HOUSE OF COMMONS

# Health Committee

## Oral evidence: Handling of NHS patient data, HC 952

## Wednesday 21 January 2015

Ordered by the House of Commons to be published on Wednesday 21 January 2015

Watch the meeting

Members present: Dr Sarah Wollaston (Chair), Rosie Cooper, Barbara Keeley, Andrew Percy, David Tredinnick, Valerie Vaz

Questions 565 - 756

Witnesses: **Sam Smith,** medConfidential, **Nicola Perrin**, Wellcome Trust, and **Professor Nigel Mathers**, Honorary Secretary, Royal College of General Practitioners, gave evidence.

**Q565 Chair:** Good afternoon. Thank you for attending, particularly at short notice. We are very grateful to you. Perhaps you could start by introducing yourselves to those following the debate from outside the room.

***Sam Smith***: I am Sam Smith from medConfidential.

***Professor Mathers***: I am Nigel Mathers. I am a GP from Sheffield and honorary secretary of the Royal College of General Practitioners.

***Nicola Perrin***: I am Nicola Perrin, head of policy at the Wellcome Trust. For this purpose, I also serve on the care.data advisory group—

**Q566 Chair:** The acoustics in this room are rather poor, so you might need to lean forward slightly so that everyone can hear you properly. For those following us who perhaps are not familiar with the detailed background, could you start by giving us an overview of where you think we are now with care.data and the key issues we need to tease out to make sure we do not miss any of those this afternoon? As you know, the focus today will be on pathfinders, but could you give us an overview of where we are now and the outstanding issues that need to be resolved, starting perhaps with Mr Smith?

***Sam Smith***: To cover the five lowlights which are mainly within the remit of NHS England, for those who opted out after the "junk mail" leaflet that went out a year ago, what do patients, NHS England and HSCIC think the people have been opting out of?

What about opt-outs from hospital episode statistics, which have caused so much concern? Has that opt-out been implemented? What will be different for the pathfinders, and what will happen beyond the pathfinders? For the pathfinders, NHS England have said they will send everybody a letter. We have not seen any change in that for several months.

Three questions remain substantively unanswered, which we first asked the Committee back in February. What will patients be told? Who will ensure that this is true? How can those things change? All the questions we have arise from hiding the interactions between those three questions. What exactly the opt-out will do is an unanswered question that is key to a lot of those things.

The first draft of the CAG regulations we have seen does not define "promotion of health". Along with the HSCIC's new data-sharing agreements, which permit commercial reuse to carry on, it was nice to agree with Tim Kelsey that drafting the regulations for CAG in a panic, after a seven-month pause, was possibly unwise.

From last summer, NHS England's commitment to publish the minutes from the care.data programme board, where all the care.data pathfinder decisions are made, is entirely unmet. I understand there is a hold-up somewhere in NHS England, but I do not know what it is.

Finally, Dame Fiona's care.data report has a long list of unanswered questions, which we agree must be answered before any pathfinders proceed, and the 2014 annual report from the IIGOP provided case studies of what goes wrong when information governance and data sharing is not handled properly.

***Professor Mathers***: Our original concerns about care.data, which we raised last February, were primarily about ensuring that the NHS was beyond reproach in its use of patient data. Our work has been concerned with ensuring that that is indeed the case. That is what underpins our concerns.

The first concern we had last February, which I think is being addressed within the pathfinder, was that people need to know what they were opting out of. There needs to be information. I know there is a facility within the pathfinder project to ensure that all patients over 15¾, I think, will receive information about whether or not they can opt out, what care.data is and so on. Therefore, that is one issue that is being properly addressed within the pathfinder project.

The other issue that we raised at the time was to do with hard-to-reach groups who might not be able to understand the communication in the form it was delivered. I know that is also being addressed within the pathfinder group.

We also had concerns about what the data would be used for, and there has been a full and comprehensive explanation of that. I know that the legislation has been adjusted to address the use of the data, particularly for commercial purposes. The current position, as we understand it, is that data cannot be used for profit—it is just to cover costs—and it does not go to insurance companies.

The two concerns that remain are that the whole thing has now become so complicated that, quite frankly, it is very difficult for any one person to understand all the bits of it. A whole range of committees has been formed—I have six on my list here—all of which have some form of scrutiny or oversight of the process. One concern would be to ensure that all

those groups work together, have good communication and make sure there is no overlap between them, and that at some point in the future there is a report as to whether this alphabet soup of organisations is functioning properly and efficiently.

The other matter is a plea to get the pathfinder phase right. This is the last chance saloon for care.data. We should not rush it; we need to do it properly. I do think that given the way it has been set out it is being done properly, but we must not rush it. We must do it steadily, in conjunction with patients and all other interested parties, to make sure that GPs and people whose records are going to be used are on board. We must take that slowly, steadily and systematically, as we have done, but with the proviso that we do not make it any more complicated than it currently is.

***Nicola Perrin***: I would agree with all of that. We have come a long way from where we were at this time last year. At that point, we were calling for much clearer communications about the potential benefits but also the risks and safeguards in place. We also wanted much clearer governance arrangements and clarity over those safeguards. The work that has gone into the communication strategy has been very helpful and impressive over the last year. There has been an extremely good engagement and dialogue exercise, and the latest draft of the communication for the pathfinder practices is a significant improvement on last year.

We still have some questions and outstanding concerns about the governance arrangements and the safeguards, in particular to make sure that who can and cannot access data and for what purposes is very clearly defined. We are looking to see that in the confidentiality advisory group regulations that Sam mentioned. I think it would be helpful to discuss those in more detail in this Committee session.

We also have some questions about the proposed mechanisms for access to the secure data facility proposed for the pathfinders. It may work fine for the pathfinders, but it is not scalable and proportionate for access beyond that, so we must take into account what needs to be achieved in the longer term, if there is to be a national roll-out. As Sam said, clarity over the opt-out is still important.

**Chair:** I am going to turn to Andrew. If, when we get to the end of the session, you feel you have not had a chance to make the points you want to make more fully, do come back to that at that point.

**Q567 Andrew Percy:** I must apologise that I have questions for the debate in the House, so I will not be staying for the whole of the session. Following the pause in care.data that you have already talked about, the pathfinder areas were announced. Do you have any comment on the choice of those areas?

***Professor Mathers***: I think the pathfinder areas were chosen systematically and rationally. We wanted pathfinder areas that encompassed about 500 general practices. I think it is now about 350. It is a whole range of areas. CCGs volunteered to take part. There are two in the north and two in the south and west, and it is a whole range of urban and rural populations, and deprived populations and not so deprived populations. It seems to me it was a very rational choice to choose CCGs that were different from one another and CCGs that volunteered to take part.

***Sam Smith***: As far as we understood it, NHS England said they would write to all CCGs asking them to take part. We know that that did not happen and they were picked via a mechanism about which we have no information.

**Q568 Andrew Percy:** Are you satisfied that in terms of the care.data advisory group they were engaged with properly and that the issues you raised were adequately answered, or do you have any outstanding concerns about the role of, and involvement with, the advisory group?

***Professor Mathers***: The advisory group is not a decision-making body. Representing the RCGP, we were listened to, our concerns were addressed very seriously and appropriate written responses were produced to every issue we raised. We have had a very large number of meetings. It has not been done very quickly and superficially; it has been done with us being fully informed and given all the information we need to answer our queries.

***Nicola Perrin***: I think the advisory group sees its role as a critical friend and, during the course of the last year, we have been both critics where necessary but we have also been friends where helpful. There were some initial questions around communication, but I think we have resolved those and we are working together effectively as a group. I have not felt that we are not being listened to.

***Sam Smith***: I agree with those comments. The questions we have are very much the last ones to be answered, but the process which the group follows has been acceptable. For example, we have seen lots of communication material. For the last three meetings, we have seen three different drafts of the care.data opt-out materials, which have been different. That is a good process. When a decision is made about what the opt-out does, I am sure it will be fine, but that is not a question for the advisory group but for the programme board and the programme itself.

***Nicola Perrin***: There is a wide range of stakeholders on that group, and the fact that often we are all giving consistent messages is, I hope, helpful to care.data in establishing its next steps.

**Q569 Barbara Keeley:** In its report to the care.data programme body, the Independent Information Governance Oversight Panel sets out 27 questions, with which I am sure you are familiar, that need to be answered satisfactorily by the board, and seven conditions that need to be met. Looking through those questions—I am thinking back to previous sessions we have had—I feel that the picture is somewhat clouded by what has gone before. I look at a question like, "How do I know my data are safe?" and questions that go on from there. We would like to have your input. Are those the right questions, and what progress do you see is being made towards them?

***Sam Smith***: If we are talking to patients, some variant of, "How do I know my data are safe?" is a question they ask. They want to know that their data being used by the NHS are safe, how that happens, whether or not there are conversations and there is a secure data facility which is being scaled up and doing more things. A secure data facility is a very good idea, and this Committee was instrumental in pushing forward that idea. The IIGOP has asked the question and the answer is, "What are you going to tell patients?" I suspect

some patients are watching this briefing, but most will not. What are you going to tell them? Is that comprehensible, and will it make them feel safe; or will you tell them something that generates another 10 questions, none of which is answered, or to which you have no answers? I think that is the sort of question Dame Fiona is looking to get an answer to. It is not just that question, but the answer cannot raise another five.

***Professor Mathers***: I think the questions she raises in this report are entirely appropriate, but it has expanded the scope. It goes beyond care.data and it is establishing more general principles that would be applicable to other programmes of work. I think the questions are entirely appropriate.

**Q570 Barbara Keeley:** From the GP point of view, and we are talking to you as the GP on the group, do you believe GPs are able to answer those questions?

***Professor Mathers***: Not at this stage. Part of the pathfinder work is to ensure that all GPs and practices have a toolkit so that, if they do not know something, they know where to look or who to ask. It has become increasingly complex over the last year, and there needs to be space and a resource available to GPs to make sure patients are being correctly and appropriately informed, particularly about the implications of opt-out.

***Nicola Perrin***: It is an extremely comprehensive set of questions. I would not be able to identify anything that is missing from it. I think we are nearer to being able to answer some than others, but they are all very important.

**Q571 Barbara Keeley:** Which of the questions do you think are furthest away? I suppose that the point we will get to today is when it might be appropriate to move with the pathfinders. How far away do any of you feel that is?

***Professor Mathers***: It is important to take this step by step. I would hope that by the summer we would know the answers to the majority of these questions, but we do not know until the pathfinders have taken place because it has been quite a slow start.

***Nicola Perrin***: Some of them, such as the one about safeguards, will hopefully become clearer with the CAG regulations. The opt-out ones have to be clarified before the pathfinders can go ahead. Some of the ones about the data that have been excluded from the scope for the moment and expanding the scope in future do not necessarily need to be answered before the pathfinders start, but a clear process needs to be set out for how those will be answered going forward.

***Sam Smith***: I would agree with those statements. Tim Kelsey has previously said to the Committee that there are no artificial time scales, and I would echo that comment. These questions are interrelated. As we get closer to an answer, it is easier to answer more of them, which makes other questions easier, but I have no idea how long it will take NHS England. "What does the opt-out do?" seems like a simple question, but they have been working on it since February and we still do not have an answer.

**Q572 Barbara Keeley:** You mentioned that there was not an open competition for CCGs to opt in to being pathfinders. Do you have any concerns about the pathfinders that are there? The question mark I have is: why three from one area? Why the whole of Leeds?

