the points that David has made and which has been emphasised and that is the importance of the pharmaceutical industry in the whole of the thinking then, not just the contribution to GDP but also the contribution of private funding of research in this country. It was by far the biggest element of corporate funding of R&D and the government wanted to use that as an example to set to the rest of industry because of under-investment in research.

I have the impression that by about 2005/6 the government, while it had formed its views about the importance of increased emphasis on research in the NHS, had a rather limited perspective of what that might achieve and how the money would be used, particularly focusing on clinical trials. Certainly the people I spoke to in government imagined that the improvement of the organisation of R&D funding in the NHS – maybe better liaison with MRC, more emphasis in MRC on translation research and so on – would purely be aimed at delivering clinical trials within the particular, special and potentially very positive environment of the NHS for organising trials. To my mind – and I am sure others will have different views – this was somewhat naïve in its expectation that that would lead to massive repatriation of trial investment in this country, which had gradually slipped overseas to eastern Europe and then, increasingly, to India and to China and so on. In fact, that has not been the pattern. That is not to say that the investment in R&D in the NHS has not been well spent and very important, but I do not think it has quite delivered in the way that perhaps Gordon Brown would have expected it in 2004/2005, do you think, David?

David Cooksey

I agree with that. There was optimism amongst ministers. You have to look at politicians' attitude towards the health service. There are votes to be lost by doing it badly and as long as they can tell a good story they expect to gain votes from it. The trouble with the health service is you have to take a 20-year view of what is going to happen and the longest horizon any politician has is the next election, which is a maximum of five years. That is our main problem.

Colin Blakemore

It is a good thing that the public, when it comes to the NHS, has a longer term perspective. That certainly exercises some influence on governments even with the limited time horizon that governments always have.

Can I just go back to the question that you really asked, which is about the MRC? When I joined the MRC, in 2003, of course this was the stirrings and the beginnings of all the discussion we have heard about in the last half-hour. There was an element of fear and concern that the contribution that the MRC had made traditionally in developing areas of research, which was certainly relevant to clinical issues – the biggest funder of clinical trials, for example, the establishment of the Clinical Trials Unit and so on – was not going to be adequately recognised. With the buoyancy of the feeling about the importance of developing research within the NHS, that the MRC's contribution and, indeed, its future might slip off the horizon a bit, we felt a bit beleaguered at times. Personally, I was very keen that we should emphasise not only what we had done in the past but also what we planned to do in the future, with the emphasis on translation. There was some resistance to that in the biomedical research community amongst basic researchers, who felt that they were threatened by that slight change of emphasis within the MRC. Tactically, politically and realistically it was absolutely the right thing to do and set the scene for the willingness of MRC to work in this very significant development that was to follow in the next four years.

David Cooksey

Can I just say that Colin kept my feet to the fire in a big way during this time. Every time I met him to discuss my pending report there would be an article about how wicked I was in *Research Fortnight.*[25] In truth, what made a difference was the fact that I got away with persuading government to not only increase funding for clinical research very considerably but to parallel it with quite an increase in the MRC's resources as well. Colin forgave me from that moment onwards.

Iain Chalmers

Very briefly, of the various Academy reports that have been referred to already I do not rate any of them as important as the one on reducing hyper-regulation in research, which was chaired by my neighbour here.[26] I thought it was very important. Taken together with Janet Wisely's appointment as chief executive of the Health Research Authority, those have been extremely important. It is just tragic that, through ill health, she has had to stand down, because she was exceptionally good at taking some of your suggestions and reflecting them in the arrangements for assessing research.

Brian Edwards

Can I come to new drugs? A lot of the political and managerial focus was on new drugs coming onto the market through clinical trials, then coming to the end of the clinical trial and then somebody had to pay for it. I remember trying to get the centre to offer some advice on new drugs, but it was difficult. It may have been mixed up with the work that was going on collaborating with the industry, but in two regions that I know of we set our own review up of new drugs, chaired by clinicians. I can recall a series of dinners with Eli Lilly, SmithKline Beecham where they offered to let our regional people into their research workshops and to see the results of all their clinical trials in order to persuade us that maybe we should provide some cash for new drugs coming onto the market. I do remember the telephone call that said, 'This is not helpful, Brian, please back off', so we did.

Nick Timmins

Telephone call from…?

Brian Edwards

Somewhere in the Department of Health, I cannot remember, but it will be one of our liaison officers.

David Cooksey

You are looking straight at me, Brian. It was not me.

Nick Timmins

This is all pre-NICE presumably. This is the 1990s, 1980s?

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[25] A reminder of how controversial the proposals for change were, and how much anxiety they provoked at the MRC, until the Government's preferred solution emerged.

[26] Michael Rawlins (chair), '*A new pathway for the regulation and governance of health research*', 2011.

Brian Edwards

1990s. There are two final things to add. One is the regional general managers were nervous about the centralisation of funding and some fought against it, but at the end we were persuaded that this was a way to sort it out and create some benefit for all of us. I know that, because I was chairman of the Regional General Managers Group and I was asked the question. We did, after some early fighting, agree to back the centralisation.

The final comment is, limping alongside all of this high science was clinical audit. It started just after Ken Clarke's reforms and had mixed success, but there were thousands of clinicians engaged in this and, as far as I know, very little research alignment, which was a pity.

Nick Timmins

Right. We should now get into NIHR and its creation. Who do I start with?

The Creation of NIHR

Sally Davies

I was appointed to follow John in 2004. At one of my early meetings of the Department of Health executive board, I was asked to discuss research and I had a slide, which went along the lines of 'Why should government invest in research in the NHS?'. [2h11'01] By the time we had had a very robust discussion, the chief exec who had appointed me, perm sec, he did both roles, Nigel Crisp, had been my director in London, so I knew him well, he had got the whole of the executive committee to agree that I should come back in some months with a radical overhaul to look at how we could use our investment better. Then we started on a programme of thinking, debate, consultation to come up with a proposal and it would not have happened without Russell Hamilton. A variety of people played key roles, but I would argue that Jonathan Grant and the organisation he worked with, RAND Europe, played key roles.

We started by looking at what were the barriers to doing clinical research and it was my view, which many seemed to share, that we had lost the art. It had changed from what it had been when we had been leaders to a platform activity and you needed teams. You needed to have methodologists, you needed the clinicians and our clinical research networks were showing you needed the support from the networks to deliver it. Over a period of about a year, we ran consultations, discussions, roundtables, teased out the issues, the barriers, thought about how we might address it. There were things like I went to listen to Richard Sykes in Portcullis House and he made the argument in his talk that if government was proud of teaching hospitals it ought to fund them.[27] I walked back to the Department and said, 'Right, we are going to have biomedical research centres. We will fund them competitively to do experimental medicine'. Thus, it came from all sorts of places and we worked things out.

