HOUSE OF LORDS

Science and Technology Committee

Uncorrected oral evidence: Innovation in the NHS: Personalised medicine and AI

Wednesday 24 June 2026

10.15 am

Watch the meeting

Members present: Lord Mair (The Chair); Lord Booth; Lord Drayson; Lord Duncan of Springbank; Baroness Jones of Whitchurch; Baroness Nicholson of Winterbourne; Lord Patel; Lord Ranger of Northwood; Lord Verjee; Lord Willis of Knaresborough; Lord Winston.

Evidence Session No. 18 Heard in Public Questions 204 – 215

Witness

I: Professor Jonathan Benger CBE, Chief Executive Officer, NICE (National Institute for Health and Care Excellence).

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Examination of witness

Professor Jonathan Benger.

Q204 **The Chair:** Good morning. Welcome to the Select Committee on Science and Technology. We are continuing our inquiry on innovation in the NHS, personalised medicines and AI. We are very pleased this morning to have as our first witness Professor Jonathan Benger, who is chief executive of the National Institute for Health and Care Excellence, NICE. Professor Benger, thank you for coming. By way of introduction, could you explain NICE's core responsibilities, as well as its role in supporting the NHS to adopt innovative technologies and medicines, particularly in the areas of personalised medicines and AI? As you know, our inquiry is focusing on that.

Professor Jonathan Benger: Of course. Thank you, chair, and thank you to the committee for giving me the opportunity to give evidence; I am delighted to do so. NICE was founded in 1999 and our core purpose has not changed since then, which is to ensure that we get the best care to people fast and ensure value for the taxpayer. In terms of the areas that you describe and which this committee is looking at, our purpose is exactly the same: it is to determine what works clinically in the NHS and is cost effective in the use of NHS resources, and to produce guidance as to how those technologies should be implemented into clinical practice.

The Chair: We have a lot of questions for you, as I am sure you know. Before we go on to questions from other members, I would like to ask you about the recent arrangement between the USA and the UK on pharmaceutical pricing, which included a provision for NICE to raise its threshold for affordability to between £25,000 and £35,000 per quality adjusted life year; in other words, per QALY. Could you give us some insight into the impact of this particular move? Can you give examples of treatments that will now be available that were not before?

Professor Jonathan Benger: I should begin by making it clear that the position of NICE and my position as the chief executive is that it is for the Government of the day to determine how much money should be spent on the NHS and on medicines within the NHS. Obviously, it is our job to do our role in the system of determining clinical and cost effectiveness, according to the threshold that has been set by government.

Increasing the threshold has the effect of increasing access to important medicines for individuals who might otherwise not have been able to access those medicines under the previous threshold.

However, it also increases the total amount of money that the NHS will spend on medicines. That is an intended effect as part of the UK-US trade deal, as I understand it. It is difficult to give examples because we do not know what would have happened if we had not increased the threshold. There is an element of commercial negotiation that goes on outside NICE's processes, which often achieves a cost-effective price for the NHS. The counterfactual, as it were, is difficult to determine.

However, our estimates suggest that an additional three to five medicines that would not otherwise have been approved will be approved by NICE every year. That will give access to patients who would otherwise have missed out on life-saving or life-changing medicines. One example I would point to would be Givinostat for Duchenne muscular dystrophy, which we approved shortly after the threshold change towards the top end of that threshold range you described. Again, I cannot guarantee, but it is very likely that we would not have been able to make a positive recommendation for that medicine under the previous threshold. As a result of that, boys with Duchenne muscular dystrophy are able to access a genuinely life-changing treatment.

The Chair: Is there any sense of what those three to five additional medicines per year might cost the country and what it means for the NHS?

Professor Jonathan Benger: Not really, no. As I say, one is trying to predict what would have happened without a threshold change and then trying to observe what happens with one. It is absolutely clear that we will spend more money on medicines, but the actual quantity is difficult to be clear about. There is potentially a general increase in the price we pay for medicines, associated with an increase in the threshold, but it is very difficult to quantify. It is likely that to start with, the financial impact would be very small because we are talking about a small number of medicines, but obviously, over time, the cumulative impact over years would be greater.

The Chair: Presumably some may be applicable to very large numbers of patients.

Professor Jonathan Benger: Yes, absolutely. If a medicine is cost effective and reaches a large number of patients, then that can be a very positive thing.

Lord Patel: Before I go on to my question, just to clarify and better understand the answer you gave in relation to what was not available before being available now: that comment refers to the

costing issue, correct?

Professor Jonathan Benger: What I am saying is that because the threshold has been increased, as we do a new appraisal—say, one that starts now—there is a possibility that under the old threshold, we would not have been able to reach a cost-effective price and therefore access—

Lord Patel: That comment relates to the threshold?

Professor Jonathan Benger: Yes, it does. Absolutely.

Lord Patel: It does not relate to medicines' availability, generally speaking.

Professor Jonathan Benger: No. It does not change the position for medicines that are already available in the NHS. It changes the position for new medicines that we are looking at in NICE.

Q205 **Lord Patel:** You apply a lot of flexibilities depending upon people's circumstances or diseases. How do you arrive at that flexibility?

Professor Jonathan Benger: It is important to be clear from the outset that NICE is a transparent organisation. We publish our methods; we also publish a lot of detail around our guidance in terms of how our committees reach conclusions. We strive to ensure our committees are fully independent. We spend a lot of time making sure there are no significant conflicts of interest, so that the people who serve on our committees are genuinely independent experts who are trying to reach the best decision based on our methods. Our methods are also in the public domain, as I say. We consult on them if we change them at all. We try with our methods to reflect societal values and to be clear and consistent in the framework that we ask our committees to apply.

That threshold range that Lord Mair has described, between £25,000 and £35,000, gives some flexibility to the committees on the basis of certain characteristics of a particular condition or medicine. For example, for more severe diseases, we have a weighting that can be applied—either a 1.2 or a 1.7 weighting—that, in effect, allows us to pay 20% or 50% more than we would otherwise pay for certain conditions where they have a very severe impact on life. We have a published economic methodology for how that is determined.

Our committees also make considerations around rarity and the potential for cure, and in some cases, to address inequalities. Our committees will apply a weighting, for example, when considering

medicines, as they did recently for sickle cell disease, because they recognise that there are inequalities that require addressing.

Lord Patel: Right. Your flexibilities are based on several different parameters that are taken into account.