***Sam Smith***: One of the things they are testing is communications. CCG boundaries, especially in a city, are probably legacies of previous local government arrangement of wards. It is one side of the street and not another, so if you put up a billboard what do you do? It makes sense that they are some form of constrained areas, and one needed to be a city so you can test a city. We know that leaflet penetration in London was well under 50%. To run a good pathfinder there needs to be a city. As a result, most big cities have multiple CCGs, and I suspect Leeds is convenient, given where NHS England is based.

**Q573 David Tredinnick:** I have listened with great interest to what you are saying, but I want to ask you about the scope of these pathfinder trials. Do you think that the whole planned scope of the system, from collection to processing, and the use of data should be the basis of these pathfinders, or should they be used to test the effectiveness of the technical process? In other words, is there a risk that we are asking too much of the pathfinders and we will not find out enough, or that the results will be confusing?

***Sam Smith***: There are two aspects to that question. Can you get the data from the GP systems to HSCIC? Yes. There is an existing process being reused called the general practice extraction service, so you can run the query. There are a few low-level mechanical questions like, "Will a GP approve it?" but that is a problem that has been solved before.

As to whether or not the data you get, when you get them to a safe setting, will be of any use, I would refer you to the expert reference group for care.data. HSCIC convened a group of experts who do data analysis on these sorts of topics. They had a list of things where NHS England and others said, "We use care.data to do these things." They would ask, "In your area of expertise, here is the specification; here are the data you will have; here is the question. Will you answer it?" It will say, "We can do that because we will have four months of data and that is enough for this question." In other cases, it will say, "No, because it is not in the specification." There is a range of questions from a clear yes to a clear no. That expert reference group did some very good work and has produced a report, which I hope the Committee has been sent.

***Professor Mathers***: From the point of view of the college, we have to look at it as a whole system rather than just individual bits of the care.data programme. From our point of view, the comprehensive nature of the pathfinders will enable us to answer most of the questions outlined in the report of Caldicott's independent group before Christmas.

***Nicola Perrin***: That is right. One of the most important things about pathfinders is to test the communications and understanding. You have to test that as the whole system, and I do not think that to cherry-pick different bits would work. Having said that, from a research point of view, we recognise that pathfinders will not be of enormous value; they are a limited dataset. The secure data facility is fairly locked down, for understandable reasons, and data extraction will also be limited. From a research perspective, we want care.data to work. If the way of getting it to work is to do it in a phased or staged process with pathfinders first, we understand that is the way it needs to happen.

**Q574 Rosie Cooper:** If the conditions that the Independent Information Governance Oversight Panel has laid down are met, do you think it reasonable that the pathfinders should go ahead on the basis of patients opting out rather than opting in?

***Professor Mathers***: My understanding is that legislation exists to say that opt-out is the way forward for care.data, and that has been our position. We think that opt-out should be the appropriate approach for care.data, for all the reasons outlined in previous discussions, in terms of participation and utility of the data being extracted and used for the benefit of other NHS patients. Therefore, from the point of view of opt-out, we think this is an appropriate way to implement care.data.

***Sam Smith***: That is a question to which there are a number of possible answers. It is very much easier to run a good opt-out system than a good opt-in system. It is incredibly easy to run a poor opt-in system. If you say that somebody has consented to the plan for care.data, or whatever replaces it, this runs for ever. What does that change as the programme changes? Is it new data, new treatment or other things? Is that something they should have opted in to again? Where do the boundaries arise?

We would look at any opt-in proposal that was offered. We have not seen one, and we have not had the time to put one together. The proposal set up by NHS England is an opt-out proposal, so we look at how we can make the proposals on the table adequate. We are aware that the British Medical Association has opt-in as a policy, and we very much look to see where that goes. If there was an opt-in proposal on the table, we could look at it.

As to opt-out, that provides, as part of a national health service, some onus "to do the right thing", for want of a better phrase. What does that mean? One of the descriptions of care.data that has been used is that it was the most data they could sneak past without anybody noticing and something else happened instead. It is a question of what is good governance, what does it look like, because there is then not quite a moral expectation but a cultural and ethical one of the various bodies involved that that is the level of engagement that you have had with the public, and they find out what you get is last February in the hospital episode statistics.

***Professor Mathers***: As I said in an earlier statement, the key principle for us is that the NHS and everyone who uses the data should be beyond reproach, and people need to know what they are opting out of. If those two conditions are met—hopefully, all this work is enabling that—that is the underpinning of our support for opt-out.

**Q575 Rosie Cooper:** Nothing would give me greater pleasure than to say, "Jolly good. This is where we are." For me, this is a question of trust. When I came in today, I was prepared to leave at the door a fair amount of cynicism, but in the past half-hour we have heard about minutes not being published as promised; whether the pathfinders were volunteered or chosen; whether or not people have been written to as promised; and regulations promised in the autumn are still not to be seen. You are almost saying it is reasonable that we should go for an opt-out instead of an opt-in. My question to you is: from where we were before, what solid pieces of information land, as I would put it, are any different? What is different so you can tell me this is really going to be good, based on

honesty and transparency? I have to say I have not seen many people keeping their word round here, I have to say.

***Professor Mathers***: We have moved an awfully long way since last February. A huge amount of time and energy has been expended. As Nicola was saying, a lot of time and energy has been spent on communications. The proposed communications I have seen for the opt-out and information leaflets are honest, straightforward, understandable and direct.

**Q576 Rosie Cooper:** We have not seen those yet; you have. When people say that minutes were promised and they have not arrived, and regulation was promised and it is not here—it is delayed until later in the year—you will probably start this without any regulation at all. It is ridiculous.

***Nicola Perrin***: I do not think it can start without the regulations.

**Q577 Rosie Cooper:** You are saying that absolutely no extraction will take place until this those regulations have been laid and have gone through the House.

***Nicola Perrin***: That is our understanding.

***Sam Smith***: That is our understanding. I would be utterly shocked if there was a different understanding. It has always been the case that there will be CAG regulations. Two things have changed since last February. There is a promise of a letter to patients, and Dame Fiona Caldicott has oversight. The question is: what does the letter say? That will say some things. Is that going to be happy? If you as an MP send that to all of your constituents, will your mailbag explode? We do not know what that letter will say; we cannot know. If there is a good opt-out and a good process, we can look at that. We do not know what that letter will say. Why do we think there is optimism and hope based on the founding principles of the NHS which are continued in that vein? That is probably the only thing I can cite—and the fact there are people who can say, "You are not meeting an obligation to the people of England. You cannot do this."

***Nicola Perrin***: Other things have changed since last February. The Care Act has clarified the role of HSCIC and has also given additional functions to the confidentiality advisory group. They need to be set out in more detail in the regulations but there is a starting point in legislation, which is a step forward. There is also the Independent Information Governance Oversight Panel. A huge amount of work has been done by the information centre to understand what has gone wrong in the past and learn lessons, and there is much more transparency about requests for data and to whom data have been given. There have been knock-on effects for the research community, with serious backlogs and delays in getting applications through. That is another set of issues, but it shows they are taking their responsibilities much more seriously.

**Q578 Rosie Cooper:** Do you think those responsibilities can be discharged with a fine of £500,000, or should somebody go to prison for breaches?

***Nicola Perrin***: I would be very supportive of much stronger and more meaningful sanctions for misuse. There is a very important discussion to be had as to whether or not

criminal sanctions are the best way forward. They would need to be clearly defined to make it clear they are for misuse with malicious intent so you do not catch the accidental re-identification which is an honest mistake that is rectified very quickly. I think there is an important discussion to be had, and the sanctions need to be meaningful to ensure there is trust in the system.

**Q579 Rosie Cooper:** Would that apply when the hospital episode information was on the internet? Should they have gone to prison for that?

***Nicola Perrin***: I think it is the data user.

**Q580 Rosie Cooper:** But that was out there and people could use it.

***Nicola Perrin***: At that point, there were no clearly defined purposes for which data could and could not be used, so you are introducing sanctions within a framework of what the data can be used for.

**Q581 Rosie Cooper:** I am not asking for it to be retrospective, but if something of that order happened should that apply to people?

***Nicola Perrin***: I would hope they would not be given access to the data going forward.

**Q582 Rosie Cooper:** But they were in the past. When you look at the future, you always want to look at history. We are being asked to allow virtually the same people to let rip once again.

***Sam Smith***: I would hope that the secure data facility should prevent that scenario from being possible, not that it should not happen, and similarly a number of steps should be taken. Those steps are not now fully available. We can make things impossible to happen. If it cannot happen because the data are only in the secure facility in Leeds and remote connections, not shipped on DVDs to anybody who wants it, you can have a very different conversation. Should the people who have committed breaches in the past be prevented from accessing it again? Yes. That goes to what CAG can take account of in the regulations and what the regulations say. They are not yet published. There is nothing we can point to that says NHIS was one of the organisations that potentially caused a breach, or was one of the organisations where massive public concern was raised—we will come back to that in a second—so should they have access to data again? What are the rules that will be in place? We do not know because we do not know what CAG can say. Therefore, they do not know what it can take into account. They would like to take it into account, but that does not mean that legally they will be able to. What happens when it is clearly the fault of a large company that has committed a breach? The example I used, and everyone wished I did not, was a large university where a PhD student gets drunk. That should not kill the research programme; it should possibly be just a matter of telling the student not to drink quite so much. If we can work that element out, that is a different problem. There is a set of processes there. Where somebody is to blame and it is clear, that

should be the case. We do not know what the regulations will say, so we have no answer to that.

***Professor Mathers***: We are strongly supportive of tougher sanctions for any abuse of data. The regulatory framework is a lot tougher than it was even a year ago.

**Rosie Cooper:** I am saying that it has to be criminal with prison, or the threat of prison, as opposed to money, which is no threat. If you are a multinational company and it is a fine of half a million, or whatever you like, you will pay it and do it again, but if the chief executive is going to jail it might be slightly different.

**Q583 Barbara Keeley:** To come back to one of Sam Smith's points, in previous sessions I raised the fact that CAG allowed the use of hospital data for what was effectively a price comparison website for private hospital procedures, which I think is an abuse of patient data. Why should the details of anybody's operation go for that sort of use? That goes to the point we have been considering right from the start, which is about reputation. If a PhD student makes a mistake because they have had a bit too much to drink, that is one thing because they have to get on and finish their course; otherwise, they will not have a career. However, if two blokes, if they are two blokes, have a website that compares prices, that sort of application can come and go. How do we reassure ourselves that we will stop seeing that sort of usage, which is an abuse? I cannot see a patient anywhere who would want their hospital or GP care data to be used in that way.

***Sam Smith***: That goes to two questions. One is that HSCIC can release data for the purpose of the promotion of health. What does that mean? Has it been written down at any point? The answer is: not that we have found. My understanding is that it will not be in the CAG regulations.

To take your particular point, a company can be created and cause a breach and then shut itself down, and the same people start up a new company. Whatever the regulations say, they must take account of corporate history and also the individuals who caused a breach. When you make a request for data, you say who will have access to the data and equally their personal history so you cannot shut down the company and get away with it. Your reputation follows you, as well as the organisation.

Equally, if an organisation and not an individual were to blame, they can get another job doing the same thing at a different company without being tarnished. If that reputation stays with an individual, they have a greater obligation to report wrongdoing because it will not be held against them unless they have done something, whereas if the actions of the company are held against an individual, who on proper investigation was not to blame, there is an incentive to keep your mouth shut.