Key in working out what we wanted to do was I invited in McKinsey, Nico Henke and his young Turks, to challenge, which turned out to be a really good move, because they were doing so much

[27] Sir Richard Sykes, Chairman of Glaxo plc: 1997-2000; of Glaxo Wellcome, and of GlaxoSmithKline 2000-02. Rector of Imperial College 2001-08.

for the Department on other areas of health reform and everything that they could fill in bits that, although I was in the Department with the team, we did not know were going on.

The other thing I did was persuade some people from the Treasury to come and critique. Two important things came out of that meeting apart from some really good advice. One was the agreement that we needed our own research budget for market failure research. The team called me the 'DG for market failure research' for ages. It was research we needed that no one else would fund and so we got that commitment from the Treasury. It built a very good relationship with someone it turns out had his hands on the money, but entertainingly, after the first one I was told, 'You are not supposed to talk to the Treasury. You can only do that through Finance'. Of course, it was too late. I had set up a series of meetings and they were with us on it.

We got to a model, which we called NIHR. We went out for consultation in August 2015. It was seen as too medical and we did not mean it to be medical. So much was iterative of our central team, was it Russell, was it me, was it Louise, was it Marc, of this concept of we have a health system so you can overlay and interdigitate a health research system? It had the dartboard in it.[28] It had the four main areas of faculty, infrastructure, market failure research and systems, with the patient at the middle, because we do it for the patient, but recognising the important role of universities and their academic leadership. The networks were then how we support the research of ourselves, of pharma, of other partners, charities, but recognise the role of people who put patients into studies, and then the research funding for SDO [Service Delivery and Organisation], HTA, all of that.

We put a lot of metrics in. We had the right politician. I had support from Nigel Crisp, but it was Patricia Hewitt – funnily enough, my husband was talking to her yesterday – who was minister.[29] That could not have been better. She had been Minister for Science and Minister for Women. When I went to see her, she said, 'Of course you have to do this. I will support you, you are going to,' and she said, 'It should not be your strategy, it should be government's'. I now know the proper terms, but she essentially took it through Cabinet and got Cabinet support, which I had not known to get, but it gave us a lot of force for when we started moving money.

We started on 1 April 2006 and, on that day, our website was a .ac website and had taken four attempts to get JANET to agree and every time the team said, 'They have turned it down', I said, 'Go back'.[30] We can debate why it is a virtual institute still managed out of the Department of Health and this is all about politics with a small 'p' and control and things and it is carefully thought through on a regular basis. On that day, on our website all the programmes were laid out, thanks to Russell and the team, Marc did his bit, Louise, everyone; what we were going to do, how we were going to run it. The HTA centre in Southampton played a massive role in writing all theirs down, the milestones, the metrics we would use, the timetable. What a wonderful team. We dropped a week every so often and then caught it back up. It was all totally transparent and metrics-driven, so no surprises that government gave us more money.

Nick Timmins

Which makes it all sound very smooth.

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[28] The 'dartboard', which Davies goes on to describe, was a graphic of NIHR's activities and stakeholders. A recent version can be seen on the NIHR website here.

[29] Patricia Hewitt was Secretary of State for Health, May 2005 – June 2007.

[30] JANET is the Joint Academic Network, the high-speed network for UK research and education, responsible among other things for allocating internet domain names to academic bodies.

Sally Davies

Do you want to see the scars on my back?

Nick Timmins

Tell us about them.

Sally Davies

Well, the hospitals did not like it. Back to what we were talking about earlier, when the Hammersmith came and said, 'You cannot take £56 million away'. With the NHS finance director beside me, I said, 'That is interesting, because I can remember coming to you three years ago and saying you were not spending it on research and you insisted'. 'Yes, but you know it was a game.' I said, 'Tell that to the judiciary when they do you for signing off accounts that you knew were wrong. Off to jail or give me the money'. That was one example.

Keith Peters

Where did you say the scars were, Sally? [laughter]

Sally Davies

Ah, let me tell a story about Keith. I really love him for this one, though he may not sit by me at dinner tonight by the time I have told it. About eighteen months in, we had a big meeting at the QE2 [conference] centre. Do you remember, Keith, coming to me and saying, 'You know we all thought you were wrong?' 'Yes, Keith.' 'You know we all thought you could not do it.' 'Yes, Keith.' 'You know we all thought you were going too fast.' 'Yes, Keith.' 'Well, we were wrong and you were right.' I loved you for that, because you had given me shit.

Keith Peters

Not at all, I supported you at all times that you will never know about.

Sally Davies

We set up an advisory committee and I remember three very senior members of the biomedical community sitting there, saying, 'You do not know how to do peer review. If you get the money, it should be given to the MRC'.

Nick Timmins

To which Colin would have said, 'Thank you'.

Sally Davies

He was one of them. It is all right, we get on well. We got to an endpoint where everyone could see we were doing a good job.

Nick Timmins

Just list the assorted vested interests that had to be taken and all squared off.

Sally Davies

The hospitals, because they were losing money, though my other robust comment was, 'If you are as good as you say you are, you will not lose the money, will you?', particularly as the money increased.[31]

Nick Timmins

That is a really important point, because what lay behind this was if you have this amount of money, you are going to have to bid for it competitively, but if you are good you will get it and, if you do not, someone else will.

Sally Davies

Yes, that was my line.

Nick Timmins

Yes. Carry on, keep listing.

Sally Davies

Many of the clinical triallists found it odd that our HTA programme was commissioned and as we upped the budget from £40 million to over £100 million, we still kept over half of it commissioned to solve problems. They did not like that; that we said we would decide the issues.

Putting in place the academic training programme – thank you again, David, for the £56 million – has proved difficult and, in fact, I hear regular gripes that medical schools and Trusts find it difficult.

The biomedical research centres; we were practising social engineering. There was a standoff in general between medical schools and hospitals. They were not working together and we said they had to be joint applications, they had to be joint vision, single management. Many of them did not get that the first time around. They did by the second time.