Professor Jonathan Benger: Yes.

Lord Patel: Some people think it is a kind of rationing.

Professor Jonathan Benger: It is trying to ensure we get the best value from a fixed NHS budget.

Lord Patel: So resource is the key issue.

Professor Jonathan Benger: It is absolutely essential. The core purpose of NICE is to ensure that we use our NHS budget as effectively as possible to achieve the most health gain for the most people. Obviously, we cannot do everything for every person. We cannot provide every drug or treatment, because the NHS budget is finite and set by the Government, which is their prerogative, of course, and their job. Our job at NICE is to say, "What's the best way of using those resources to get the most health gain for our population?"

We talk a lot about opportunity costs. Obviously, if you spend a pound on something, you cannot spend a pound on something else because you spent it in one place or another. Opportunity cost helps us to understand the best way of allocating resources to get the most health benefit.

Lord Patel: Does that mean some patients might miss out on treatment?

Professor Jonathan Benger: Yes. It means, for example, that there are some medicines we do not approve because they do not achieve sufficient quality of life or health gain for the cost of that medicine.

Lord Patel: Is that fair to patients?

Professor Jonathan Benger: It is fair to all patients, to a whole population. Clearly, if you are that particular individual who is not receiving a medicine, it feels very unfair.

Q206 **Lord Drayson:** I want to ask a further question on the recent change to the threshold. I was really quite surprised to hear that you are not able to give us any sense as to the impact, as we asked. Is that because the data is not collected, or is it because the data is collected and that sort of analysis is done at the

Department of Health and Social Care and not within NICE? It is very strange that a negotiation has taken place on pharmaceutical pricing, which has led to a significant increase in the threshold, but it is not possible to measure the impact. If you are not able to measure the impact, how on earth do you negotiate such a thing?

Professor Jonathan Benger: Obviously, the trade negotiations are outside my remit as the CEO of NICE. As I understand it, the Government have completed an impact assessment of the changes in the threshold and the UK-US agreement. We at NICE have provided some information that feeds into that. However, I have not seen that particular impact assessment, and I do not know whether it is available in the public domain. I certainly have not seen it.

As I said before, the challenge is that we are trying to predict what would have happened if we had not increased the threshold. To some extent, that is obviously unclear. Had we stuck with the previous threshold, we would have continued to approve drugs. What is not certain is whether a particular drug that we approved now—for example, if we approved a drug at £29,000 or £30,000—would have been had the threshold not changed. To some extent, we are speculating on events that we cannot predict because they have not happened.

Lord Drayson: Professor, surely that is always the case. One is faced with making a judgment based upon estimates and assumptions of the future, but these estimates and assumptions are helpful guides when trying to make good decisions. Would it be helpful if that impact assessment—assuming you are right that it was done as part of the preparation for that negotiation—was made public, to improve the quality of understanding of the process that NICE is going through for the general public and patients?

Professor Jonathan Benger: As I said, Lord Drayson, this is a decision that has been made by the Government in relation to their negotiations with the US. There was a consultation that the Government ran on the change to the threshold, and I believe the impact assessment was part of that. I do not believe the impact assessment has been published. I really cannot comment further than that.

Lord Winston: Can I come back briefly to your semi-answer to Lord Patel? It is on the issue of rationing. Should we not recognise—this may be a difficult word politically—that we ration through the internal market? Are we not rationing, for example, with some treatments for dementias and mental ill-health increasingly? Is that not inevitable if we are going to run the health

service?

Professor Jonathan Benger: It is a choice of words, Lord Winston. I would see our job at NICE as being to ensure that we get best value for a limited health budget. That means we recommend treatments that are cost effective and do not recommend treatments that are not cost effective. You could say that is rationing, but I would also say it is good health economics. It is good stewardship of a limited budget to ensure that the most people get the most benefit.

As I say, inevitably, the budget is fixed. There are more requirements on the health service than we can meet. You cited an example about some medicines for dementia that we recently looked at and have not approved because we do not believe, on the basis of the evidence presented to us to date, that they achieve sufficient benefit for the cost. If we were to invest in those medicines, we would have to disinvest in services that we know are better value for money for the whole population. It is obviously disappointing for those individuals with dementia, but NICE's job is to think at the level of all the people, all the population, and to recognise that we are in effect stewarding a limited resource. I feel very accountable for making sure that we do our very best to make sure we get the most benefit for the taxpayer's health budget. That is my principal job.

Lord Winston: I am sure you are right, and we would admire and value that. However, ultimately, our politicians are not being strictly truthful about rationing, are they?

Professor Jonathan Benger: I really do not want to comment on what our politicians or the Government are doing. I would rather stick to what NICE does.

The Chair: Lord Winston, do you want to ask about arbitrary unfairness? Perhaps you have touched on that.

Q207 **Lord Winston:** This comes back to your QALYs, for example. It is not only the quality of life up to death; it is also the quality of life during life. To my mind, that is very difficult to calculate, particularly when, as is so often the case—perhaps in the majority of the cases—there are particular issues with regard to mental ill-health. We might well decide to give that treatment to a person because of their mental state, or degree of anxiety, or their particular living. I wonder how you manage that in NICE terms.

Professor Jonathan Benger: The first thing to say is that quality adjusted life years are the tool that we use because they are widely

and internationally used. They are also widely available through research work. However, they are not perfect. We are often criticised for some weaknesses in quality adjusted life years. Mental health is included in that: clearly, if people have significant mental illnesses, that will impair their quality of life. It may shorten their life because we know there is a correlation between life expectancy and mental illness. We take those issues into account.

We are also always very willing to review our methods. At the moment, we are changing our value set that sits behind our quality of life adjustment from an old three-level version to a new-five level version through our methods, to better reflect societal values and preferences. Unfortunately, it is one of those situations where it is the least worst in a series of measures. It allows us to effectively compare a wide range of different options: hip replacements with medicines, with general practice appointments, with prevention, and so on and so forth. That helps us to do the job I have described that we see as core to our work. We are always willing to look at our methods and seek ways of improving them. Quality adjusted life years are not perfect, but they are the best tool we have available, particularly when we are trying to compare across such a wide range of treatment options.