**Q584 Barbara Keeley:** You have told us in your evidence that you have concerns about updated data access request forms because they do not require verification, even if a customer is a legal entity, and ask only for a company number. That seems the most cursory of checks on an organisation. The departure we have got into is away from the research community. Students and people forging a career in research have their future to think of and

their integrity is important to them. Is the type of organisation I talked about, which throws together a website app and tries to make some money out of it, another concern that needs to be addressed?

***Sam Smith***: It goes to that point. In the research community, you have a culture where the people in it will generally stay there for their working lives. Nicola can speak to that point a lot better than I can. Companies have very different motivations from researchers and so should possibly be treated at least slightly differently, but not completely.

***Nicola Perrin:*** A lot will depend on getting the right definitions in the CAG regulations to be clear about what purposes are or are not allowed and to limit purposes that are solely for commercial use. We have to recognise that pharma companies do some very valid and important research that improves human health. There may also be some commercial gain as well and we should not be stopping that, but we need to prevent purposes that are solely for commercial use. We are concerned that the CAG guidance needs to set that out more clearly. We recognise that there cannot be an exhaustive list of what is and is not allowed. It needs to go further than it goes in the Care Act itself, but our understanding is that that is not the intention at the moment.

**Q585 Barbara Keeley:** You understand that is not the intention.

***Nicola Perrin***: It is not the intention.

**Q586 Barbara Keeley:** That is a concern.

***Nicola Perrin:*** Yes. Our other concern about the regulations is how they fit with CAG's other roles which were defined within the 2002 regulations, particularly in relation to section 251 and the provision of approval for the use of identifiable information without consent. It should be very clear that they still have that function. They have had a very transparent process to administer it; they give robust challenge, but they also recognise why they have that function and do it very effectively. There is a danger that the two regulations could end up conflicting with each other. The full remit of CAG needs to be absolutely clear.

**Q587 Chair:** Have you set out what you think the wording should be? As a group, have you made clear where you think it is lacking?

***Nicola Perrin:*** No. We had discussions with the Department of Health. They have said they will put more detail into the explanatory notes, but we have not yet seen their latest draft. Until we have seen their revised version, we have not provided wording.

**Q588 Chair:** As a group, have you made your own suggestions? What would satisfy you to see in those regulations? If you have done so, or are about to do that, would you send it to the Committee as well?

***Nicola Perrin***: We have suggested some things; we have not gone into detail, but we can do that, if it would be helpful.

**Q589 Chair:** Thank you. One final point. I do not ask about the culture among those who are going to receive the information but, as a group, do you feel that within the Health and Social Care Information Centre and NHS England, which to be fair led to a certain sloppiness in the way this was first set out, there has been a recognition and culture change about how we should be going forward?

***Sam Smith:*** Within NHS England, no. Within the Health and Social Care Information Centre, they have a new chief executive in April who was appointed before this blew up. There have been lots of changes to HSCIC. We are having ongoing productive discussions. We are being listened to and steps are being taken. We can go into more detail.

**Q590 Chair:** Could you set out what you think are the issues that need to be resolved within the culture of NHS England?

***Sam Smith***: I think that decisions are made and then are not reviewed in the light of further conversations. Taking the opt-out, which may not be the best example, what will it do? There will be one opt-out and all the problems that come from that decision seemingly cannot be entered into. I would not say "neglect", but it is a lack of attention to detail.

***Professor Mathers:*** In my view, there has been a raising of consciousness in NHS England. They are much clearer about what they can or cannot do and much more reticent about just going for it without ensuring there is adequate consultation and feedback. My view would be slightly different from Sam's.

**Q591 Chair:** You feel there is a response.

***Professor Mathers:*** This time, for NHS England, they have been amazingly responsive in my experience.

***Nicola Perrin:*** I would agree there has been a significant shift in the information centre's attitude to all of this. I would support Professor Mathers's comment that the parts of the care.data team we have had exposure to—"NHS" is too broad a term—do get the issues now.

**Q592 Valerie Vaz:** I suppose it was the screech of everyone else that caused NHS England to backtrack on certain things and they feel there is not much accountability, which is why we are all sitting here today discussing this. I want to pick up one or two points on the pathfinders and then maybe ask a series of questions that have arisen from your evidence. You talked about NHS England not writing to everybody but just a few CCGs for the pathfinders. Are you satisfied that patients were involved and properly consulted on that? Is there any way of finding out or knowing?

***Sam Smith***: It was different within different areas, and I do not think there was one answer. One of the pathfinders and one of the CCG's patient groups was not consulted. I do not know whether that was because there were multiple patient groups. You will have a range of answers. I do not think there is a single answer.

***Professor Mathers***: Decisions were made pragmatically rather than ideologically that everyone had to be involved at every single stage of this and it needed to be done. My understanding is that CCGs were selected on the basis of them volunteering. Everyone was invited, but it was the volunteers who have taken part in the pathfinders. There has been variation in the amount of patient involvement. There has been some patient involvement in all of them but it varies.

**Q593 Valerie Vaz:** Were patients written to and told they were part of the pathfinder?

***Professor Mathers***: That is part of the pathfinder project; they will be.

**Q594 Valerie Vaz:** Were they all written to?

***Professor Mathers***: Yes, they will be.

**Q595 Chair:** To clarify it, they have not been written to yet but they will be.

***Professor Mathers***: Not yet.

**Q596 Valerie Vaz:** You said that they were volunteers. Did money change hands?

***Professor Mathers***: I do not have the foggiest idea.

**Q597 Valerie Vaz:** We do not know whether they were given incentives to be part of the pathfinder.

***Sam Smith***: That is a question for NHS England. I believe the public statement was that costs would be covered. What that means I do not know. I think the intent on the part of NHS England was that this would be cost-neutral to the CCGs, but then you get into questions of accounting.

**Q598 Valerie Vaz:** Professor Mather, can I turn to some of the comments you made initially? You said that legislation was adjusted. Could you say which legislation that is?

***Professor Mathers***: Provisions were put into the Care Act just before Easter of last year about "not for commercial purposes". This is for the benefit of NHS patients and the NHS. As Nicola has pointed out, in some circumstances, the data may be available to pharma companies, but that is in the interests of direct patient care. I think that was the phrase that went into the legislation.

**Q599 Valerie Vaz:** When you refer to legislation you mean the Care Act.

***Professor Mathers***: Yes.

**Q600 Valerie Vaz:** You talked about a range of committees overseeing this. You mentioned at least six. Could you name them?

***Professor Mathers***: I am sorry about the acronyms. There is GPESIAG, which is the General Practice Extraction System Independent Advisory Group. I apologise if that is not right, but that is for GP release of data approval. DAAG is the Data Access Advisory Group; HSCICCAG is HSCIC's Confidentiality Advisory Group; there is the Independent Information Governance Oversight Panel; there is the Expert Reference Group; and there is the Pathfinder Programme Board. I do not fully understand how they fit together, but they all have distinct remits and functions.

**Q601 Valerie Vaz:** Does anybody know how they fit together?

***Nicola Perrin***: Some but not all of those. On top of that we have the National Information Board and the National Data Guardian.

**Q602 Valerie Vaz:** Presumably, we can get that from somewhere, can we? We do not want another organogram. Do you want to comment on that, Mr Smith?

***Sam Smith***: Probably not briefly. Possibly, the short answer is that they do fit together and there is overlap. Many of those, hopefully, have an affiliation to HSCIC, so they may wish to write to you with an explanation or diagram that would be very useful clarity for everybody.

**Q603 Valerie Vaz:** I make a general comment and ask a question of all of you. Lots of research took place prior to care.data. What is so different that has to happen now in terms of research? You say it is useful for patients, pharma companies and so on. What is so different now about the research, evidence and information you get that you were previously able to access?

***Nicola Perrin***: If care.data goes ahead, the real difference will be that we will be able to link primary and secondary records from GPs and hospitals together with other related datasets, disease registries and prescribing data, and to do it on a population-level basis. That is the key difference. These things have happened on a small scale, but, if you can do this nationally, you make use of the NHS's unique asset which is the cradle-to-grave records of 50 million people. That means you can ask questions at a population level that you cannot ask with limited datasets. It also means you can ask questions about much smaller groups. You can look at rare diseases, or unusual conditions, where it is difficult to conduct a clinical trial—for example, the impact of prescribed medication during pregnancy and medication in children. For that kind of question, it is the scale of the dataset that would make a real difference. This has been done on a small scale with CPRD already, to add another acronym to the equation.

**Q604 Chair:** For those following this, can you say what that is?

***Nicola Perrin***: That is the clinical practice research datalink. That is an evolution of GPRD, which is the general practice research datalink. What is different about these proposals is that they would open up access to data across all primary care records.

***Professor Mathers***: Care.data itself provides a fantastic opportunity for research. That is one reason why we think the benefits outweigh the risks, provided they are properly managed, for improving patient care. The linking of the datasets between the hospital episodes and care within the practice is where the real power lies in the programme.

**Q605 Valerie Vaz:** My concern is exactly what you have just mentioned: it saves clinical trials. I just wonder whether we are in the process of getting a massive amount of information about the population to save drug companies from doing their clinical trials and work. Some population studies have been going on, have they not? My question is: if someone has an idea for a piece of research, what is wrong with identifying, via GPs or different areas, which they must have done before, those patients and asking their permission? You will find that patients probably would like to help further research. It seems to me you have a massive amount of information about people, which you really do not need to have, that means people can dip in and dip out. I am hoping you will tell me that there is an opportunity for patients to know what information about them has been passed on.

***Nicola Perrin***: I think there are two slightly different issues within that. You can ask very different questions if you are looking at real-world effects in the population. Of course, there are examples where you can do it on a small scale and ask every individual patient, but you will not be eliminating clinical trials. This is not about novel drugs before they have been approved; it is looking at the effects of drugs that are already being prescribed and picking up side effects which would not otherwise be seen if you were looking at just a small population. It makes it that much easier. Because one can look at large numbers, the costs and resource implications of asking everybody separately to consent would be huge, and would reduce the amount of research that could be done. You also end up with that sort of opt-in process. You will often have a skewed dataset which can lead to an unhelpful and potentially dangerous bias. You will have some groups that are much more reluctant to give consent and they are missing from the dataset. Therefore, population-level data are of the most value to get the best possible answers from the research.

**Q606 Valerie Vaz:** It seems to me that not everybody will be on that particular drug. If it is about the effect of a particular drug on a person, or group of people, and you want to find out how they have gone through the system, you do not have to have information about everybody, do you? If it is a rare disease, you do not have to have information about people who do not have it; you can target your research. People make an application for the information to do that research. You target it; you do not have everyone's information. I am thinking about being very safe about people's personal data.

***Nicola Perrin***: This helps you to target it. The resource implications for a researcher from a charity or university to contact every single GP practice to find out if they have that one patient in their practice are huge, and it also puts an added burden on the GP practice to respond to all these separate inquiries. If you can do it at national level with appropriate safeguards, it is the most effective and efficient way of getting the data.

**Q607 Valerie Vaz:** We have to do exactly the same for FOIs. We are continually having to ask CCGs and everybody else under FOIs, so there is a huge cost implication. It

seems to work for one person and not another. Mr Smith, can I ask about the report on personalised data usage? In your evidence, you suggested there was good news too. Can you expand a bit on where we are on that?