The fact that for the first few years academics did not value the money. Russell changed that. He clocked we needed HEFCE to value the money, so he went and got HEFCE to put it into their system to value it and that changed it.[32]

Women in science. On the second biomedical research centre competition, when the panel asked the people they were interviewing, 'What are you doing for women in science?' I was embarrassed in front of our international colleagues by the medical schools' responses. Ten days later, I sent a letter to deans, chief execs, vice chancellors, you name it, saying we would be unlikely to shortlist

[31] Part of the motivation for establishing Biomedical Research Centres was to manage the reactions of the existing major players in clinical research, and their concern about the possibility of losing resources.
[32] This refers to recognition of clinical academics' work in the Research Assessment Exercise (since 2014, the Research Excellence Framework).

them if they did not have Athena SWAN Silver Awards five years later. One letter I received, from the then head of Universities UK, who was medical, was so rude we sent back a letter from my office saying that I had seen it and asked for it to be filed.[33] Another vice chancellor rang me up and, after shouting at me, said, 'Well, it will be one-legged black Jews next, will it not?' It was abusive and racist, it was unpleasant. They have all come in line and are doing better. I think they need another shake, but they are doing better.

Can you think of some more? Come on, Marc, Kay and Louise, you must have had some of them. It was a battle.

Kay Pattison

There were individual vested interests from particular topic areas. I can remember one was the forensic mental health lobby, which had previously had a programme, thought that the forensic mental health research agenda would be lost. We had to explain that it was perfectly possible to apply to Research for Patient Benefit programmes. We have had to launch an assessment programme to put suggestions in for topics. That is just by way of example. There were other lobbies that felt that their research interests might not be pursued as a result.

Nick Timmins

Sally, I can remember you saying to me once that you did it under the radar. Is that right and would you like to explain it?

Sally Davies

The power players in this field were all male, most of them were rather older and most of them thought they were really rather important and I felt that if I challenged them head on it would not work.

Participant

Softly, softly catchee monkey.

Sally Davies

Yes. I never stood up and said, 'My budget is bigger than yours', though it is still – although it is not mine now, I have handed it to Chris Whitty – bigger than the Wellcome's budget. I never stood up and said, 'Look what we are doing. We are doing massive change' or anything. I just got on and did it below the radar. If we had stood up and talked about it too much, what do you think, Nick? You were there.

Nick Black

I was just thinking as you were saying that, at that time, I was on the Medical Schools Council, even though I was not a dean of a medical school. Every year, we had a retreat at Ditchley, where you had the 35 or 40 deans of the medical schools sitting around for two days. There would be a research afternoon and Colin or whoever at that time was head of MRC would come, Sally would come and it was fascinating, because there were two sides. There was the side you [Sally] saw,

[33] Professor Sir Eric Thomas, University of Bristol, President of Universities UK, 2011-13.

which was a silent, passive hostility, but reasonably polite and the chair always said nice things to you, but afterwards I would hear them talking over drinks and there was considerable hostility. What you were trying to do was rubbished, in the sorts of ways you have just said – it will not work, it is the wrong thing, and so on.

Nick Timmins

Was that purely intellectual or was it misogynist?

Nick Black

It was protecting their interests. I do not think misogyny came into it.

Sally Davies

They do not like change. I do not think it was sexist.

Nick Black

It may partly have been.

Keith Peters

Be careful. Not all medical school heads felt like that. I can tell you one who did not. The truth of the matter is there were winners and losers in the system. [2h25'28] Cambridge, for example, was a huge winner from this, winning one of the first biomedical research centres, so that was not a uniform view.

Nick Timmins

That is a post hoc view, though. You turned out to be a big winner. Presumably, when this was all being proposed there was a risk you might not be a big winner.

Keith Peters

Not at all, no. At the time, it was quite obvious that there was unequal distribution of funds for research centres. You did not have to be a rocket scientist to see that. I can mention the Hammersmith, where there was £60 million a year going in, to an organisation that had about one-tenth of that.

In the middle of the great successes of all this there were some genuine concerns, which are worth articulating. For example, there was a loss of local autonomy. The combination of the money going into the centre, on the one hand, and the loss of the regions, on the other, meant that there were a lot of things that you wanted to do and, in the old days, it was a matter of picking up the phone and getting something done, now you had to go through a process. Of course, the places that were good at that process or well organised did very well indeed. Cambridge's budget came in very substantially. I was not involved then, but it was doubled in no time at all and now it accounts for something like 20% of the Trust's income; it is a vast change. In the middle of changes like that, it is understandable that people should be upset and concerned. It is not that they are luddites exactly.

Marc Taylor

I would be interested to know how you feel about the way that this process was standing on people's sore toes. There was a long period in which the people, who were eminent people who were used to competing for money according to the opinion of their peers, by a process of competitive excellence, were really not at all comfortable with the idea that Sally should be bringing in a process that had other dimensions to it, which were asking about the research agenda from the point of view of the patient –

Sally Davies

The patient, the public, value for money, methodology, yes.

Marc Taylor

Exactly. It felt a bit, to me, like the period very early on when we were bringing together the national programmes, when we wanted to build up research in primary care and we advertised against the budget and there were, initially, no proposals to speak of that passed muster at all. You just had to go on and on stimulating people to think that this was a respectable area in which to bring forward high quality proposals. That is bound to crash against, as Sally said, the right way to allocate money is by doing excellent science that established people think is excellent.

Keith Peters

Sally's process, as I saw it, at a distance, was to lift it up and get international people on board and emulate, as best one can when dealing with things like infrastructure, a fair peer reviewed process. I do not think people were really too upset by that. What upset people was that they saw their infrastructure being threatened.

Sally Davies

Except that, of course, we then got a lot of capital and we were able to put that into hospitals and they did very well for a period of time.

Keith Peters

That comes back to the point that you were doing this against an increasing budget in the NHS, which was absolutely vital.

Sally Davies

Well, yes, but key was David Cooksey going into the back of No 10 and No 11 and the Treasury support that we had. In the end, the Treasury more than doubled the budget and even in the last spending review gave me, and I handed it Chris Whitty, was it £150 million of overseas development assistance as well to spend? Part of it is because we say what we are going to do, we get the metrics and you lot deliver it.

Nick Black

Going back to the comment I was making before about the medical school deans. By, say, 2014, their attitude to you [Sally] had changed in private as well as in public. It was now full of

admiration, not least that you had not only protected the NIHR budget while all other budgets in the NHS were being cut over that period, but you had increased it. It had switched, they had been won over and what you had done was admired.

Brian Edwards

Can Sally remember which clinical or public health arguments turned out to be the most persuasive?