Lord Duncan of Springbank: I want to pick up on the same point: the notion of the quality of life. Longevity is something you could measure in the sense that there is a particular lifespan, but the rest is wholly subjective. You are forecasting into a clearly subjective area. What, then, are the means of appeal for those individuals who look at what you have done and think, "You haven't captured the quality of life that I, as a sufferer, potentially will experience"? Is there an appeals process? I know you say you revisit, but could somebody particularly affected make an approach and then have it reassessed, or at least more publicly assessed?

Professor Jonathan Benger: Yes. We have a number of mechanisms for this because you raise a very important point. First, we take engagement with patients, the public and those who are affected by diseases we are looking at very seriously. We recently expanded our interaction with patients and patient groups that represent those who are suffering often with long-term health problems in the NHS. Our committees always contain lay representatives—experts by experience, as it were—who have direct experience of the condition itself and are very helpful in helping our independent committee to understand the impacts of the disease on their life.

That also helps us to discuss some uncaptured benefits that may exist in treatment, which goes back to Lord Patel's earlier comment about flexibility in our methods. We have an element of flexibility built into the framework so that the committee can take account of benefits that are not necessarily appearing in research data, but which they are hearing about from lay representatives who are affected by disease. That flexibility is very important because it allows that option.

Secondly, we always consult. For every piece of guidance, we have a public consultation, and stakeholders—including patient and public groups and individuals—can register and return their views. We respond directly and completely to every response we receive, and our committee will meet and reconsider its views. There is an appeal process, which is more formal, on technology appraisals for medicines and some health technologies. That is sometimes used by patient groups if they feel that we have fallen into error in the way we have applied our methods and processes. However, that is a last resort. We would much rather work with groups to ensure that we reach the right decision.

Baroness Nicholson of Winterbourne: Professor, you have kindly informed us that you include mental health medications in your analysis. Is that purely the medication used by the National Health Service, or does it also incorporate the enormous amount of work on mental health done by social services?

Professor Jonathan Benger: Obviously, because this is the Science and Technology Committee, I am focusing on technologies but NICE's remit extends into the much wider provision of all services, which would include health and social care. Again, through quality adjusted life years, we can make comparisons between different types of treatment. Talking therapies, CBT, et cetera can be compared with medicines for depression, as an example. Our depression guideline does just that.

While QALYs are sometimes problematic, they allow us to make independent, evidence-based judgments on recommendations for mental health. In fact, there are a limited number of drug treatments for mental health, and it is an area of real need. There is a little hope in this regard, given some new medicines coming through, but it is very much an underserved population at the moment.

Lord Winston: You just touched on this, but could you give us a bit more expansion on what other countries do with regard to the kind of activity which you undertake for the UK? A number of

sovereignties in Europe, obviously, have a fairly similar system. Australia and New Zealand have very similar systems to ours. Those are particular countries but, in general, it would be very interesting to hear how this works elsewhere.

Professor Jonathan Benger: Yes, at the risk of sounding a little arrogant, other countries follow NICE. The model that we established in this country at the end of the last century is a model that has been widely copied around the world for how best to establish—particularly for medicines—whether a medicine is cost effective for use in a healthcare system. For example, when Singapore started its health technology assessment arm, it initially called it a mini-NICE. With our agreement, it took a lot of our methods and processes to use in Singapore as a way of identifying how to calculate whether medicines were cost effective. Similar mechanisms are used throughout Europe, as you have described, and in Australia, New Zealand and Canada.

The main exception globally is the United States, which does not really have a health technology assessment process, at least not through government in the way that we do here. As a result of that, as you will be aware, drug prices are much higher in the United States than they are anywhere else in the world. The reality is that this country has once again set the bar for health technology assessment, and NICE is looked to internationally to drive methods and set the pace for how we respond to increasing technologies.

For example, when GLP-1 agonists were introduced in relation to weight loss, we could see there were some real challenges in looking at these medicines. We rang up our colleagues and chief executives around the world and said, "What are you going to do about these medicines?" They said, "We're waiting for you". Our AI statement of intent, for example, has been picked up globally as being world leading in relation to how we are going to assess health technologies that incorporate AI.

I am sorry if that sounds a bit arrogant, but the reality is that NICE has a lot of advantages. It is the only publicly funded system in the world where all these things—guidelines, health technologies and medicines—are considered together. Often in other countries they just look at drugs or at health technologies. We are genuinely world leading in this country in this particular field.

Lord Winston: I am very familiar with the Singapore system, particularly. I have also worked in the States. I still wonder: do you meet people from those other centres or regulatory bodies and see how this is going on? Do you discuss how those things are done?

Professor Jonathan Benger: Yes. Last week, in fact, I was on a call with the chief executives in Australia, Canada, New Zealand and Scotland. Wales was unable to attend. We meet regularly and often discuss similar challenges, because all HTA bodies around the world face similar pressures.

Q208 **Lord Drayson:** Turning to questions around wider economic benefit, some of our witnesses have argued that through the QALY-based approach, which we have discussed, NICE can take too narrow a view of the long-term economic benefit. We have had witnesses arguing that curative therapies, which could return people to the workplace, for example, are undervalued in your analysis. Others have suggested that NICE should take into account treatments that have the potential to reduce in cost as they are scaled up or treatments that support a domestic industry in the UK, in terms of looking at the impact on the potential economic growth of the country. How would you respond to those arguments?

Professor Jonathan Benger: These are very important arguments. As I said earlier, we are always very willing to review our methods and to discuss whether what we are doing is correct. Over the 27 years that NICE has been in existence, we have made many changes to develop and improve what we do. Our purpose at the moment and our policy direction, as it were, from government is to take a health lens on the work we do. That is our starting position, so we look at health benefits and balance those against health costs. That is not just the cost of the drug; it is also the cost of delivery, supporting diagnostic services, monitoring and ongoing care. We also look at the benefits. The time horizons we use are long time horizons. We are quite capable of looking at long-term preventive care, and we often do.

Where a medicine is curative, we have the opportunity to adjust our discount rate. We can reduce that rate if the committee identifies the potential for cure and genuinely very long-term benefit, which will favour those medicines. That allows us to make a decision that increases—probably by about 10%, in effect—what we will pay for a medicine that has genuine curative intent. Again, that is something we continue to think about.

There are a couple of really important considerations in the challenge of looking beyond health. This is all possible. In fact, in directing NICE to complete a technology appraisal, the Secretary of State can invite us to look at other factors. It has rarely been used to date. A good example would be when we were looking at cochlear implants, and the Secretary of State asked us to look at benefits in education, because cochlear implants have a huge

impact on people's ability to succeed in education through improved hearing. We indeed did so, so we can take additional factors into account.