***Sam Smith***: Everybody would like to know where their data have been used, and HSCIC can now tell them. Back in February, you asked them where they send data that month. They could not answer the question. Now they have worked it out and can tell you exactly which studies you are in, going to your question, "Do you have this rare condition?" or, "Are you in the control group for that study?" which is normal people selected at random. Where did your data go? "You went to these studies, and, after however long it took to do the research and publication, this is what we learned as a result." You tell patients about every single usage. When it is everything, what causes concern is that people think things are being hidden. If you say, "We will tell you everything. Here is the list," people can go through it and say, "I'm not sure about that particular project, but I'm happy with all the others." It is not trusting that the governance is good, or trusting CAG or the other parts of the alphabet soup; it is being able to see this is what happened. "This is where my data went, this is why, and I like those projects." If you tell people that, it massively reassures them. They do not have to trust the system; they can read it and know.

If you have fundamental consent, based hopefully on where we are going, and you opt out of all research, your research section is empty. You may have been in some studies in the past and they have been published, but you know where your data have gone. If you start having that conversation and provide that electronically to every patient in the country, it is a confidence-building measure.

Going back to Rosie's earlier question about trust and why we think this is a good idea, there is what the Royal Statistical Society calls the data trust deficit. If you ask a person how much they trust an organisation, and ask the same person how much they trust that organisation about data, the data one is always a lot lower than the organisation itself. That sort of transparency is a confidence-building measure.

Some time last year, a company in London which did breast cancer screening was fined a lot of money because it had a single username password for the entire company for all their patient data. That was front page news in the *Metro* for two days. Nobody knew who it was. It could have been you, but you did not know, whereas if you had a list of where your data had gone, with all the direct carers and all the secondary usages, the NHS statement can be, "Go and read your data usage report, which is a big red box on page 1 telling you what happened. Click here to find out what happened, what we have done about it, how it affects you and what you need to do," that would be very reassuring. It is not a question of, "Well, that might have been me." It was a bad story; it really should not have happened, but fear comes from, "Was I involved, or does it affect me?" That is one of the things personalised data usage reports are trying to achieve.

**Q608 Valerie Vaz:** GPs do text. When you go and see your GP they can ask you. The costs are minimal. Given that Korea hacked Sony, do you think our data are 100% safe?

***Sam Smith***: I do not think anything can ever be 100% safe, because you get into really odd cases. I was talking to a journalist who writes articles about pharmaceutical companies. The people he covers know when his wife gave birth and his kids' birthdays. He is massively identifiable, and he is giving data to the people he writes about. The only

way you can make it 100% safe is for him and his family to be able to opt out and not to be in the dataset, so you get into certain cases.

Is it possible to build a system with proper consent, a secure data facility that checks who goes in and data usage reports, all overseen by statutory governance? Can that make it safe enough that the vast majority of people say, "Those are the safeguards. All of the benefits come from research. We like the potential cures, and this is a good thing in a national health service?" A trade-off can be found. I do not think the current care.data programme is that trade-off. I think that bits of what HSCIC are doing are moving towards that, but that is what this Committee and others should have as a conversation when this is in place. What do we want that to look like, and where do we draw the boundaries?

***Professor Mathers***: I do not think it can be 100% safe, but I go back to my opening remarks. We have to be beyond approach and do our absolute best within the constraints of our resources to ensure it is as safe as it possibly can be. The benefits should outweigh the risks. Most patients are willing to share their data if they are being used for altruistic purposes: to improve other people's care, to find the side effects of drugs or whatever. It is about making sure that people who do not opt out understand that, although it is not 100% safe, it is as damned near safe as we can make it, and that their data are being used for appropriate altruistic purposes, in which case most people will retain trust in the system, in our belief.

***Nicola Perrin***: I would agree. I do not think we could ever say it will be 100% safe, but the important thing is that, if you cannot eliminate the risks, you make sure you can manage them appropriately, proportionately and effectively and ensure the benefits outweigh the risks.

If I may return to Sam's comment about notifying everybody about how their data are used, there is a real benefit in having a clear and transparent audit trail, but it is worth recognising that it personalises the use of your data much more than it would be. If a researcher used your data, they would not know it was yours; they would have a line of code with a whole series of numbers and it would not look like a person. My concern would be that if you saw, "Researcher X used my data," people would have a very different impression of what is actually involved when researchers use patient data.

**Q609 Chair:** Mr Smith, following up the points that have just been made, for you is there a point at which that balance will tip in favour of being confident to share your personal data through this programme, or do you feel that this is such a fundamental step too far there is no point at which you would feel happy to sign up?

***Sam Smith***: That decision is made at a different point for everybody—for example, the previous example of the journalist. There is probably nothing you can do about that. Equally, there are people with rare diseases who put all of their medical records freely on the web for everybody because it might help somebody. Those are diametrically opposed. In likelihood, everybody is in the middle of the spectrum. Most people probably do not want to think about it; they just want the right thing to happen. What that means is probably the topic of the report by this Committee. If somebody does not want to pay any attention, what should happen and how is that treated safely? In the same way, when somebody goes to hospital it is not that nothing bad will ever happen, but there are

processes whereby if something happens it is learned from. That may be very sad for you or your relative, but equally the system as a whole should run.

**Q610 Chair:** I take your point that the tipping point will vary from person to person, depending on how they feel about these issues, but one of the disadvantages is that, the more safeguards we pile on, the more bodies we end up adding to the list. I think we got to more than seven in the end when we looked at the number of people with oversight. Do you think that, if we keep piling on more and more layers of safeguards, in the end you can make the programme less effective without adding extra reassurance?

***Sam Smith***: Yes.

**Q611 Chair:** You feel that is also an issue.

***Sam Smith***: There should be appropriate governance, and the answer is not that constantly adding more bodies is better. There should be statutory oversight and information governance in the NHS, again. I think that in the 2014 report of the IIGOP there are case studies going to that point. That should be put back. That is not to say there should be multiple statutory bodies. There should be one based in medical ethics that is responsible for that aspect. If care.data had been designed by somebody with a medical ethics background, it would not look anything like it does now, and the programme would probably have been running for 18 months. Some people would have opted out. Those are the people with the most concerns, and everyone else would probably not have noticed.

**Q612 Chair:** The fundamental problem is that we started from the wrong place.

***Sam Smith***: The wrong ethos. It was designed to be the most data they could give to certain types of companies without the public becoming unhappy, and they misjudged it.

**Q613 Barbara Keeley:** I have a few more questions to put to medConfidential, but others on the panel might want to comment. You have raised with us the question of putting the National Data Guardian on a statutory footing and pointed to a couple of examples from her report. In one case, her group tried to advise on the opt-out leaflet, which was disastrous. They were told it had gone to the printers and that was that. The report also indicates that they have not been able to achieve the cultural change that they called for in relation to information governance. You have just said you think this should be put on a statutory footing, but what do you see as the main benefit of that?

***Sam Smith***: The main benefit we would see is that, certainly in that case, NHS England would have had to have consulted IIGOP rather than notifying them after they had sent it to be printed. When somebody can say no rather than say no and be ignored, that is a very different world.

**Q614 Barbara Keeley:** Can I draw out some of the things in your briefing that we have not touched on? You still have concerns about the 9BNu4 opt-out code and whether the

use of it will affect the care that you receive. We have been informed that that is an issue and patients who have opted in that way will have to be written to. Is that also your understanding, and is that still a concern?

***Sam Smith***: That is still a concern. Just before the Committee started I was handed by the Clerk a copy of a letter from HSCIC which goes into more detail than we have seen before. As of yesterday, when we last checked, NHS England said that opting out with 9Nu4 will not affect your direct care. We believe that intent could be true. We wait to hear from the people who give evidence after us what is there, because I think that is a question you have to ask NHS England.

**Q615 Barbara Keeley:** I am sure we will. You said you had not seen the list of medicines that are considered sensitive and which will be removed from the dataset, and presumably that would be a concern.

***Sam Smith***: In November, I was told that it would be published within days, and it still has not been. I do not know what is in it. I know that, when the care.data specification was originally published, we went through it in more detail than everyone else had, and the changes that I have in my spreadsheet reflect various things that really should not have been in it.

**Q616 Barbara Keeley:** You also talked about consultation on the dissemination and use of sensitive data. In previous sessions on this issue, we touched on the fact that the most sensitive information in GP records is often the GP's handwritten notes. In a previous session I raised the fact that there were already research projects picking up those notes from GP records. That is still a concern. What is your view about what audit or transparency there should be? We were told by somebody who knew about particular projects that that was going on, and yet it is undoubtedly the case that the patients involved, who were having their notes copied, did not know that was happening.

***Sam Smith***: We would hope that a patient who ticks the box which says, "I would like to opt out of everything," can say, "I have this condition and I want to opt in to that." If a patient says, "I'm completely happy for this to go on," in that particular case, the most specific objection is the one that should be applied, or the consent. You can override them and it gets complicated very quickly.

**Q617 Barbara Keeley:** The question was specifically: should there be uses of often much more sensitive handwritten data, not the codes referring to dates of birth, conditions, when you were in hospital and what procedures you had, but whatever the GP writes down? We were given examples of research projects where that information was being used. Has that been discussed in your group? Have you raised it? I had an issue with it. I just wonder whether it is also an issue for you.

***Sam Smith***: We recognise many very obvious issues that come up from there. To say it should never happen is not the question. This is a question we would look to discuss with the research community, the GP community and the affected patient groups for that condition. What is appropriate for this case and this type of project? That is why, for general research, the answer is that you go and ask CAG and possibly ask another body as

well. What should the process be rather than any particular project? Generally, there should be personal consent for looking at notes, but I am not aware of a deep process there. Possibly, that does not answer your question.

**Q618 Barbara Keeley:** It might be one that your group could answer. I know that medConfidential had a lot of issues about data reuse agreements and the fact nobody would really know who was using their data. When we asked about it, we were not always told, or were told that people did not know who the end user of a data reuse agreement was. Do you still have those concerns?

***Sam Smith***: New contracts came into force a few weeks ago which require the people who use it to fill in a form. Whether that is all cases or whether they will be published in a register, we do not yet know. It could be solved; it could be just as much of a problem as it was before, but the main problem with reuse agreements is the fact that it is commercial reuse. It is the commercial bit that is the underlying problem; reuse is just a second level there.

**Q619 Barbara Keeley:** Thank you for your briefing; it was very helpful. Any final thoughts?

***Professor Mathers***: To answer Dr Wollaston's questions about governance, it is the law of diminishing returns. There comes a point where the governance itself prevents the project being discharged either efficiently or effectively.

In terms of the personal level at which one is prepared to share data, at what point do you reach that tipping point? Personally, I think we need to wait to see the results of the pathfinders. The pathfinders have been crucial in ensuring that care.data goes forward or not. There needs to be a very clear review of the pathfinder results. The pathfinders are not just a step to implementation; they are another opportunity to pause and say, "Have we got it right here? Are we answering the right questions? Have we covered all the bases? Have we addressed everybody's concerns?" before rolling out any further parts of the programme.

**Q620 Valerie Vaz:** Who does that? Is it NHS England who will do that? Is it the people who have organised care.data? Will they say it is a success?

***Professor Mathers***: It has to be the programme board for the pathfinders, and that has on it representation from all the different stakeholders. It is not just NHS England. We have a role in the advisory group to say that we think this should be done.

**Q621 Valerie Vaz:** You would be contributing to that process as a group.

***Professor Mathers***: Yes.

***Sam Smith***: The answer is that it is an NHS England question. They can listen to whoever they like, but it is a decision for them. The advice of the Information Commissioner's Office is that you cannot write to people and say, "We might do this." You have to say you are going to do so. Equally, if the letters fail as badly as delivery of the leaflets, we

would not have done fair processing, as it is called, adequately. Therefore, you cannot extract and there is a breakdown and review. It was originally two steps and they were merged into one. I think Dame Fiona has a role in that, about which I am not entirely sure. The ICO and advisory group will take a view, but it is up to NHS England what they take account of, and whether or not there are other factors to take into account.