Sally Davies

For what, with the government?

Brian Edwards

For increased investment in research and development.

Sally Davies

Oh yes: that the NHS owed it to the nation to play its role in our scientific excellence, whether it is universities and supporting them or industry. It was those.

Brian Edwards

It was not smoking or diabetes or cancer.

Sally Davies

No. We get the money and then we spend it on what it needs to be spent on.

David Cooksey

Sally, I remember, when all this was starting, having debates with you over funding health research and you being very concerned that we were not producing an answer at that stage. Are you satisfied with the progress that is being made now?

Sally Davies

We have upped the amount a lot, but I do not think it is where I would want it, not just in amount but in the main – and Nick could talk to this better than me – the academics are very divorced and separated from the delivery. In one sense, we are covered for the academics because the MRC funds their hypothesis-driven work, the Michael Marmots or whatever, but what we need is, again, for the customer, which is public health and local authorities and social care, a cadre of researchers who are embedded there who can do the work we need. We are slowly growing it; we have a National School of Public Health, one in primary care, one in mental health now to try to develop that, but it is a long struggle and it is not for want of trying. I know that the Office for Strategic Coordination of Health Research (OSCHR) is having another look at it with a subcommittee.

Michael Rawlins

Can I say three things? First of all, the capital budget that Sally mentioned a few minutes ago was very important. It allowed us, for example, in Newcastle to build a clinical trials unit, which we had never had before and I can remember you came and opened it for us, Sally.

The second thing to say is, as far as NICE is concerned, the health technology assessment programme was absolutely critical and, certainly at one stage, Kent Woods emailed me to tell me that NICE was utilising 50% of the HTA capacity in Britain.

The third thing to say is when David Cooksey was getting ready to produce his report, he came to see me and said, 'Should NICE have its own research budget?' I did not know he was going to ask the question, so I winged the answer and I said, 'No'. I said that for three reasons. One is how much? Fifty percent of the HTA budget, would Sally really give that up? No, she would not. Secondly, we would have had to devise a whole research bureaucracy, which was completely stupid because the NIHR had already done all that and were doing it very well. Thirdly, it would be a fixed sum and if we wanted one year a bit more and another year a bit less, we would not be able to fiddle around in any way. I said no to David and I think I was right. NICE has had very good value for money, as it were, from NIHR and will be always very grateful to it.

Sally Davies

Tom played a big role in that.

Michael Rawlins

Absolutely. Is he blushing?

Tom Walley

It was not my money.

Kay Pattison

There is another reason why it is good to have the two budgets separate and that is that it seems independent of the NICE decision-making process. When you go on Radio 4, you can say, 'We did not do that research'. That independence is really important.

Nick Timmins

Yes. Colin, given that the MRC had reservations about what Sally was up to when she was up to it, if you see what I mean, before it was completed, did the MRC get reconciled and, if so, how long did that take?

Colin Blakemore

I would question the assumption that the MRC was opposed to it.

Nick Timmins

I did not say 'opposed', I said 'concerned'.

Colin Blakemore

We were concerned about our own future, the survival of the MRC and our ability to go on doing what we thought we did well, not to the increase of investment in research in a clinical environment. A lot of the discussion of the last 10 minutes goes over my head, because I am not a clinician and therefore did not see the effects in clinical environments. I only later began to see the enormously positive impact of NIHR funding and the skill with which NIHR, but also senior clinicians themselves, had worked the system to make it effective in their favour. If you go into medical research centres and see the leaders and ask where their funds are coming from, the core of support in the clinical environment of course comes from NIHR far more often than anywhere else. You see that that focus has acted as a magnet in attracting other major funding – BHF [British Heart Foundation], Cancer Research UK, MRC, Wellcome and so on – coalescing the core support from NIHR and so that is an excellent thing.

Just reflecting on some of the points that have been made, the concerns that I saw – and not me alone, I assure you – about the emergence of NIHR with its budget was no longer the threat to the rest of us, because as far as we and many people in the NHS were concerned, this was essentially new money that had been pulled back from service support, it was how it was going to be used effectively. There were concerns in the very early days about peer review. There was also – and I am very happy to admit this – a lack of recognition of the value of commissioned research at the delivery end of medical research. The notion of going and saying, 'We would like this bit of research done and we will find people to do it and ask them to do it' was anathema to Wellcome and to MRC. It ran against all the principles of investigator-led, quality-driven research proposals and all of us could have pointed to depressing failures in earmarked calls for proposals in the past that had not delivered, because the capacity to do the work was not there. What we have all learned is that clinical research at the delivery end is different. You have a problem, there are good people around you who can identify it, you can get it solved if the money is there and you draw up the commission, effectively.

The other issue that concerned us – and I would like to think that at the early stages of the discussion the advisory group to NIHR in the early stages, for instance, had an impact on this – was the balance between NIHR's investment in the core for high quality clinical research in hospital environments and the fraction that would be allocated on a more commissioned basis for specific channels with funding for applied research. The emergence of the biomedical research centres – I can remember very well the initial call for the biomedical research centres – was really greeted by everybody with an element of surprise, but a feeling that this was a very positive move. I remember very well Sally saying that she had asked John Savill to chair the charabanc that whizzed around the country doing the peer review. That set the seal on the process of harmonising the relationship with MRC, because John was, at that time, chair of the clinical sciences board at the MRC. It really set the seal on the effort to develop a good working relationship.

Nick Timmins

Almost as an aside, I would be interested to know if people shared the view that you can commission applied research, service-driven research, but it is difficult to commission more basic, blue sky research. You have to rely on people having the ideas rather than you saying, 'We need this problem solved'.

Sally Davies

Then it is mission-driven. If it is fundamental research, it is mission-driven research that you are commissioning.

Marc Taylor

I want to remind everybody about a very interesting working example. Do you remember that preposterous manifesto commitment to have genetics knowledge parks?

Sally Davies

Oh, indeed.

Marc Taylor

John led a process that somehow turned that into a series of linked calls, so that you would do something around genetics from early science through to the clinical application of it. I am taking the words out of your mouth, John. I am sure you could say what you thought we made of it, but at the beginning it seemed so unpromising.