If the benefits are felt outside health, then we run into the challenge that the health budget is, in effect, now paying for benefits that are realised in other parts of the system. That can be a logistical challenge when identifying how best to balance the benefits. If benefits are being felt in education or other parts of the system as a result of investment in health, how do we ensure that the flows are correct in terms of recognising that?

Another very important issue is that the data can be quite sparse in terms of understanding what those benefits might be. NICE is fundamentally an evidence-based organisation. We need good information on which to work. There is a wide range of potential societal benefits. There may be a benefit in carers, in education—as I have described—reduced transport, or improved environmental issues. You referred specifically to an area that has come up quite a bit recently, which is workforce participation and productivity. We can take all these things into account if we are directed to do so, but it is very much a policy decision. We stand ready to review and adjust, if that is the policy direction the Government wish to set for us.

The only other thing I would say, as a CEO of NICE, is that there are some quite complex ethical issues if we start looking in relation to workforce productivity, because of the risk that we then start having conversations about whether medicines should be provided for individuals who are capable of returning to the workforce and not for others who are not. There is a risk of inequalities developing if we were to focus on medicines that would target individuals who are capable of working but, for example, then said, "Well, these aren't cost effective in older adults because they cannot return to work and be productive in the economy". That makes me uncomfortable.

As part of our duties, NICE performs an equality impact assessment on all our guidance to ensure that we are not inadvertently introducing inequalities. This particular area is one that we would need to think through quite carefully. We can do it, but it would be helpful to understand that we are really wrestling with these issues. We are not unaware of the challenges and opportunities, but we also see difficulty in terms of data quality and attributing costs: investment in the UK is very important, but it is difficult to know how we would attribute that to a particular decision. There is a risk of inequalities if we move away from a health lens alone.

Lord Drayson: That was a really comprehensive answer to my questions. I think you were not being arrogant in describing NICE as a world-leading organisation. That is really accurate and fair. The positive effect that the organisation has had is clear in terms of health outcomes. However, if you look at the relative decline of the UK pharmaceutical industry over the time that NICE has been in existence, some argue that it is due to the UK being seen increasingly as a market which is not an early adopter of new innovative medicines. That really hurts UK-based life sciences companies that operate at the forefront. That is an argument that has been made. Do you believe that argument is fair? Would you say that, as a result, NICE's economic scope is too narrow? If it is, what could be done by NICE to broaden out and take into account these wider economic and societal values to the country? My final question in this area is, currently, is anyone at NICE assessing the wider economic value of new medicines and new technologies? Is that being done at all?

Professor Jonathan Benger: It is an objective observation that we have perhaps been struggling in terms of pharmaceutical investment in the UK, as you say. That is a verifiable fact, in that we are seeing a decline in investment and companies investing in other countries overseas. The reasons for that are very multifactorial. I do not believe that NICE's appraisal process in the way we approach this is a significant contributing factor. The reason I say that is that we approve just over 90% of all the medicines presented to us. We are working very hard to find ways of bringing innovative medicines into the UK. For example, we have a highly specialised technologies programme that will pay up to 10 times our normal QALY threshold for ultra-rare diseases. In the last 10 years we have approved eight gene therapies and 12 cell-based therapies, and we were the first jurisdiction in Europe to approve a CRISPR-based gene-editing therapy for patients to receive in the NHS.

NICE is doing its part and I reject the idea that investment decisions being made by pharmaceutical companies are directly related to NICE's methods or approval. The picture is much wider than that. There are issues about the translation of our excellent research base into appropriate early start-up companies, and the attractiveness of those companies to scale and spread within this country compared with other markets, particularly the USA. There is something about the commercial environment and the tax environment. The incentives we put in place for investment in the country are far, far broader than NICE.

From a health perspective, we are also still not adequately joined up in terms of making sure that the medicines and technologies we approve at NICE reach patients in the NHS. That means even things NICE has approved are not necessarily returning on investment in the way that the companies that have supported them through the R&D process were hoping. There is a problem, but NICE is not a significant part of that problem. In fact, we have done a remarkable amount over the last 10 years to support the kind of investment in modern technologies that I have described. Patients in this country are getting access on the NHS to truly innovative CAR-T therapies, gene-editing therapies, and a range of technologies that are curative for long-term diseases with a genetic basis, such as beta thalassaemia, haemophilia, et cetera—I am getting a bit passionate now, apologies.

We are doing our bit. Could we do more? Yes, of course we could. We are actively looking at how we improve to work more closely with system partners and deliver more effectively, particularly around uptake and implementation for medicines that we have approved. What can we do to further support innovation in this country? We all have a role to play in that. I recognise that, as CEO of NICE, we have to do our bit to support innovation and investment in the UK. I am always interested in what we can do to support that.

In terms of the wider picture, we are talking a lot to colleagues across the Department of Health, Office for Life Sciences and MHRA, about how we work together more effectively to achieve a more attractive approach. As I said, there is a real challenge in directly linking investment in the UK—for example, building a factory and making drugs in this country—to the price we then pay for the medicines that are made in this country. However, it is not impossible. I would be open to discussing other approaches that we think could work, bearing in mind some challenges that I have already raised.

Q209 **Baroness Nicholson of Winterbourne:** Our witness kindly reminded us that the Secretary of State of the day is competent to overrule weightings. Without drawing you into politics, since Secretaries of State will always be political appointments and therefore can be bent by colleagues or constituents and so on, might it be worthwhile considering us putting in a suggestion that you have a different form of overruling—a different form of final authority, as it were—over and above? Would it be better if some half dozen more than competent people in the field of practice took the decision, rather than a politician?

Professor Jonathan Benger: The legislation that supports NICE makes it impossible for the Secretary of State to directly influence the individual decision-making that we engage in through our committees. NICE's independence is very important, because trust in NICE's decision-making and in the wider system, in our clinical and other colleagues, relies on the belief that NICE is truly independent and driven by data. While the Secretary of State can set the overall threshold for all medicines that we look at, that is a level for all medicines, and the Secretary of State cannot interfere directly in a decision that we make. That independence is critical and, in my view, has never been compromised by a Secretary of State.

Baroness Nicholson of Winterbourne: I merely raised it because the example our witness gave us is a reflection of very competent lobbying that I have been watching.