**Q622 Valerie Vaz:** There is no role for elected representatives.

***Sam Smith***: I would imagine the Secretary of State can take a view, but I am not quite sure whether Parliament gets a say.

**Q623 Valerie Vaz:** Or come before us again.

***Sam Smith***: I suspect that will not stop you.

**Q624 Chair:** It is perhaps a role for our successor body. Thank you very much. Before you depart, I mentioned that there would be an opportunity for you to raise any issues you did not think you had been specifically asked or had been covered. Is there anything else that you feel we need to take account of?

***Nicola Perrin***: When I was asked to give evidence today I sent a message round the sector asking whether there were any real points they would like me to raise. We all think it is extremely important to get care.data right and that needs to take as long as it takes, but in the meantime it is worth drawing the attention of the Committee to the significant delays that have been caused to researchers in accessing information from the information centre. There was a clampdown on any access. HSCIC are now open for business again and they are getting through the backlog, but in the meantime there have been a number of significant delays, including the accessing data that are non-identifiable and are at aggregate table level and could be publishable. It is important for you to be aware that these delays are happening and they are preventing very valuable research as a result of the uncertainty about care.data, so the sooner we can get everything clarified the better. I was inundated with examples and I am very happy to pass any of them on, if that would be helpful.

**Q625 Chair:** It would be quite helpful to have an idea of the level of delay and how that is impacting on important research and therefore patients ultimately. It would be helpful to have a note from you and those you represent about the extent of it.

***Nicola Perrin***: We would be happy to do that.

**Rosie Cooper:** Would you copy in NHS England so they know what they have done?

**Q626 Valerie Vaz:** You said something about asking the sector. Can you say whom you represent?

***Nicola Perrin***: This was not comprehensive research, but it was particularly across the medical research charity sector. Charities were reporting examples that they had heard from researchers they are funding. It is quite a broad range and included some of them.

**Q627 Chair:** It would be useful to have examples and an idea of the severity of it. Are we talking about weeks or months?

***Nicola Perrin***: Months.

**Q628 Chair:** We are talking about months of delay, and also the kinds of projects being impacted by this. Whom do you hold responsible? Who would be in a position to move it on while we are waiting for this to be resolved?

***Nicola Perrin***: Some of that is the information centre and some is the result of an increasingly complicated and fragmented approval system, people feeling that they have to duplicate applications and go to a number of different bodies. Because of the uncertainties, there is a risk-averse approach to dealing with these applications. A number of the case studies commented that individuals at the information centre were extremely helpful and insightful in their advice but, regardless of that, there were still a number of different approval processes, and the extra complexities in the data-sharing agreements were not always proportionate to the type of data being made available.

**Q629 Chair:** That is very helpful. Thank you for coming this afternoon.

***Professor Mathers***: Unfortunately, I was asked whether I could come to today's session only last night, so we have not had time to consult our members. However, in previous discussions at our council, the members have supported the progress that has been made with care.data.

***Sam Smith***: I think there can be a good outcome, and I hope we get there. I like the fact that the researchers Nicola funds, the institutes and all the good work that is done produce good outcomes for everybody. It has to be done safely.

**Chair:** That is a good closing comment. Thank you very much.

Witnesses: **Tim Kelsey**, National Director for Patients and Information, NHS England, and **Dame Fiona Caldicott**, Chairman, Oxford University Hospitals NHS Trust, gave evidence.

**Q630 Chair:** Good afternoon, and thank you for sitting through the first session as well. It has been very helpful. Perhaps we could start by asking you to introduce yourselves and your role for those who are following from outside the room.

***Dame Fiona Caldicott***: Thank you very much, Chair. My background is as a clinician. I started my career in general practice and went into psychiatry. I became involved in the

world of confidentiality in the ’90s. I was involved in producing a report for what was then the NHS Executive, which led to the establishment of Caldicott guardians in all the provider units in the United Kingdom, who I think have played a role in assuring patients that data is kept confidential and used for the purposes for which they have provided it. I had a break from that particular activity until 2012, when I became chairman of the National Information Governance Board, which at that point had only 18 months to run before it was disestablished.

Since then I have been involved in working for the Secretary of State for Health on an information governance review, which came out of the listening exercise for the Health and Social Care Act. That led to a report which had 26 recommendations, I think it was, about how information governance could be improved in the country. From that came the establishment of the Independent Information Governance Oversight Panel to try to ensure that some of our recommendations were implemented. Indeed, the Government accepted all of them in 2013. That is what we have been doing for the last year.

In November, the role of national data guardian was established by the Secretary of State, and I was asked if I would take it on as the first post holder. As the title describes, it relates to England and is about health and social care data. I thought the word “guardian” was extremely important. One of the things that have happened in the recent past is nervousness, if I may use that word, on the part of the public about what happens to their health and social care data. As a clinician, but also a patient at times and a member of the public, I recognise the crucial importance of the public having confidence in those they consult about their health and social care needs. It seemed to some of us that that trust and confidence had weakened, hence the work that has been done to ensure that the balance between protecting information and confidentiality, but also ensuring that information is shared in the patient’s interest, was acceptable to members of the public, and that it was a balanced exercise. One of the things we found in the review was that the sharing of information in the interests of the patient/care user was not as strong as it needed to be to give the best possible care. That is the background to the new role. It was established only in November.

In the last two years we have worked with a very small panel. One of the issues is the resource to support the work, and that is being considered at the moment. As you have already heard, there is also the question of putting the role on to a statutory footing, which relates to, yes, the independence of the role, but also the authority and the extent to which somebody holding it can exercise it and ensure that the standards we want for the whole of the health and social care system are established throughout and are in the patient’s interest whenever they present to our services.

**Q631 Chair:** Thank you. That is a really helpful background. Before I come back with some more detailed questions, perhaps, Tim Kelsey, you could set out your role as well.

***Tim Kelsey***: I am Tim Kelsey. I am the national director for patients and information in NHS England. I was also appointed by the permanent secretary to the Department of Health to be the national information director who chairs the National Information Board. I can you give more details about his role should that be necessary.

In addition, I am also the senior responsible owner of care.data. To make one point clear, the governance of care.data is a very important issue and has been reviewed and amended

over the last several months. It is a national informatics programme; it is not an NHS England programme. As a national informatics programme, I am accountable as SRO to the informatics accountable officer in the Department of Health, who is then accountable to the Secretary of State directly. The Secretary of State takes a great deal of interest in this programme. When we come to decision making on how the pathfinder process may or may not be initiated, it is in the context of a direct line of accountability. It goes from me to the Department of Health. NHS England funds part of the programme, but it is not the sole or discretionary decision maker.

**Q632 Chair:** Thank you very much. Can I return to you, Dame Fiona? Could you set out for the public in more detail, following on from your initial piece, how you will be able to hold this system to account and answer the kinds of concerns you heard raised in the previous panel? What are your powers at the moment? We have heard that you would like to have those powers on a statutory footing, but, as things stand at the moment and we move towards the pathfinder projects, are you satisfied that you are able, if necessary, to call that process to a halt? What influence and power do you have to reassure the public?

***Dame Fiona Caldicott***: As far as the pathfinder stage of the development of care.data is concerned, I have a very clear remit from the Secretary of State for Health. I have to be satisfied that the conditions we have put to the care.data programme board, in order for any data to flow from general practices to the Health and Social Care Information Centre, are met. That piece of responsibility is very clear. We already have it under the Independent Information Governance Oversight Panel in relation to care.data, but it has been strengthened in the words around the national data guardian.

In terms of authority in other respects, this is to a large extent to do with building good working relationships. There is a clear remit in the terms of reference as drafted—they are still at draft stage—to work with the Information Commissioner's Office and the Care Quality Commission, because they do have statutory powers. There is an expectation that, if we encounter issues that we think are not in the public's interest, we are able to refer them, through partnership working, if you like, to whichever of those bodies is the most appropriate. There are some powers in terms of trying to influence. It is clear to me already that the CQC and the ICO are going to take that relationship seriously. We are setting up meetings to look at how the working together will operate and may well reach the need for a memorandum of understanding. While we are not a statutory body or person, there is a lot of goodwill in the system to ensure that we are able to advise where appropriate. There are strong links with the National Information Board, the new Information Governance Alliance and other bodies within the system. I feel confident going forward that because of the strengthening of the role, even though it is not statutory, more notice will be taken of what we have to say.

**Q633 Chair:** We will come later to the 27 points you raised, so I will not pursue that now.

***Tim Kelsey***: Perhaps I may make the point that, although it may not be statutory, the objective of the entire programme since we brought it to a halt, and subsequently when I became SRO, has been to co-produce at the most fundamental level in every direction both the design and culture. I am sure we will come to the cultural issue raised earlier. The

culture of the programme is fundamentally committed to a level of co-production and oversight on a scale and with a commitment that, frankly, I have not often seen in public service programmes.

Regardless of statutory authority, the programme board will proceed with this only if Dame Fiona is satisfied. The CMO—chief medical officer—whom we invited to the programme board to take an independent view, has passed on that responsibility to Dame Fiona as well, so it is a very fundamental part of the commitment. We have to be open, transparent and committed to getting this right. It may not be statutory, but we are bound by Fiona's position.

**Chair:** Thank you for clarifying that.

**Q634 Barbara Keeley:** This may not be a question you can answer. I do not see a reason for it not to be on a statutory footing. I understand the Minister has said it will be done at the first suitable legislative opportunity. We were chatting among ourselves before the panel started. We think that could be next week, because this Parliament has so little to do at the moment, apart from the meetings and hard work that we do on this Committee. As to the concerns highlighted in your report, there are two things. You tried to stop a disastrous leaflet going out last December/January. That would have been a very sensible thing to do because it was a disaster. We were told that it had already gone to the printers. There is also the point about cultural change. Dame Fiona, do you believe it would be right to put your role on a statutory footing?

***Dame Fiona Caldicott***: I do. Can I take this opportunity to say how much I welcome the support that is coming from the political parties? Initially, the suggestion came from members of the public and medConfidential. The support for that development has grown until the discussions on Mr Lefroy's Bill took place. I think both of the major parties support it. It would be very helpful. You could think of the February leaflet as a little bit of a low point or quite a bit of a low point.

**Q635 Barbara Keeley:** We thought that too.

***Dame Fiona Caldicott***: There was a lot of learning from that, but, as the year has gone on, as Mr Kelsey has said, there has been more acknowledgment that there are those of us within the system who are very concerned to get it right for patients. There has been closer working. None the less, I think there is an opportunity in the statutory nature of it. I certainly learned as chairman of the NIGB, for the 18 months that I did it, that it is possible to have all the key people in the room and for the work you do to be promulgated out to where it will be most useful and taken real notice of. I have had that experience, which leads me to think that this would be very welcome, given the developments that have taken place in information technology in recent years where the public are much more alert to the possible dangers to their information and want to know the answers, as you have already heard in the earlier session and in your previous hearings.

We are at a point where we cannot avoid strengthening the reassurance to the public that there is someone with a body supporting him or her, giving this issue of trust in the system and how data are safeguarded and appropriately used as much attention as it deserves, with

the people who are trying to implement change and do all of the things we want done in the interests of improving health and social care.

**Q636 David Tredinnick:** I want to talk to you about the basis for selecting the pathfinder areas. Can you give some indication of how this was done?