John Pattison

Did it seem so unpromising, Marc? One thing I have not explicitly stated is that, as director of R&D for five years, you had to operate in a system that was governed by politicians who had been elected and who had the power to tell you what to do and if you kept saying no, no, no, no, no, no, no, no, then you would have to find another job. I think that is why my predecessor, John Swales, had such a difficult time. There are some impurities in the water and you just have to tolerate them otherwise you are going to have a real problem. They wanted knowledge parks, so we had to deliver knowledge parks as part of a big package of seeking resources to try to promote genetics in the NHS. It was not such a bad idea. They were called knowledge parks for reasons I cannot quite remember, but what you were doing really was trying to set up centres of excellence in genetics and that is not necessarily a bad thing to do. I have lost track of what happened to them, Marc. Did they endure?

Marc Taylor

For a while they did quite well, but the interesting thing was that we managed to include some calls, for example, for people to think about the legal implications of changes in genetic science and about how to explain genetics and the possibilities to the public. This was something that had hardly been thought of at the time and was generally an area for fear and anxiety rather than hope and imagination. [2h41'31]

John Pattison

Part of that came, Mike, from Newcastle, which seemed, to me, to have done that brilliantly with your Centre for Life.[34] I do not know what particular bit of cloning they were doing in the department that day, but I asked John Burn if there was any anxiety in the public about this and he said, 'No, we are open to the public, we engage the public and there is a slightly tribal feeling in Newcastle that says, well, if we are doing it here it must be alright then'.[35]

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[34] The Centre for Life is a science village incorporating a visitor attraction, educational facility, research facilities housing biotechnology companies and an institute of Newcastle University, and two NHS clinics.
[35] Sir John Burn, Professor of Clinical Genetics at Newcastle University.

Sally Davies

It might be worth picking up on something you said about this interrelationship between politics and NIHR. Thanks to Russell, I am expert at Rothschild and separation – Haldane, sorry, you see I cannot even remember which now. Now I am only CMO I forget what I am talking about. One of the things we have managed to shift is that though they still ask for things and we are expecting an ask on prostate cancer any day again, they understand that they can say, 'This has to be a priority in some form'. Our present ministers have understood that if they say, 'We will ring-fence a budget for this' then they have opened themselves to every single group, so they do not say it, they are quite clever, and they have let us get on with it.

I had lunch last week with the Cabinet Secretary. I was seeking his advice on something else I am doing and he said, 'Your strength in NIHR was to get them to agree to let you set it up, then to go away and do it and not bring the politicians in, and just let them open things and get all the credit and congratulations'. He advised me on this other problem to do exactly the same and I think we have managed and that is why it is still safe to leave it there. We argued it was best as a virtual system because one of our values is equity and fairness across the country. We debated it regularly and I am sure the debate goes on should it be separate from DH or should it be sited there. The minute you put it as a sibling of the MRC outside, then it has to compete with the research councils for money rather than going on its own and the ministers for the health system have no ownership of it. The ministers overseeing the MRC felt no ownership and therefore they do not fight hard for the money, they do not help you; they are passive, it goes through and around them. The quid that we pay the ministers of listening to their needs and trying to help is worth the quo – or whichever way around it is – of the support we get for the budget and the fact it exists. That is why we have done it that way.

Michael Rawlins

And you do not cause them any trouble.

Sally Davies

No, of course I do not. [2h44'47]

John Pattison

The other thing to say about them is that they have not got to where they have by being dumb. They are quite intelligent people and I know that it is all politics and it is responsive and what have you, but most of it is not a bad way of carrying on, to be honest. Prostate cancer is still the best example, I suspect, Sally.

Sally Davies

How much did ProtecT cost us? £37 million. Who else has spent that much on one clinical trial across the world?

John Pattison

Yvette Cooper rang me up one day. She was Minister for Public Health at the time and she was standing in Alan Milburn's office. We had been asked how much we spent on prostate cancer and it was £90,000 that year and I cannot remember the exact words, but basically she said, 'John, can you find £1 million out of your existing money to put into a prostate cancer programme?' Things

were pretty tight, Sally, at the time, particularly in the regions, which was where we were reducing things. Before I answered, she said, 'Alan and I will support an application for £5 million per annum increase in your funding in the next spending review'. With those odds, you just say yes and you find the money somewhere.

Iain Chalmers

I have the impression we are approaching David's report, but we have not got there and I want to say something that is related to that.

Nick Timmins

Yes, we are about to get there, so shall we?

David Armstrong

Yes, my comments fit in. Just to follow on from Colin's earlier observations, can I bring in the role of the scientists on the ground, who have not been in the picture so far? At the time of the Cooksey Report and at the time of NIHR's creation, I chaired the board at MRC that looked after clinical trials, the Health Service and Public Health Research Board. There were five boards, this was the fifth board and, as we have heard, it had a rather uneven gestation vis-à-vis the DH and was, in many ways, culturally different from the other boards. The other four boards were basic science whereas we were applied science, because we are dealing mainly with thinking about the health service and how would our research impact on the health service. When the news came through that NIHR was going to be formed and all the trials were going to be transferred across, there was some disappointment across the board, because we were the bit of MRC that was being affected. There were two things that stuck in my mind as important. One was MRC always seemed to be high quality research. It was international, so all the reviewing was international and so on, we had to be internationally competitive. The second thing was MRC had MRC trials. They had started trials and an MRC trial seemed to be an internationally recognised term for good quality trial, and we were concerned that both of these were lost.

These were fairly short-lived concerns, because eventually that community who were on the board migrated across into NIHR. Many of the NIHR members of the programmes or chairs of the programmes came from that MRC board. Many of my colleagues then went into NIHR and even myself, I eventually took Sally's shilling and I too went on to direct an NIHR programme. It was interesting that the scientists themselves simply migrated from one home to another.

Nick Timmins

Yes, right.

Kay Pattison

There is a point as well about setting the agenda, if I may. As has been mentioned, we have a significant budget now for global health research. I have not been very involved in that, but I did see a list of commissioned research projects and I anticipated that I would not recognise any of the names, that these would be new people I had not come across before because I had not come across global health research. In fact, I recognised almost all of them, because what has happened is good people who have been involved with NIHR in the past in different areas have migrated towards global health research because there is some funding there. You can move people into those areas where you would like to see research commissioned, whatever that might be. We have been very

successful in that and with global health research it proves that you can pull people into different areas to follow the money.

Nick Timmins

Right, great. We ought to move to 2006 and your funding health service research report, because that changes some of the ways the money flows.