Professor Jonathan Benger: To respond to that, I think what you mean is that the UK-US deal—the pharmaceutical arrangement—has, in effect, been the cause of the increase in drug spending. There is no doubt the two are related. As I said earlier, our view at NICE and my view as the chief executive is that it is for the Government of the day to decide what the levels of health spending and drug spending are. But it is NICE's decision only—our independent decision on each medicine—to apply that threshold consistently and fairly, according to our frameworks.

That is critical, and critical to our confidence in the system and the trust we hold that NICE is genuinely independent on a decision-by-decision basis. In fact, that also protects the Secretary of State and others in government from lobbying, because they can say in all honesty that the decision on whether a particular medicine will be approved is a decision for NICE as an independent organisation.

Q210 **Lord Winston:** I think we greatly respect your achievement with these specialised treatments and new technologies. We would congratulate you on doing that. It is true that the UK leads on them and we are very grateful, because of course it leads to more therapies. You also managed to get in vitro fertilisation on the map. However, the diagnosis side of that was not very well done; we should have given you much better evidence than you actually were given. I just want to say that to start with.

One of the big issues in the 10-year plan is the notion that we are going to do much more preventive medicine. The previous Secretary of State, who has recently retired for various reasons, was very keen, for example, on testing babies even at childbirth for their genetic predispositions, which many of us would feel was

probably a rather unwise suggestion. Can you give us some idea of how you can—and if you can—cost out preventive medicine? Of course, we will see many cases where patients do not develop a disease which is going to be there until many years later. Costing all this is therefore very difficult, or perhaps you do not regard this as part of your job. It may be very difficult to do anyway.

However, it seems ultimately that if there is a political drive, and to some extent a drive in the population, to prevent far more disease, whether that can actually be achieved and whether it might even be more expensive would be another question I would be very interested to hear what you might say about.

Professor Jonathan Benger: Just because something is hard does not mean to say we do not do it at NICE. Indeed, we relish the opportunity to tackle difficult problems, and prevention is definitely part of that set of difficult problems. Just in terms of role, though, the UK National Screening Committee makes decisions on screening. For example, if you wanted to talk about genetic screening of all newborn babies, that would be a matter for the NSC, not for NICE. However, we have an extensive portfolio that looks at preventive medicine or preventive measures at a variety of levels: primary, secondary and tertiary prevention. Our methods allow us entirely to look at preventive medicines and to provide high-quality, evidence-based recommendations for the NHS even over long time horizons.

As I have described already, we can change our discount rates and we look specifically at long time horizons. We have many recommendations on alcohol and tobacco use, smoking et cetera, which are often more in the primary prevention space. We also have recommendations for cholesterol management in people with hypercholesterolemia, for example. There is lots of opportunity in those spaces. We also do a lot of work in things such as secondary prevention. Obviously, our recommendation of GLP-1 agonists for weight loss is really about preventing the complications of obesity. Similarly, hybrid closed loop systems for type 1 diabetes have been hugely effective in reducing the long-term complications of diabetes. All these matters can be managed by our committees, and our recommendations are based on those.

One of the challenges for long-term prevention is whether the system is set up to provide, because the tricky bit is that we can make the recommendations, but implementation in the NHS often requires a business case that requires quite rapid return on investment. It can be difficult to argue for investments today that will achieve benefits in 10 or 20 years' time. That is difficult at a

political level, and at a local systems level as well. When a commissioner is trying to identify how best to use the resources available to them, it is probably human nature to focus on the disease that one can see rather than investing in long-term prevention, because of the problem of availability. You can see the disease that is present today; you cannot see the disease that will occur in 20 years' time.

It is a system challenge to think about how we actually incentivise prevention and preventive measures. We have recommendations at NICE. The challenge is to make sure those recommendations are then picked up and implemented successfully, over decades, to achieve the benefits that we know will follow, and that we have calculated are cost effective in the long term.

Lord Winston: I presume that you could do things like this with regard to drugs such as statins.

Professor Jonathan Benger: On statins, the case is well proven. That is exactly what we do: we recommend statins. We are also looking at other lipid therapies. Another example would be lipoprotein (a), which is becoming very prominent. It is not yet available in this country, but we recognise the opportunity for further cardiovascular modification through some medicines that we know are in the horizons pipeline, and which we are now preparing for at NICE, to think about how we would recommend those be implemented into the system. Lipoprotein (a) was a genetically determined challenge. We could test people, and then treat people, to reduce long-term cardiovascular disease. However, as is the case with hypertension, high blood pressure and high cholesterol, you have to convince people who have no symptoms to take medicines, which can be a challenge.

Lord Winston: There is still a big question about how much it would cost and whether it would be even worth trying to do this in much greater detail, as has been suggested, particularly using genetics, which of course is the issue for this committee.

Professor Jonathan Benger: Yes, and we stand ready. We are doing a lot of work in genetics at the moment. Another example would be Genedrive, which is just completing our early-use assessment. It is a genetic test in neonates to identify whether they would suffer hearing loss from gentamicin therapy. Antibiotics used routinely in neonatal intensive care units can cause long-term hearing loss. A simple genetic test from a cheek swab will give you an answer in 30 minutes that will prevent hearing loss. That is a straight, genetically targeted piece of pharmacotherapy. There are

lots of examples of those. We already recommend that for early use. I anticipate that we will now look at it for routine use in the NHS. It is a good example of where a simple genetic testing technology can make a huge difference to long-term outcomes. We are very interested in continuing to develop our work in that area.

Q211 **Lord Patel:** Lots of interesting points are thrown up by what you just said. I will come to my slightly different question in a minute, because it is not as interesting as following up some of your comments. You refer to the fact that your procedures, broadly speaking, have not changed since NICE was established. That speaks a lot about how it was established. It was probably well thought out. However, after your experiences at NICE, you must have thought about things that work and things that do not. The things that do not work are because you do not have the powers to influence the change. For instance, let us say that you advise that certain drugs, after appraisal, are beneficial for usage, but a trust does not adopt that. It does not procure for it. That is reality; it is a fact that you get lots of variation, so the patients miss out despite your positive appraisal on getting the correct treatment.

Do the trusts ever engage with you on procurement issues? How could you influence that and would you like to do so? Should the powers of NICE be changed in any way to become more effective, so that people with diseases get the right treatment at the right time? A similar case may apply to guidelines, which are not mandatory and yet, properly applied, deliver better care. You responded just now about gentamicin and hearing loss. The application of pharmacogenetics will presumably become more common, not just in the example you gave but in other areas of treatment, including drugs you have not appraised. I am challenging you to say what needs to change to give you better powers to make a difference for the people.