***Tim Kelsey***: By its nature, it is rather a complex programme. Let me give you some straight facts about the process. There was a panel for the selection of the pathfinders, which consisted of the RSGP, BMA, Healthwatch England and also a number of NHS England's voluntary sector partners, which is a group that NHS England has brought together. Subsequent to their independent selection of the pathfinders, after volunteering had taken place—so pathfinders volunteered—one of the criteria, going to the point about patient involvement, in order to be accepted, having already volunteered as a potential pathfinder, was that you had to have the assurance from your local Healthwatch that they felt properly engaged, and patient participation groups from GP practices in the pathfinders also had to give an assurance that they had been involved in the development of the proposal.

**Q637 Chair:** Mr Kelsey, can I clarify one point? Were people invited to volunteer, or was there a universal invitation to all CCGs to volunteer, because there is a difference? If you do not know that you could volunteer, it is different.

***Tim Kelsey***: We wanted this to be a very concentrated experiment in setting new standards for fair processing. We were approached, unexpectedly, by rather a large number of CCGs.

**Q638 Chair:** But did every CCG know it could volunteer, or were certain ones approached, tapped on the shoulder and told they should volunteer?

***Tim Kelsey***: No; we did not tap CCGs on the shoulder. I cannot tell you that every CCG knew. We announced our intention to run the pathfinders, but we were approached very quickly by quite a large number of them. So, in the end—

**Q639 Chair:** That is not a very clear answer. There is a difference between putting out a general notice saying, "We're looking for volunteers," and phoning up a selection whom you would quite like to be volunteers and saying, "Could you please apply?" Either it is open and everybody knows there is an opportunity to volunteer, or you have a group selected by a group of people who have decided they would like these people to volunteer. There is an important difference, surely.

***Tim Kelsey***: I agree. What actually happened was that a group of CCGs chairs were aware we were moving to this space, although we had not publicly announced it through things like the commissioning—

**Q640 Chair:** How were they aware? Did somebody phone them up? Did somebody make them aware? Clearly, there is a difference.

***Tim Kelsey***: It was very widely known among the commissioning community—

**Q641 Chair:** How was it widely known—by word of mouth?

***Tim Kelsey***: I will find out, but it was not—

**Q642 Rosie Cooper:** Tarot cards.

***Tim Kelsey***: No, no, no.

**Q643 Chair:** There is a difference, is there not, between approaching people and saying by phone call or e-mail, "We've got this opportunity for you to apply," to individual—

***Tim Kelsey***: I will investigate how it was done.

**Q644 Chair:** It would be helpful to know, because how the selection was made is of interest.

***Tim Kelsey***: I totally understand that. I will find out.

**Q645 Rosie Cooper:** Chair, this goes to the heart of where the distrust comes. Statements are made throughout these hearings, and when you test them they fall apart, like this. You cannot say they volunteered to do it. It falls apart because you do not then know the detail of whether they did or did not.

***Tim Kelsey***: They all volunteered and were then independently assessed by a group of independent people.

**Q646 Barbara Keeley:** But they self-selected.

***Tim Kelsey***: They self-selected.

**Q647 Barbara Keeley:** You did not go out and ask for volunteers. They self-selected themselves.

***Tim Kelsey***: That is correct.

**David Tredinnick:** Okay; shall we proceed, Chair?

**Chair:** Yes; let's move on.

**Q648 David Tredinnick:** So we have established that. Do you know how many of the practices in those areas will be taking part in the pathfinder project?

***Tim Kelsey***: At the moment, 80 practices in three pathfinder areas have said they want to participate. We anticipate it being significantly more, but it varies by different CCGs and how far they have got in their activity and conversations with different practices. In Blackburn with Darwen all GP practices are participating. I can provide figures for the current state of play in West Hampshire. It varies on a day-by-day basis, but as of today 80 practices have said they wish to participate.

**Q649 David Tredinnick:** Is there anything about this process that you would do differently now that you have been through it?

***Tim Kelsey***: For the pathfinder selection?

**Q650 David Tredinnick:** Yes. We have had one or two concerns raised this afternoon about selection, and I imagine you are going to write to us about that.

***Tim Kelsey***: Yes.

**Q651 David Tredinnick:** From what you know now, would you have done things differently at this stage?

***Tim Kelsey***: Well, no, I don't think so. The CCGs are not represented at the table here. It is a shame that the CCG chairs are not here, but the process of their selection was robust and independent, and as SRO I would not have changed it.

**David Tredinnick:** Thank you.

**Q652 Chair:** I do not know whether you can answer a question raised during the previous panel, which was whether or not the pathfinders will be paid. The last panel could not answer it. Are you able to say?

***Tim Kelsey***: I was at the back when you asked that question. We will provide the Committee with a note of the amount of money which may or may not be paid to pathfinders for material production and so on. They are not being paid as a CCG, but we have agreed to subsidise some of the costs of the evaluation. For example, we have Ipsos MORI running polls with the public, and we have a range of surveys with patient participation groups to ensure that Dame Fiona is able to evaluate the degree to which people were informed. We have agreed to bear those costs centrally, and I can provide an accounting for that.

**Q653 Rosie Cooper:** You said "some of the costs". Are you going to meet the costs, or some of them?

***Tim Kelsey***: Some of the costs.

**Q654 Rosie Cooper:** So patients in CCGs will be contributing roughly how much?

***Tim Kelsey***: GP practices have existing legal obligations, as we have discussed, to do certain types of fair processing. For example, we are not subsidising them to speak to their patients. We are subsidising aspects of this in order to test it. We are contributing to or paying for the cost of letters to go to each patient and the evaluation that surrounds that. We are also paying for other points of evaluation which we have agreed with the CCGs.

**Q655 Rosie Cooper:** While I appreciate that, can you give us any rough figures? What would a CCG be contributing to this?

***Tim Kelsey***: I cannot answer that question, but we will very rapidly come back to you with the CCGs' own estimates of the costs of the programme and how much of that cost is being met by the programme.

**Q656 Chair:** I have been asked to clarify something. The three are Blackburn with Darwen, West Hampshire and all of Leeds.

***Tim Kelsey***: Yes. There are seven CCGs in four geographic areas, so it is the three CCGs in Leeds; it is Blackburn with Darwen, West Hampshire and Somerset.

**Q657 Chair:** Which of these three pathfinder areas are the ones where so far you have 80 practices signed up?

***Tim Kelsey***: They are in the West Hampshire, Somerset and Blackburn with Darwen areas. Leeds is developing some proposals which it wants to test with its GPs first, so it has not yet started the recruitment process.

**Q658 Valerie Vaz:** I am a bit confused. You are running a pilot but you do not know what the costs are.

***Tim Kelsey***: I know what the costs of the central programme are. I don't know what the costs are—

**Q659 Valerie Vaz:** No. At the pathfinders you do not know what their costs are. You just said you would write to us and tell us about it, but surely you must have put a bid out to someone—the Secretary of State or NHS England—and said, "This is what the pathfinders are going to cost." What is the cost of that?

***Tim Kelsey***: Yes, I can give you that. I know what the cost to the programme is for the pathfinder phase.

**Q660 Valerie Vaz:** Presumably, it covers the letters.

***Tim Kelsey***: It does not cover all the costs such as the opportunity costs for training of GPs and the CCG.

**Q661 Valerie Vaz:** But why not? Presumably, it is a pathfinder and you must have a project in mind. You must have in mind the amount of money you want to spend on it. You are saying you are subsidising the CCGs. You must know how much it is going to cost.

***Tim Kelsey***: I do know. I know exactly how much it is going to cost for—

**Q662 Valerie Vaz:** But you just said you did not know.

***Tim Kelsey***: I thought I was being asked about the total cost to the local NHS of fair processing in relation to care.data. I can tell you the costs that are being provided by NHS England, but individual CCGs are additionally spending, or local GP practices are engaging in costed activity, in order to meet the fair processing requirement.

**Q663 Valerie Vaz:** Which you have just said you are subsidising.

***Tim Kelsey***: Not all of them, because for some of them it is a legal responsibility.

**Q664 Valerie Vaz:** Not all of them but some.

***Tim Kelsey***: Yes.

**Q665 Valerie Vaz:** So you must know what the costs are of the "some".

***Tim Kelsey***: Yes, I do know the costs of some.

**Q666 Valerie Vaz:** Why are you not doing it all, if you are asking them to do something? I just find this horrifying. Is that how NHS England operate? They do not know how much things cost.

***Tim Kelsey***: Okay, to be clear, I know how much the programme costs from the care.data perspective, but an individual GP has an existing legal responsibility to fair process consents or opt-outs with local patients. That is part of their existing responsibility, so when the care.data programme initiates we are not, as it were, recruiting staff to help them do that.

**Q667 Valerie Vaz:** I am talking about the pathfinders and the project you are trying to evaluate. You must know how much it is going to cost and how much you will subsidise people to find out this information, and how much the evaluation is going to cost. You must have said to someone in NHS England that the whole project is going to cost such and such. Who signs the cheque for that? Someone must have written that off or someone must be signing it off.

***Tim Kelsey***: Yes. We have a programme budget for care.data, and I can provide you with all the details of that; absolutely.

**Q668 Valerie Vaz:** And the pathfinders in particular, because that is what we are asking about.

***Tim Kelsey***: Yes, and the costs to—

**Q669 Valerie Vaz:** Mr Kelsey, there is a confusion about whether you are or are not subsidising. You say that you are helping some CCGs but then you are saying you are not really helping them; they are doing it themselves. You will pay for the postage but not something else; you are paying for the training but not other things. We need a bit of clarity, please.

***Tim Kelsey***: Sure; as I say, I will provide that.

**Q670 Rosie Cooper:** What would make this pathfinder project attractive to a CCG? You say that by osmosis they found out about it and are throwing themselves at your door to do it, and you are not paying for it all. It is going to be at some cost to them. What is it about the pathfinder process that would make a CCG want to be involved?

***Tim Kelsey***: Perhaps I may read a statement from Sarah Schofield, chairman of West Hampshire CCG. Her message to the Committee, understanding that that would be a legitimate question for it today, is: "Whilst the sharing of patient information across the NHS helps to ensure that the quality and safety of services is consistent and provides valuable insight on diseases and conditions, it is essential that this is done in an appropriate and secure way. We are therefore extremely pleased to have the opportunity to work with our patients to test communications on care.data and ensure GPs are equipped to manage this locally and are able to support patients with making informed choices."

**Q671 Rosie Cooper:** She would prefer to do that rather than put money into some procedure or other that patients could direct. What would make a CCG want to contribute money to your project? If you told them they were going to do it, I could understand. They are volunteering to be part of it in principle, but they are not benefiting; you are suggesting that it is going to cost them, so why would they do it?

***Tim Kelsey***: They very much hope to benefit, because as commissioners of services—

**Q672 Rosie Cooper:** But all the other CCGs who are not pathfinders and are not doing it will get the benefit of whatever comes out of this and it will not have cost them any money, time, effort or whatever. I cannot understand what the hook is that would attract them to it.

***Tim Kelsey***: Hopefully, it was communicated to them to such a degree. Perhaps the Committee needs to sit down with the CCG chairs, but the truth is that commissioners and GPs want to get data to flow in the NHS safely and as quickly as possible, in a sense, to enable them to make better decisions to improve care for their patients. These pathfinders have volunteered and have self-selected; they have gone through a relatively arduous

process, so we can defend the selection of the CCGs, in order to educate themselves as to how best this should happen. It is an experiment. It is not my project, nor is it NHS England's project; it is a project of seven CCGs and four regions in which 250 GP practices want to learn how best to do this, and meet the new standard Dame Fiona has set in relation to fair processing for patients.