David Cooksey

It has had a very positive effect in terms of pulling everything together, but that has depended on people like Sally and so on to make it happen rather than the very fact that more money was on the table. That report is now 11 years old and, to me, one of the really big disappointments in following it has been the way that during the gestation of the report I had a huge 'come on' from the pharmaceutical companies for what I was trying to do, but in fact, if you look at what they have done since then, it has been to largely remove themselves from discovery research and rely on government, charities or universities in one form or another to provide the discovery research. To me, that is a huge disappointment, because one was looking for a parallel effort from the industry to move the whole agenda forward. Look at the way that AstraZeneca now only has 7,500 people working in the UK and Pfizer has closed down Sandwich and so on. Interestingly, Pfizer has announced that it is withdrawing entirely from dementia research, which is extraordinary, to my mind, if they want to be taken seriously as a pharmaceutical company.

Nick Timmins

I hate to be thick, but by 'discovery research' you mean…?

David Cooksey

I mean basic biomedical research to get to the fundamentals. They are relying increasingly on the capabilities that we are providing in biomedical research for everything that we have discussed. One of the things I am really concerned about is the pricing of drugs by the pharmaceutical companies who are allowed to charge a large margin over cost. This merely encourages them to pump up the cost of Phase III trials in order to justify increasing the price of their drugs. Quite frankly, I am horrified at what has gone on.

Sally Davies

It is interesting you say that – and I know and I agree – but President Clinton was in town this weekend speaking at a patient safety conference and he said he thought the pharma model was broken. They could not go on charging these very high prices in rich countries.

David Cooksey

Quite frankly, if this report could be slanted in a way that draws attention to the need for that, I would be delighted, I really would, because we have to completely review where we stand on the patenting of drugs and what protection the drug companies get for that.

Michael Rawlins

About the drug pricing, sometimes it is absolutely awful, but one of the things NICE has managed to persuade the pharmaceutical industry to do is to negotiate commercial-in-confidence discounts and that has been very important and you do not know what the discounts are. When I was chairing NICE, I was criticised heavily by equivalent organisations overseas, which kept on saying, 'We do not know what you are paying'. I said, 'I have to look after the British public, you have to look after yours. What I am doing is looking after British patients'. [2h53'43]

Nick Black

May I ask David a question? You say you have been horrified by subsequent events, but have you been surprised?

David Cooksey

I was surprised by the commitments that they were prepared to give at that time. Roche undertook to Gordon Brown to move approaching 30% of their clinical research capability from Switzerland to this country; it never took place.

Colin Blakemore

Your point about investment, I think you said 'inflated payment in phase III clinical trials' as being part of the argument for the overt pricing, how does that work economically? If they are paying more for trials, then is the increase in pricing not directly justified?

David Cooksey

It is justified according to the current model, which I am querying. Secondly, what I am saying is that it is not the regulators who are driving up that cost, it is the pharmaceutical companies themselves in order to justify higher drug prices. We do not have a policing mechanism to really challenge that situation other than the NICE model, but it comes at it from a different direction.

Nick Timmins

Is there not also a problem that, in a sense, the only people who understand what is going on in pharmaceutical companies are the pharmaceutical companies themselves, so it is really difficult to challenge their model?

David Cooksey

Absolutely.

Michael Rawlins

When you ask them, as I have done on many occasions, they still admit, in 2017 anyway, that they just charge what they think the market will bear.

Tom Walley

They charge what the US market will bear then try to get the rest of the world to pay.

Michael Rawlins

That is why NICE is keen to get discounts, it has been so important.

Nick Timmins

Yes, indeed.

Brian Edwards

Nick, what do we learn about the government putting money into dementia? How much of that is research and how much is treatment? Is that what we want governments to do, to pick out disease areas and put a load of money in? [2h55'58]

Sally Davies

It was David Cameron who decided that there were a couple of areas he wanted to really push. One was dementia and he supported me a lot on antimicrobial resistance. I started off quite sceptical; I have come around. By getting us all to put money in, the Medical Research Council led the setting up of the Dementia Research Institute, it has pulled in more money and more focus. We put more money in, all of it linked to the dementia platform. Although we do not have an answer yet, the people in it are challenging the beta amyloid theory, which is good. We need people continuing to work on the standard theories and others coming in and challenging. We have more work going on on how to care for patients, how to diagnose them earlier, all sorts of things that would not have happened if the Prime Minister had not said, 'I am going to do this' and had a report every six months about what was happening. It was driven from No 10 very hard. We had a committee that met with dementia experts, all the funders and everything.

David Cooksey

One of the things that David Cameron started was the Dementia Discovery Fund, which is run by SVLS, but was initially funded with £15 million from the Department of Health.[36] It is having its final closing tomorrow at £250 million, with some extremely eminent investors in it, but the government has put in £15 million more through the British Business Bank. [2h57'42] That £30 million from government has generated £250 million and I sit on the advisory committee on behalf of the government and they are making some good progress. I am not saying they have got anywhere near a solution, but –

Sally Davies

That is also quite interesting, because it started off with Cameron saying he wanted it and the Department must do that, then the bureaucrats got going and could not do it. I do not know whether it was Cameron or the Cabinet Secretary who brought you in, but you managed to sort it by bringing in the private sector to help sort it out and run it and then to raise some money. We do have to look at what government can do and what they are not very good at.

[36] SVLS is SV Life Sciences Managers LLP, a healthcare and life sciences venture capital and growth equity firm.

Keith Peters

We need to be very careful about this. The fact of the matter is that one reason dementia has done so badly is that there has been a paucity of good new ideas. People with a view of the history of the MRC would point out that Lloyd George started the MRC because of tuberculosis, a problem that needed to be solved. Let me remind you Nixon went into fixing cancer in the 1970s and that resulted in an awful lot of money being wasted; luckily, a bit of it laid the foundation for understanding retroviruses and HIV. The importance of the system that we have enjoyed in this country is that, by and large, politicians are kept away from decisions of how money should be spent.

John has pointed out that there is a realpolitik about this. I, personally, think the Dementia Fund is a mistake. I have seen a lot of dementia research in the last 10 years and most of it is based on ideas that were formulated in the 1970s and most of it has not delivered. Now, of course, there will be good new ideas, but they are not going to come top down, they are going to come from investing in brilliant basic scientists who want to understand the basic processes and that kind of money, frankly, is much better spent by the MRC.

David Cooksey

We would agree with you on that, Keith. There is no question about that at all. This Fund is there to take on the ideas from the brilliant scientists –

Keith Peters

But you know it's not early treatment and clinical trials and so on. I am not an expert, but I know a bit about it and there are not enough good ideas in the system yet.

David Cooksey

I would agree with you. [3h00'29]

Keith Peters

It is just like cancer was in the 1970s, I feel.