Professor Jonathan Benger: I begin by saying that NICE was very well thought through and set up at its inception. It is also the case that our principles have not changed, but our methods and approaches have developed substantially. Obviously, a lot of what we are talking about—genetics, for example—was only a pipe dream in 1999. We had not sequenced the human genome yet. That is the first thing to say.

Secondly, I agree that there is a big challenge in relation to uptake and implementation. It is not NICE's role in the system to drive uptake. We are an organisation with a particular mandate. Our job is to use the best available evidence from a wide variety of sources, and our independent committees turn that hard data into

knowledge and recommendations for the system. Part of the system then follows that in commissioning and provision, and in working with clinicians and professional bodies. The reality is that guidelines are guidelines, not tramlines; there are some times when not following a guideline is the right thing to do. Even I would say that, as a practising clinician; I still work in emergency medicine in Bristol.

The challenge of uptake falls to other parts of the system and does not fall within the remit of NICE. Making NICE guidance mandatory is not necessarily the desirable outcome. At the moment, for example, we are required by law to appraise all new medicines and significant licence extensions. There is a funding mandate that says those medicines should be provided within 90 days of a positive NICE recommendation. We know that that does not happen universally, for some reasons that you have described. That tells us that mandation does not really have the impact we were hoping it would, in a system that is as stretched, complex and challenged as the NHS.

It is a challenge for the system because there is a lot of fragmentation. It is about creating pathways and systems that will enable and support people to implement our guidance effectively. Those pathways and systems fall outside our remit. They are about how services are commissioned and delivered. A lot of the challenges that we have are in that space.

The National HealthTech Access Programme that we have advocated for, over many years, and which we were delighted to see adopted in the 10-year plan, is exactly that. We have worked closely with the Department of Health, NHS England, the MHRA, Office for Life Sciences and others to try to create that pathway, which goes all the way from initial data, through regulation and the work that NICE does, and then through an approved and commercial route that allows consistent uptake and adoption in the NHS. That route gives us real hope that it is possible to achieve an end-to-end pathway, within the existing system and framework, which provides equitable access to a number of selected, high-impact, cost-effective technologies.

Lord Patel: You did not quite rise up to the challenge I put to you. Let me phrase it differently: do you think there are any additional powers that if they were given to NICE would make more impact on NICE's work?

Professor Jonathan Benger: I do not think we need additional legislation or additional powers. The legislative framework has

served us extremely well. We are genuinely independent of government. We are internationally and nationally respected for that. I am confident that we continue to produce independent, transparent and rigorous evidence-based advice for the health and care system. The challenge is then how we implement that effectively and consistently, but legislating around NICE is not the answer to that difficult problem. We need to look at how the wider system works, and how that system is integrated to deliver. As I say, I have high hopes for the National HealthTech Access Programme. That is the big challenge for the system and, regrettably, changing NICE's legislative powers would not change that problem, which is the downstream implementation.

Lord Patel: You are a practising clinician now, and Lord Winston and I have been practising clinicians before, and you know that there is a variation in care and outcomes across our country. If the NICE appraisal is, to a degree, to try to focus on drugs' availability to all, with equity at a level that is affordable, what are we going to do about reducing this variation without a body—whichever body that is—having some powers to make sure that there is a uniformity in care provision?

Professor Jonathan Benger: That falls to the commissioners and providers of care, which has historically been NHS England. Of course, that situation is now changing and more of that responsibility will sit with the Department of Health and Social Care.

Lord Patel: But it ignores your advice.

Professor Jonathan Benger: I do not think that is true. The reality is that it respects our advice, but it has to implement it in a system that is already under pressure and where there is a high degree of fragmentation. Some issues you describe are actually within the remit of the CQC—the Care Quality Commission—around the quality and consistency of care that is delivered in our hospitals and other settings, such as general practice and community services. We have a regulator whose job it is to ensure quality. One thing we do is to work closely with the CQC around our quality standards and guidelines, and it inspects against those and uses them as a benchmark of care that it expects in our system.

Lord Patel: Would it help if your guidelines were converted into standards of care?

Professor Jonathan Benger: We do have powers under the 2012 Act to draft quality standards. We have a range of quality standards that are used throughout the system to support care;

they are also used by the CQC. We also support the QOF framework for general practice.

Lord Patel: Are they not mandatory either?

Professor Jonathan Benger: They are not mandatory, but they are a powerful lever for improving care in general practice.

The Chair: Just to follow up on Lord Patel's questions, how much do you collaborate with MHRA?

Professor Jonathan Benger: We work closely with the MHRA. Our relationship has become a lot closer in recent years, for a variety of reasons. The main challenge we have been tasked with is improving timeliness of access. One criticism that has historically been levelled, appropriately, at NICE was that the MHRA would approve a drug as safe for use in the NHS, then there would be a delay—sometimes a delay of months or even years—before NICE produced a technology appraisal indicating that it could be reimbursed by the NHS and its cost-effective use. Clearly, if you are a patient with a serious disease and the MHRA has said the medicine is safe, and you are waiting for NICE committees to make a decision, that is immensely frustrating.

The Chair: Do you feel there are ways in which the timeline for innovations to get to patients could be improved?

Professor Jonathan Benger: Absolutely. We are currently working much more closely within an aligned pathway with the MHRA. Again, that is set out in the NHS 10-year plan. We are now doing our work in parallel, so we are working with companies to streamline their submissions, so that there is less regulatory burden and it is easier for companies to make a submission that can be used by both the MHRA and NICE—although we use quite different datasets, there is some overlap. We think that doing our work in parallel will lead to approvals between three and six months sooner than has been the case historically.

We are now getting to the stage where it is not uncommon for our opinion to be released almost at the same time as the MHRA's, with one or two occasions where we have given approval on the same day. We will be looking to continue with that trend so that access is improved. This is helpful for industry because it increases the period of exclusivity during which the medicine can be marketed in this country. Most importantly, it gets medicines to patients faster. We have an aspiration here to be the third fastest in Europe in terms of our speed. We have gone from seventh to fifth, and we are working to get to third. My predecessor made that commitment

previously. We really are working very hard to get medicines to patients faster.