**Q673 Chair:** The impression from the letter you have read out is that they want to do it for the greater good.

***Tim Kelsey***: Yes.

**Q674 Barbara Keeley:** A point of clarity is needed. You said you were not aware how many GP practices in Leeds wanted to opt in or not opt out because it is developing its own proposals that it wants to test. Is that something extra?

***Tim Kelsey***: I said at the beginning that the premise behind the redesign of the entire programme has been around co-production and co-creation with local front-line services. Each of the CCGs has developed variations with different communities—some are rural; some are urban—on the kind of strategy they think would be appropriate as GPs to meet their obligations, with support from NHS England. As a city, Leeds wants to test some digital solutions for giving people granular opportunities to opt out, so it is developing those proposals with the GP community. It has not yet got to the point where it is recruiting GPs to test out those proposals. It will do so over the next few weeks, and we will be very happy to keep you updated on the process of their selection.

**Q675 Barbara Keeley:** The GP practices in Leeds and elsewhere can opt out, if they want to.

***Tim Kelsey***: Yes; it is entirely voluntary.

**Q676 Barbara Keeley:** That was not clear. There was a stage in all of this when it seemed that pressure would be put on GP practices if they did try to opt out.

***Tim Kelsey***: To be clear, in the pathfinder stage this is a voluntary exercise to test the new approach to communicating the opt-out rights to patients. GPs are not being forced to participate at all.

**Q677 Barbara Keeley:** The question I have—I do not know how easy it is to answer it—is precisely what you want to learn from the pathfinders. I must have mentioned before in all of this that I used to work in IT. We had leading-edge customers who would always want to test things. It does not test something absolutely where you have really keen people who self-select. That is not the acid test, is it, because for the ones who do not want to be first but last in the queue and are not very keen on this it is not going to work as well? I am sure you will learn something from them, but I have to say I am uncomfortable with that process. I would be more comfortable with it if you had offered other areas chances, because there is

always a danger in working only with the leading edge. Can you tell us what you do want to learn from the pathfinders?

***Tim Kelsey***: This is why I really welcome the report from Dame Fiona. That set out some very clear standards that need to be achieved by the local NHS properly to explain both the opt-out rights we are providing to patients and the learning we need to get from the first pathfinder phase. There may be more. There is no artificial deadline for national roll-out. We just do not know what happens next, but this pathfinder phase is intended to test the degree to which Dame Fiona and her colleagues in IIGOP feel that we are achieving, have achieved, or need to do more to achieve, a proper standard of fair processing. Those are the 27 recommendations, and they need to be achieved and independently assessed. That is the purpose of the pathfinder stage.

**Q678 Barbara Keeley:** Is the plan to use the data extracted in any way in the pathfinders in planning health and social care, or are they simply testing the process? Is it just communications, the leaflet, opt-out, how it works with GPs and so on?

***Tim Kelsey***: There are two parts. The first is, indeed, to test the quality of fair processing against the standards set by Dame Fiona. The second part, which the care.data advisory group and others are very keen we also do—Sam mentioned this in his earlier evidence—is that in the extraction of the data from this limited number of practices, which will be held in a totally locked-down secure environment, as I think you are aware, we should run some analytics over them to demonstrate there is actual value in the data as well. Therefore, on the one hand, there is evaluation of fair processing, but, on the other hand, we have already constructed an independent expert group who will look at the outputs of the data analysis and confirm whether or not the hypothesis, or evidence that says linking the data can support improvements in the quality of local service, is to some extent evidenced.

**Q679 Barbara Keeley:** Is it only for that, or is there any intention or plan to get into commercial end users?

***Tim Kelsey***: No.

**Q680 Barbara Keeley:** Absolutely nothing.

***Tim Kelsey***: No.

**Q681 Barbara Keeley:** How is that guaranteed?

***Tim Kelsey***: It is guaranteed because the data will be held. There will be no access to data that flow from the pathfinder practices, other than in the secure data environment. There will be researchers, who are identified already, I think, from only three organisations: NHS England; the Health and Social Care Information Centre; and PHE—Public Health England.

**Q682 Rosie Cooper:** In previous comments we have talked about attempts to communicate with patients being a low point. I suppose that was where I came into it. Have the communications with patients for the pathfinder areas been finalised? Are they going to be different in those different areas?

***Tim Kelsey***: I was reassured to hear some of the comments made earlier. We feel we have done an enormous amount of co-production with GPs, voluntary groups, Healthwatch and various others to develop the materials. To get it on the record, more than 3,000 people in 180 workshops across the country have helped us to develop these areas. In the CCG areas that are pathfinders, they have also been running their own independent engagement with voluntary organisations, patient advocate groups and so on. Collectively, we feel that with the CCG partners we have got the materials to a place which is unrecognisably better than the previous place we were in, but part of the pathfinder test will be to establish that that is measurably the case. If we need to improve them further, we will do so.

**Q683 Rosie Cooper:** Short-circuiting it, a version of that answer is that, yes, you have developed it and you have got to them. Has the Independent Information Governance Oversight Panel seen those proposed communications, and what is its view?

***Dame Fiona Caldicott***: We saw some back in November/December, but we understand that even further refinement is happening. We have not yet seen the further refinement.

**Q684 Rosie Cooper:** What was your opinion of it?

***Dame Fiona Caldicott***: It was certainly better and clearer, but still lacking the sort of clarity we would like to see. It is quite a complicated thing to explain to the average member of the public, dare I say? This is not simple; it is not quite like explaining, for instance, the issue of consent to a procedure; it is more complex than that. There is quite a challenge facing those who are preparing the material to get it absolutely clear what the patients are being asked to agree to or opt out of. There has certainly been progress through the meetings that Mr Kelsey describes. What we saw before Christmas was better, but we think it could be better still.

***Tim Kelsey***: I hope that over time this Committee will recognise the steps we have taken. One particular aspect of this, as well as the broader issue, was accessibility for disabled groups. I have here a list, which perhaps I can make available subsequently, of all the organisations that have been involved in helping us shape the materials for specific interest groups and constituencies in order that we can help GPs to discharge the responsibility we have to the entire community, not just to those who are able-bodied or able to read.

**Q685 Rosie Cooper:** It is a really difficult thing. I opted out, as you know. I totally approve of this project. I am absolutely 100% behind the principles, but the way it has been handled is an absolute disgrace. I do not need to go into that again. I have opted out. When I looked at medConfidential's advice on the various levels of opting out and our exchanges at previous Committee hearings, it absolutely confirmed that I did do that. I would like to go on and ask what has been done to make the process of registering an objection transparent and straightforward. Are you trying different forms of wording?

***Tim Kelsey***: Yes.

**Q686 Rosie Cooper:** I would then like to go on to the impact of that after.

***Tim Kelsey***: We have done an enormous amount of testing of the wording for the opt-out. I mentioned that as well. The individual CCGs have tested it with all sorts of constituents. We are now very close to resolving a form of words which appears to be both very accessible and explains simply what the opt-out now is. It was not just a matter of communication; it was also a matter of fundamentally changing what the opt-out meant. In the previous situation with this programme there were two layers of opt-out. There is now just one opt-out, and the opt-out means that no identifiable data will leave the GP practice at all and transfer to the information centre, which makes the job of explaining it much more straightforward. That is a very important part of the evaluation of the pathfinder phase in relation to fair processing, where people felt they did understand and were informed by the form of words we used, and also simplification of the opt-out that has now been decided upon.

**Q687 Rosie Cooper:** That is very good news and takes the onion down to its most meaningful level. It is now one level of opt-out. What does that actually mean for my care and treatment? In previous panels you have suggested that the GP would not get paid; he would not be part of reviewing screening programmes. If I opt out, what will happen to my care?

***Tim Kelsey***: To be absolutely clear, there will be no impact at all upon your eligibility or entitlement to treatment on the NHS. In so far as clinicians are exchanging data for that treatment, this has no impact on it at all, so direct care is in no way affected if you choose to opt out of care.data at all. The opt-out of care.data relates to the secondary use, as we sometimes call it, of data for analysis to support the improvement of quality in local services and, as Nicola said, benefits in research territories.

The chief medical officer would argue—many others do—that in the longer term, if large numbers of people opt out, it will impact on the ability of the NHS to improve the quality of care provided, and in that sense it could affect your care in the future, but it in no way affects the treatment you will receive on the NHS if you choose to opt out.

**Q688 Rosie Cooper:** That is really very good news. Are you consulting patients before you roll out these plans in the pathfinder areas? Are patients going to be involved sooner rather than later?

***Tim Kelsey***: The CCGs and local GPs are working as local consortiums with a large number of different sorts of voluntary organisations. To some extent it is dependent on where they are, but all of them are working with their local Healthwatch. One criterion for the selection of CCGs was that there was a good, active local Healthwatch that could properly represent the views of local communities. Patients are fundamentally involved in the way the process has been designed.

**Q689 Rosie Cooper:** Healthwatch is new, and I would not have thought you could say it has a great reach into communities right now.

***Tim Kelsey***: I think it varies. Some are very effective, and my own experience of the pathfinder areas and Healthwatches involved there is that both are very active. People are working under considerable resource constraints, but they are very active and committed to try to get this right. I think that the partnership that has been developed in response to the decision to stop the programme last year has been a very good demonstration of the way in which local health communities are getting together for the right reasons.

**Q690 Rosie Cooper:** Could you explain to me exactly what that patient engagement via Healthwatch means? It is a nice flowing sentence, but what is actually going on on the ground?

***Tim Kelsey***: A lot. I am wondering whether or not we should arrange for the Committee to come and see a pathfinder and talk directly to those involved. They are very active. I am just trying to find the right page for West Hampshire.

***Dame Fiona Caldicott***: While Tim is doing that, last autumn I had a meeting in our locality, not a pathfinder locality, to discuss the care.data programme. Healthwatch for Oxfordshire was very active in getting together 200 of the local public to come and debate the issues. As is being said, there is tremendous variation, and if it is an active team running Healthwatch it can be done.

**Q691 Rosie Cooper:** Absolutely. That is the reason for the follow-up question to find out what is going on and what has happened in those areas.

***Tim Kelsey***: In West Hampshire CCG there have been 16 meetings since October involving all 51 GP practices, patient participation groups, Healthwatch, the local medical committee, CCG boards and internal staff in order explicitly to develop the materials and strategy. It has been a consensus-based approach.

**Q692 Rosie Cooper:** Mr Kelsey, they are all the usual suspects. Where is the public?

***Tim Kelsey***: The patient participation groups for each GP practice are there to represent the public. Those are the independent bodies which all practices now have to have. It is perhaps a question for the CCGs in a way.

**Q693 Rosie Cooper:** It is self-selecting again.

***Tim Kelsey***: I do not think so. Most patient participation groups are relatively representative of the local community.

**Q694 Rosie Cooper:** It might be one or two people. I am engaged in health; I was chair of a hospital and all the rest of it. I could not tell you who the patient representatives are

at my GP practices. They do not communicate with me. I am a member of the public. How do I know?

***Tim Kelsey***: All I can say is that when I have been to practices and have engaged with patient participation groups, who are contractually required to exist under the GP contract, they have been very robust.

**Q695 Rosie Cooper:** The point I am making is that you are talking to the health population; you are not going out there to real people who are not engaged in health and are not sitting there worrying about health matters day in, day out. These are the people—98% of the population—you are missing altogether.