David Cooksey

Yes, and that is why we have given this thing a very long runway. It is not the usual 10-year fund, it is nearer a 20-year fund.

Iain Chalmers

Last week or the week before, I spent three days in Hanover at a meeting about translational research in the neurosciences, which was set up by a professor from Berlin and a professor from California. The mood was very down about, basically, the failure of many attempts to translate what seemed to be good ideas into something that might be useful for patients. One of the themes that came up again and again was that because so much of this early research is secret people keep on going up the same blind alleys. That is because the contract research organisation that has done trials for one company on a particular hopeful stream, is not allowed to tell the next company that asks them to do a trial with a similar agent what they have found. There is absolutely built in redundancy and inefficiency into the ways that things currently are. There was a paper by

Glenn Begley and Ellis published in *Nature* about four years ago, where they were writing from Amgen and saying that they had been unable to replicate 40 of the 44 proposed exciting things and they raised the question about the quality of the preclinical research that was being done.[37] What was really exciting about this downbeat mood was it moved people from that world to saying, 'We have to do something about this. We have to start doing better designed trials on animals that look at appropriate sample sizes instead of 15 and 20 animals as a basis for going forward to human research. We have to register the trials and we have to bloody well publish what we find, otherwise this built in inefficiency is going to remain'. There are some fundamental things that have to be looked at in that world of research and its quality before it is going to be possible to see more productivity coming from brilliant people's ideas, but then handled efficiently from a research perspective.

Impact

Nick Timmins

Right. I want to keep the story moving forward, because there is about a quarter of an hour to go. We have done OSCHR, in a sense. What is the next thing that matters? Academic health science centres (AHSCs) and networks are beginning to emerge, how does that all plug into this, or does it not?

Sally Davies

It does not. These were concepts that came out of Ara Darzi's –

Nick Timmins

High quality care for all.[38]

Sally Davies

Yes, that. He is right about what he wants, which is to extend the social engineering we manage with BRCs to bring in the delivery of healthcare and the university much closer together across the broad bit. It was unrelated to us. It was a competition, though we ran the first competition and it was pretty messy, for academic health science centres. You either are or you are not. Given the names, it does not matter that much.

The networks were also a great idea to broaden to health economies. They were a particularly good idea not just in concept but when there was going to be money associated with them, but as the money dwindled after the concept and telling people they had them, they have had less impact than we would all like to see them have. They do keep being given roles from the Accelerated Access Review and things, but it feels a bit like your classic Christmas tree. What happens in DH and the NHS is something is set up and it works well, so along they come – 'they' being ministers or senior officials – and say, 'We need this doing. Oh, they are doing really well and it is not that far away

[37] C. Glenn Begley & Lee M. Ellis, 'Drug development: Raise standards for preclinical cancer research', *Nature* 483, 531–533 (29 March 2012).
[38] High Quality Care for All (Department of Health, London: 2008).

from what they do, so let us give it to them', so you get these Christmas trees that then fall over, because they have lost their focus and never got enough money to do it or staff. Does that sound right to you?

One of the reasons NIHR is a success is I have what are known as sharp elbows. We have never done a Christmas tree. I would not take the AHSCs or the networks, but we helped them. They are great concepts, in some places they worked, the competition made people up their thinking and their games, but have they delivered across the nation?

Nick Timmins

Yes, and the enthusiasm for them comes and goes, does it not, over the years, a bit.

Sally Davies

Although it is not that they are not the right idea: they are.

Nick Timmins

Yes, right.

Colin Blakemore

Just some thoughts about the immediate past and the future, good news and bad news. The good news is developments that perhaps were not so much anticipated at the time of Cooksey. The emphasis on genetics, genomic research, 100,000 Genomes and the huge investment in that area which, apart from cancer, is slow to deliver, but we all feel very strongly that it will eventually deliver very positive growth in the development of new treatments and the stratification of patient classification and organisation of medicine and clinical care in new respects. The other is the interaction of the UK Biobank. It is a slow burn. It is a long-term investment, which of course DH is involved in as well as MRC and Wellcome. It is just now beginning increasingly to deliver really important evidence and will continue to do so: it is a massive cohort.

On the downside, I am very surprised that no one has mentioned the problem of record keeping and the increasing impact of data confidentiality and concerns about data handling, which have certainly impacted on the capacity of the NHS to deliver fully an understanding of disease. That was part of the great promise the NHS, because of uniform systems and record keeping and everything, really would deliver. I do not know what others feel, starting with the failure of Connecting for Health and then the impact of the increasing concerns about data confidentiality. Is that going to be a restriction on what NIHR can do, what clinical science can deliver in general?

Sally Davies

Just so you know, it is NIHR that has funded Genomics England and the 100,000 Genomes Project as an infrastructure project and we did it in a very novel way. With the support of the Cabinet Secretary, I persuaded the Secretary of State that we would set it up as an entrepreneurial start-up company, which gives subsequent ministers some indigestion. One of the things they are doing – it is going to be, it is agreed – is setting up the NHS in England Genomics Database. It will hold all the genomic data behind the NHS firewall, linked to NHS Digital, so we'll get all the HES

data.[39] [3h08'33] They should be signing tomorrow an agreement with a company, following an NHS procurement on their behalf, to get the software ready for October to suck much more clinical data, phenotype data, out of all the different hospitals' systems into that. We are going to have an amazing platform and we now have to use that – and this is where I am optimistic, having met Fiona Watt and talked it through – to move to platform funding in the way that we do in particle physics and astronomy.[40] Meaning that when the MRC, Wellcome or ourselves fund a clinical study or a study with patients, we make sure that all the data goes into that database so that it is available to the clinician, because the treating clinician can get it, but it is also available for people to come back to and look at in different ways. As we get more biomarkers and more genomics into that platform, we could become extraordinarily powerful. As we have an agreement that NHS England, in commissioning its new genomics medicine service, will fund a large number, I have forgotten how many, I think it is 60,000 a year whole genomes, this is going to get bigger and bigger with whole genomes as well as the exomes and the arrays. We have a real opportunity within the NHS firewall to access that data, as academics, researchers and as industry. That changes it around; instead of taking data out and asking patients' permission, keeping it in the firewall and going in, having got the proper permissions and training, could give us great dividends.

Nick Timmins

Does anyone else have a view on that?