Q212 **Lord Ranger of Northwood:** Thank you, Professor, for your evidence today and for coming in in this heat. We have heard a lot about cost models, value for money and medicines approvals. I am going to move on to a bit on the thing that is changing a lot of the world around us at the moment: AI, and the development and intervention that AI is having in medicines. I have a number of questions. I will put a few of them to you initially and we will come back to the others. I am sure you are aware that a wide range of AI tools is being developed for use in healthcare. Could you give us some insight into NICE's approach to appraising AI tools as well as recommending their use? If you know, approximately how many AI tools are you currently recommending for use in the NHS and under what circumstances?

Professor Jonathan Benger: This has been a huge growth area for us, as you would expect. We have had a huge growth in digital technologies in general and some of that is inevitably in AI. But in all kinds of digital technologies—apps, wearables, et cetera—we have seen a significant and substantial increase in our portfolio. We are redirecting some internal resources to support that because we recognise the need that the system clearly has in this space.

In relation to AI specifically, our approach is not different than for any other health technology in that our job is to identify what is cost effective for the NHS and good value for money clinically, and to produce guidance for implementation. But with AI, there are challenges given the speed at which the technology moves, so our framework reflects that, using what we describe as a life cycle approach.

For many of these technologies, we will start off with what we describe as an early use assessment. That is where there is a signal of benefit and where the MHRA has declared that particular technology safe. We do not look at technologies that are not appropriately regulated by the MHRA. If the MHRA says it is safe and there is a signal that suggests benefit, but it is insufficient for us to reach a definitive conclusion, we undertake an early use assessment. In effect, we say that this technology can be used in the NHS, but we require significant data collection to understand how it is performing in reality when implemented.

We then come back to that after a period, which has been three years, but we are shortening it because three years is too long. We will then look at that through what is called a routine use assessment: should it be adopted for routine use in the NHS and

therefore potentially rolled out consistently across the NHS? That is where it falls into the National HealthTech Access Programme that I described, where potentially we will take it all the way through that pathway through a commercial and implementation approach, to ensure that it is consistently adopted across the whole NHS.

However, that is not all. We will also review technologies as time passes, particularly as more evidence accrues. AI has a habit of developing and improving over time. Our life cycle approach allows us to go back and review technologies. Our established use is also at the end of the life cycle, where potentially we make recommendations for mature technologies. Sometimes we identify that there are opportunities to stand down older technology, in order to make headroom within the NHS to pay for newer technologies. That is our whole life cycle.

In terms of the numbers, there are two parts to this. Often, we have what we describe as a use case. For example, histopathology AI in breast cancer or prostate cancer are two of our National HealthTech projects at the moment. We look at systems to assist in the interpretation of cellular histology, but there are often multiple products in that market. There might be lots and lots of different suppliers which all meet that use case. Our evaluation has to look at multiple solutions from different companies in order to reach a decision as to which of those are safe and effective.

Lord Ranger, if you and Lord Mair are agreeable, the best thing would be if I ask my team to send in a detailed summary of all the AI work we are doing at the moment, both the use cases we are looking at and the technologies we have evaluated. That is, the different proprietary products that meet those use cases and where they are in our assessment cycle.

The Chair: That would be very useful.

Lord Ranger of Northwood: Yes, that would be very useful. You raised the point about wearables and apps, so could you include that as well? I am sure there is an overlap between the hardware and software in some areas. Perhaps I could follow up with one or two other points. I really appreciate your broad answer to that question. Can you give me a view on how the HealthTech Access Programme relates to your approach?

Professor Jonathan Benger: Yes. That is a subset of what I have just described. The challenge, as I alluded to earlier, is how we secure a pathway to genuinely ensure that technology that we know is clinically and cost effective, and will really benefit patients in the system, reaches all the systems and all the patients who

really need it? I really welcome the 10-year plan's commitment on this because we have seen that as a real weakness. While we have a medicines pathway, we do not have the same mechanism at the moment in health technologies, which is such an important growth area.

That means that once we have completed an early use assessment, or if another technology already has good evidence for it, we can enter it directly into a technology appraisal. We have used those previously largely for medicines, but we use similar very high-quality methods and economics to determine the clinical and cost-effectiveness of that. A technology appraisal, which is commissioned by the Secretary of State, then has that funding mandate, so there is a requirement for the NHS to fund it within three months. We then work closely with commercial partners in NHS England, the Department of Health and Social Care and local commissioners to ensure that it is then implemented consistently across all the eligible populations.

I am really pleased that we have managed to achieve that, because the problem we have had historically with health technologies is that people have tried to implement them with the best will in the world, but they have not really seen the whole pathway. NICE's recommendations are really critical because it is a very confusing system out there. There are many proprietary systems and companies approaching commissioners and clinicians directly, saying, "I have a digital technology. I have an AI tool that will help you".

Our job at NICE is to provide independent, evidence-based guidance so that people can make the right purchasing decisions and know that if the MHRA says that this technology is safe and NICE says it is clinically and cost effective and will benefit patients, they can implement that with confidence. The trust that people place in NICE is critical to the implementation. That is a really key part of the pathway.

Lord Ranger of Northwood: I can understand there is probably some friction there in how it works. It would be remiss of me not to say that we have heard from some witnesses that the static, one-off appraisal models of approach can be poorly suited to assessing AI algorithms and continuous post-market surveillance. I am sure that in your written evidence you can expand on some of the approaches you are taking.

As my final point, you mentioned that you are adapting to the use of looking at wearables and AI tools. The Royal College of

Pathologists has suggested that NICE would be the natural home for a central unit focused on AI governance, including standard agreed rules for testing AI in real-world clinical contexts. Is that a role NICE wants and could you take it on?

Professor Jonathan Benger: Some of the areas you touch on are actually within the remit of the MHRA in relation to the safety elements of that, particularly as AI tools learn and develop. I am sure you will be aware that a formal commission on AI in healthcare has been initiated by the Government, which is being led by the MHRA, with a lot of support from us and other partners. It is looking specifically at this issue around what the right mechanism is for governance.

NICE is not a governance body. Governance sits elsewhere in the system. The MHRA has a natural role, as does the provider-commissioner relationship. We are not a governance organisation. We are a science-based organisation that makes recommendations in relation to clinical and cost effectiveness. I appreciate the compliment from the Royal College of Pathologists, but I am not sure that NICE is the natural home for that. I very much look forward to the outputs of the AI commission on healthcare, which will directly address some regulatory and governance issues that you refer to.