Michael Rawlins

It is the same sort of area, but NIHR and NHRA co-sponsor the Clinical Practice Research Datalink (CPRD), which actively has nine million people on it and 25 million people historically, so we are getting there, but Care.data was a disaster.[41] With CPRD, patients can opt out and over the 20 years it has operated about 2,000 have opted out. Within a month of Care.data, 80,000 opted out. Now, when you've got a total of 5, or 6, or 7 million, it's not a very big deal, but it was mainly – and I am sorry to say this – middle class women.

Nick Timmins

You might be alright in those examples, but a lot of social science researchers are in despair about the ability to share data.

Marc Taylor

Is this not the big anxiety and the big opportunity, and the NIHR, probably more than other actors in the field, has built the capacity and has, if you like, the legitimate place to do more explaining, to convince more people that it is a good thing that science should make use of their health data, with the right sort of protection. It is important for two reasons that somebody should seize this problem. First of all, there have been these scandals, as presented, and the state of the law makes things worse. We have an EU regulation that is coming in and is being translated into domestic law, which defeats anybody to read it and understand it. Alongside that, you have the law on confidentiality. It is beyond most people to understand what on earth is going on in this area, so that seems, to me, to be a really significant difficulty that someone needs to seize.

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[39] HES: Hospital Episode Survey.
[40] Professor Fiona Watt FRS has been selected as the government's preferred candidate to be the Executive Chair of the MRC when it becomes a constituent part of UK Research and Innovation (UKRI) in April 2018.
[41] Care.data was an NHS data-sharing project, launched in 2013 and closed in 2016.

On the positive side, most of us here, the older ones, went to university when hardly anybody studied science and most people believed in arnica, so you have a massive opportunity, particularly with the improved education of women in scientific subjects, to change the understanding and the view amongst the general public about what is going on in this area.

Nick Timmins

We have five minutes left and I have two more questions it is worth having a go at.

Brian Edwards

A prediction. My bet is that the bigger Trusts and the bigger commissioning organisations, as they are blocked up, will get back into the research business by appointing their own research officers.

Sally Davies

They already have. They are working with us and funded by us.

Nick Timmins

Brian, just hear the last two questions and then we will have a chat. One is, we have talked a lot about the positive impact of all this, are there disappointments that remain? Linked to that, what should happen next?

Keith Peters

One thing that is happening in the whole system, which bothers me, being in one of the beneficiary towns, Cambridge, and Oxford the same, is that to them that hath has been given a great deal more and to those that have not they are starved. I worry that we will have isolated brilliant areas with tremendous resources and then deserts. I said earlier that I hoped the networks would spread the culture of research right across the NHS, but the truth of the matter is even within one institution there are people who are major beneficiaries of the system and the others are sweating in outpatients. I do not know what the solution to it is, but I do worry that that is happening.

Kieran Walshe

Building on what Keith and Brian said, the story of NIHR is one of a number of notable successes about research production and research infrastructure; the gap or the problem remains the engagement of the system in the use of knowledge to bring about innovation and change. It was interesting, that earlier discussion about the MRC, NIHR and others. I think people in the NHS, senior managers and leaders, saw all of that as a bun fight going on between different factions within the research community, which was really pretty irrelevant to them.

One of the adverse consequences of taking the money out of the NHS has been to strip capacity; it is the point that Brian was making. If you talk to people on boards in the NHS now, there is a limited understanding of research and innovation. That is partly because we have turned research from an intramural to an extramural activity for those organisations. Going back to an earlier point I made, if, in this room, you had a bunch of senior NHS leaders, chief executives and so on, the issues that would be concerning them would be things like productivity and efficiency, demand management, flow, the interface between self-care and professional care, the workforce, service integration, and it remains true that NIHR is not addressing those issues very effectively. The weakness, therefore, is that if NIHR in the future is going to need support – the point John made

earlier about the support of a community that says, 'We really value what you do and we think it is really useful' – from those NHS leaders, there is some way to go to get them on board even now.

Peter Sneddon

I am formerly of the DH R&D, currently of one of the largest NHS Trusts in the country and regularly attending the NHS Trust's board in order to talk about research, promote research and report to them on research. I can certainly say, contrary to Kieran's concern, that our Trust is intimately engaged in research and wants to contribute as much as it can, primarily because it sees that as a way of serving its patients better. The idea that into the NHS constitution Sally and others manage to put research as part of the integrated service of what the NHS is providing is extremely powerful. Our board must be focused on producing that service of getting our patients into research and they do see that.

One of the other reasons that I am able to communicate to our board the value of NIHR is something that Sally and her team took an enormous amount of time in order to set up and that was around the metrics and the performance-based allocation of funding, so that you get more funding, can do more research and you will get more money. That is a very persuasive argument to the board and it has worked on a number of occasions.

Nick Timmins

To pick up Keith's points, you are talking about an extremely large Trust and Kieran might be talking about Kidderminster. [3h18'47]

Kieran Walshe

I am involved with a research-active Trust as well and there are some Trusts that take much more interest in research, but it is interesting. You presentation, Peter, is conceiving of research as an income stream for the organisation. In fact, research should be an investment by the organisation in the future development of innovation and advantage and that is not how very many NHS organisations see it. They think, 'Okay, if we do research we get money from NIHR. We are a site for research'. That is not the attitude you would see in other industries.

Peter Sneddon

It is not about bringing the money in; it is about the value that the research brings to the NHS and its patients and how it transforms their treatment, etc.

Nick Timmins

We really are running out of time. What should happen next? Does anyone have any great ideas on what needs to happen next?

Keith Peters

Clone Sally.

[Laughter]

Nick Timmins

We just need a big round of *Mustang Sally* and that would be fine. Can I just say thank you very much for coming? Unless anyone has anything burning to say, it is really good of you to get here, I hope you all get home.

Concluding Remarks

Sally Sheard

I just wanted to say thank you very much. Thank you, Nick, for chairing, because I know this is slightly out of your comfort zone. For me, this has been a tremendously useful afternoon. I have learnt an enormous amount and I hope you have learnt something as well. There is an active role for history in these very contemporary policy debates and issues. George [Binney] asked me earlier how I would describe myself, and I bill myself as a 'useful historian'. I know Tom [Walley] was a bit dismayed to inherit a department where he had a historian in residence and he was not quite sure what to do with me. I hope this has given you some ideas. We have learnt a lot about the importance of collaboration, community, competition. We have fleshed out some of those niggles that we had about relationships between MRC, DH, NIHR and we are better for it, so thank you very much.

Nick Timmins

Thank you very much indeed. [3h21'08]