Q213 **Baroness Nicholson of Winterbourne:** I have a slightly different question on AI. Who takes responsibility—if there is such a responsibility or wish—to ensure that the patient knows that AI is being used in their diagnosis and potential treatment, or do you not think that is an imperative view at all? Should it just be with the GP or someone else?

Professor Jonathan Benger: It is an imperative view, but that falls to the individual clinician. As ever, in that relationship between a clinician and a patient—usually a doctor and a patient, for example—there is an important element of consent and information that needs to pass between two individuals. There is a duty on healthcare professionals to explain, for example, treatments they are proposing and tools they are using, and to seek consent for various things.

I am aware that in many general practices, there will be information given to patients where AI is being used to support general practitioners. It may be that patients choose to opt out of that or want to discuss it further with their healthcare professional. That falls very much within the direct relationship between healthcare professionals and patients, and their informed discussion.

Baroness Nicholson of Winterbourne: Would you assume that at the moment—there is coming legislation on this—the patient knowledge depends upon them owning that knowledge, with the patient data as their own? How do you think that will work if the current Bill going through Parliament is effected and the Secretary of State owns all patient data?

Professor Jonathan Benger: It is a very interesting subject. I am a big fan of patients owning their own data. Having said that, again, this is slightly outside my area of expertise. I do not really have a view on data management in the NHS, which falls outside NICE's remit. Sorry.

Q214 **Lord Booth:** I would like to dig down a little into the approach on highly personalised medicine. With the most personalised therapies—for example, gene and cell therapies—these individual treatments are designed for a single patient, so-called N-of-1 treatments. Inevitably, they challenge a system around population averages and clinical trials on large groups. Nevertheless, we have been told by NICE in written evidence that it has recommended some cell and gene therapies, for example, CAR-T therapies. Could you tell us how NICE has adapted, or will adapt, to the appraisal model for therapies for a single patient?

Professor Jonathan Benger: Yes, this is a very important question. As you say, some of it is in the written submission. As I mentioned, we have approved eight gene and 12 cell therapies in the last 10 years. It is well within our remit to do so. The challenge is quite complex because evidence is inevitably extremely sparse in these situations. Often the approach that we will take is that we have an evidence standards framework which we work to. Clearly, the evidence standards we can accept have to be different when the numbers are very small. We also prefer to take these kinds of challenges through what we describe as a managed access programme, which means that we may recommend for use. But data collection is very important, so that as more N-of-1 patients build up over time and become a larger group of patients, we can understand some long-term effects and thus do our work with more precision.

However, the reality is that a lot of the challenges that exist with N-of-1 are not so much in our ability to approve them as in the ability of the system to deliver those technologies, because they are expensive to manufacture and to deliver to patients. Again, that is an area where the system as a whole is challenged, in that we can recommend them as cost effective, but it is really important

that we are then confident that the system is capable of doing the diagnostics, manufacturing and delivery of those treatments.

It is absolutely clear that this is part of the future of healthcare. As ever, it is our job at NICE to ensure that we respond to that. Our HTA lab—our Health Technology Assessment Innovation Laboratory—is a methodological unit run by our chief scientific officer. This is one of the areas that it has been looking at specifically: how do we further develop methods for these kinds of challenges and conditions?

The Chair: Lord Willis has our final question.

Q215 **Lord Willis of Knaresborough:** Thank you very much indeed, Professor, for what has been an incredibly useful session this morning. Obviously, people are hugely supportive of NICE. It is great to hear your comments about the success that it has had so far. However, as a committee, we have tried to suggest one or two things that you might want to take on board. On most of them, you have said, "No, they're with other people", or indeed that it is not really part of your responsibility.

We want to make recommendations to government that will actually improve what you have to offer. What would your top three recommendations be if you were to become the Chair of this panel and had to report? What extra resources does NICE need to deal with the vast influx of new technologies that are coming online? Just three.

Professor Jonathan Benger: I am going to do two, Lord Willis. First, in relation to your last point, NICE has sufficient resources. It is my job to use those resources effectively and to steward them. We are moving resources, for example, to support more health technology, but I do not require more resources. My job is to use the taxpayers' money that I am charged with dispensing in the most efficient way possible. Just for the committee's note, we are introducing into our own processes some automation and AI to try to improve our productivity and ensure that we can continue to support the system as demand increases. I am not asking for an increase in budget.

There are two things that I would ask the committee to turn its attention to. First, there is data. For NICE to do its work, we have to have high-quality data. Not necessarily randomised trials; we get a lot of value from real-world evidence and observational data when technologies are implemented. In our early use assessment, as I described, and in our managed access programmes and early licensing approaches, we really need more data to be collected by

the system for us to be able to produce really reliable and robust evaluations of clinical and cost effectiveness. The system is not yet set up to collect data routinely and to integrate that data and provide it in a way that allows us to do our work more effectively. The clinical focus is obviously on care, and so it should be. Therefore, getting data back from the system that we can use to continue our evaluation and drive the life cycle approach that Lord Ranger was discussing is very important, particularly for AI. We need to know how it is performing over time and that requires better data collection.

Secondly, as I have alluded to a couple of times, there is fragmentation in the system. I am sure it is frustrating for the committee that witnesses come in front of you and say, "That's not my problem, it's somebody else's", and then you speak to somebody from another organisation and they say the same thing. My recommendation would be much more around how we can more effectively integrate the system so that we can really see that pathway from basic science—through the development of early research, through regulation by the MHRA, approval by NICE, and the commercial and implementation environment that works to bring technologies into the NHS—so that they reach all the people that NICE recommends they reach in a clear and consistent way.

The National HealthTech Access Programme is a good starting point. We have a pretty good pipeline on drugs, but it could definitely be a lot better. That would be the key area where I would be delighted if the committee could help make that pathway a clear and attractive, end-to-end functioning way of getting innovation. We are brilliant in this country at developing research. We punch well above our weight; we are third after the USA and China in terms of research data. Companies need confidence that we can translate it through the whole pathway and that it reaches patients consistently. That is also what our patients need and deserve. Anything we can do to make that a reality would be hugely welcome.

The Chair: Professor Benger, that is an excellent point to end up with, particularly your last recommendation. Thank you very much indeed for answering our questions about NICE. We have learned a lot and are very grateful. We are now going to pause this session as we prepare for our next panel.