***Tim Kelsey***: Oh I see; okay. Outside of those particular local engagement exercises, we have been supporting a whole range of national exercises that have brought together about 3,000 people from all walks of life. They are absolutely the general public. I went to an open meeting with Sam's colleague, Phil Booth, from medConfidential in Manchester for the public to debate some of these issues. It was a pretty robust conversation, as you can imagine. People are genuinely interested in understanding what we have done, holding us to account for what went wrong initially. My experience has been that of a pretty open and frank level of debate. We have very actively tried to make sure that the general public are engaged. In addition to those meetings, the care.data advisory group has hosted three open events on its own initiative, which have involved more than 200 members of the public, in Peterborough, London and Manchester. We have really tried, and the net result is that the people who are helpfully giving us constructive challenge, like the advisory group, the programme board and Dame Fiona, are, I hope, beginning to feel we are making some progress, though yet more needs to be made.

**Q696 Chair:** Mr Kelsey, could I return to a point you made earlier about opting-out not affecting your direct care? Of course, opting-out of some types of type 2 data could affect your care if it means you are not going to be approached to be offered, say, bowel screening, or you will not have the opportunity to take part in e-prescribing. There are some implications. Will that be made very clear to people? Some concerns have been raised with this Committee in advance of the hearing about type 2 data of patients who have opted out leaving the Health and Social Care Information Centre. There are quite complex reasons behind that. I know you will now have seen the letter from the Health and Social Care Information Centre. Would both you and Dame Fiona like to comment on that? I know that it is quite a complex area, but it is an important one.

**Rosie Cooper:** Through you, Chair, I put that to you earlier and you said it would not interfere with it.

***Tim Kelsey***: I can only really speak for the care.data programme, to be honest. In the care.data programme there is now just one type of objection. Data do not leave the GP practice if you raise that objection. That is the opt-out which will be offered and tested in the pathfinder areas. To be absolutely honest, although I have seen the letter, I am not that familiar with the arrangements HSCIC have for allowing people to opt out of data that they store.

**Rosie Cooper:** But you should not give assurances if it is not 100%, and that is why we are in this mess. When you say something categorically, you should say, "I mean it 100%."

**Q697 Chair:** With respect, Rosie, there are two issues here. One of them which has been raised with us is about whether at the moment the data of people who thought they had opted out are leaving the Health and Social Care Information Centre, or whether people may not have realised that they had opted out of being approached to be offered bowel screening. It would be nice if you could clear up the situation on where we are now. Are data related to people who thought they had opted out leaving, and what is happening with those people where data are not leaving but they were unaware it meant they were not being approached for bowel screening? There is a separate issue on the future situation.

***Dame Fiona Caldicott***: Perhaps I can help. This is a letter from the chairman of the information centre, which is only of yesterday's date. I do not think everyone has had the chance to read it. As I understand it from Mr Manning, in the case of type 2 objections, which have already been lodged with GP practices, the care.data programme board decided in November that the HSCIC should put in place an appropriate process. In the letter they found that about 100 patients had already made that objection, and because of the implications you have just outlined they are writing to all of them to discuss with them the effects of that opt-out and what they want to do in response to it[1].

**Q698 Chair:** In other words, it is not leaving but they might have been unaware that that would have implications for them.

***Dame Fiona Caldicott***: Exactly. They may wish to make a different sort of decision, but it is something that has only just been brought to your attention or ours in the last 24 hours, so it is quite difficult to take it further than that.

**Q699 Chair:** As far as you are aware, as the person who is likely to be entrusted with keeping an eye on the system, are you confident that data are not leaving the Health and Social Care Information Centre on behalf of people who thought they had said they did not want their data being shared?

***Dame Fiona Caldicott***: I am confident, on the basis of what I have been told in the very recent past in relation to the question.

**Q700 Chair:** So, for those who have raised it with the Committee, the answer is that it is not currently leaving and being shared.

***Dame Fiona Caldicott***: No.

---

[1] 'On further consideration of Mr Manning's letter after the hearing, I learned that the 100 or so patients to whom I referred in answer to the Chairman's Qs 697 and 701, had written to the HSCIC by completing a 'Preventing the Use of' form. That requests that the HSCIC does not use any information held about the patient for health and / or social care purposes other than direct care. These objections are being acted on.' *Correction made by Dame Fiona Caldicott on 2 February 2015*

**Q701 Chair:** But for those where that could have implications they are unaware of, they are being written to in order to explain the implications.

***Dame Fiona Caldicott***: About 100 people.

**Q702 Chair:** Moving to the separate point, which is the future of the pathfinders, you can give us a complete reassurance that those who decide to opt out will still have access, for example, to being approached to be offered screening; it will not impact on their ability to be included in screening programmes.

***Tim Kelsey***: No; it will not have that impact.

**Chair:** Thank you. Those are the issues I wanted to clear up.

**Q703 Barbara Keeley:** Could I just clarify this? Referring to the figure of 100, is that 100 in the pathfinder areas or 100 in the whole country?

***Dame Fiona Caldicott***: As I understand the letter, it is all together.

**Q704 Chair:** Sometimes people approach the Committee and say they believe their data are leaving. If people say to us they believe data are leaving the Health and Social Care Information Centre without consent, clearly that is a really serious allegation. I want to be sure from you, Dame Fiona, that we can say you have looked at the issue and you do not believe that is the case.

***Dame Fiona Caldicott***: That is my understanding from what I have heard from the information centre, Chair.

**Q705 Valerie Vaz:** Dame Fiona, what are the implications of that?

***Dame Fiona Caldicott***: There is an issue about the sorts of interventions Dr Wollaston has mentioned, such as bowel screening, aspects of medication prescribing and so on. Although the assertion has been made in the past that opting out—type 1 and type 2 as they were known—would have no implications for direct care, it looks as if there are implications for this small group of patients. That is what has just come to light. That is why there needs to be an—

**Q706 Valerie Vaz:** I want to be clear what those implications are.

***Dame Fiona Caldicott***: That is to do with these particular aspects of what can be considered to be direct care.

**Q707 Valerie Vaz:** I know it is nothing to do with you, but the letter that goes out is quite important, is it not?

***Dame Fiona Caldicott***: Absolutely.

**Q708 Valerie Vaz:** I do not know whether you get to see that letter.
***Dame Fiona Caldicott***: I hope I will. I am meeting the chairman on Friday and I will ask to see the letter.

**Q709 Chair:** We would expect that you would see it.
***Dame Fiona Caldicott***: Yes.

**Q710 Valerie Vaz:** Perhaps you could ask them to send one to us.
***Dame Fiona Caldicott***: Absolutely.

**Q711 Valerie Vaz:** Thank you very much. I want to move to your role as guardian of all this. You were appointed by the Secretary of State very much on the basis of the good work you had done previously. What was your job description?
***Dame Fiona Caldicott***: I haven't got that yet. We have been discussing it. I have it written in broad terms: my role in relation to the public, and preserving trust in how the data are to be safeguarded and shared appropriately. It is written quite generally, and we are now working on the job description, and also the fact that the Independent Information Governance Oversight Panel will in due course become an advisory panel to me as national data guardian. Clearly, you cannot do all these things as a single person; you need to have experts. So that is work in progress.

**Q712 Valerie Vaz:** I wish I could get jobs like that where you can write your own job description and you are just given the job.
***Dame Fiona Caldicott***: Well, yes, I am contributing.

**Q713 Valerie Vaz:** You have an absolutely fantastic CV anyway, but I wanted to clarify how that came about. I am slightly confused. Are you the guardian of the data that leaves HSCIC, and are you also the guardian just for care.data?
***Dame Fiona Caldicott***: I am the guardian of data generally, so it goes well beyond care.data, whether it is health and/or social care data that the person gives to those they are consulting and who are then responsible for it and its use. It is all of those data, so it is quite a big remit.

**Q714 Valerie Vaz:** Yes. You mentioned one panel, which I think you said was already formed. Are there people on the panel; if so, how many?

***Dame Fiona Caldicott***: I had a small panel in my previous role. I think it has eight or nine members, the names of whom you can find at the back of our annual report. We think we need a slightly larger one. We lost our member representing local government, who had to resign for personal reasons, so we have some gaps at the moment. We are building the panel to make sure that all of the elements of the health and social care system are represented, because it is necessary to have that input from people who really understand the detail of how these things relate to one another. They have not been on the previous panel, and in the future, because of our independence, they will not be representing anyone, but inevitably they will come from particular groups of professionals and/or the public. We are thinking about that at the moment.

**Q715 Valerie Vaz:** You are gauging the expertise that you need on this panel.
***Dame Fiona Caldicott***: Exactly.

**Q716 Valerie Vaz:** Do you have a secretariat, or is that what you are talking about when you refer to resources?
***Dame Fiona Caldicott***: When I talk about resource, it is largely people who will help us do the work, organise meetings, prepare papers and help us all get to where we should be to come and do the work. At the moment it is a tiny team, and we will need more people to fulfil the brief we have been given.

**Q717 Valerie Vaz:** It sounds like it. Are they coming from NHS England or the Department of Health at the minute? Where are they coming from?
***Dame Fiona Caldicott***: There is an independent consultant in the role of director, and there are one or two people who have been either in the information centre or other parts of the existing system.

**Q718 Valerie Vaz:** You might have been here earlier when Professor Mathers talked about six committees.
***Dame Fiona Caldicott***: Yes, I was.

**Q719 Valerie Vaz:** How does it all fit in with what you do and what you have been tasked to do?
***Dame Fiona Caldicott***: We could produce a very nice diagram. One of the things that has been very reassuring in the last few months is the report of the National Information Board which shows how the parts of the system relate to one another. We are at the right-hand end of page with an assurance role, and there is the strategic developmental left-hand side of the page, which is NIB and information governance. I cannot remember what IGOG stands for now. That is under the aegis of Mr Cavendish and Mr Kelsey. In the middle, there is a group of people like the Information Governance Alliance, which is producing guidance for the system. Once they have been given a task, such as producing a good

glossary that we can all sign up to and agree means the same things to everyone, they will check it with us for assurance, but in the end that will be a joint production between, if you like, the three arms. The strategic group commissions work; the middle group does some work; and we are involved in the iteration of that to get it to a state where we can say, "Yes, you can now have the imprimatur of the national data guardian," and then it can go out to the system.

One of the things being worked on at the moment is a simple guide to information sharing, which I know Ministers are very concerned goes out to front-line staff. There has been a reluctance to share because of the penalties the Information Commissioner has, rightly, placed in the context of breaches. That is one of the issues of culture which came up earlier. We found in our review that people have become very anxious about sharing information because of the fines that have been put in place in the past. There has never been a fine for sharing data inappropriately, so it feels as if the balance is a little bit out of kilter. It is that sort of issue.

**Q720 Valerie Vaz:** In terms of the decisions you will be making, is it you on your own? Do you get reports from these different arms? Do you discuss it with your panel?

***Dame Fiona Caldicott***: Some of these things are very difficult to make judgments about on your own, however expert you are. It is a very complicated field. Over the last year or two on many occasions I have had to turn to colleagues, be they from general practice, social care or public health. Perhaps a group of us discuss an issue to see what it looks like in terms of where we are now and where we need to be. If you look at the reports we have written, you can see that they are based on a lot of consultation and debate. This is not an exact science at the moment—I do not know whether it ever will be—because the system changes, but we do our best to try to be up to date and current in supporting best practice, and I think that shows through in the way we have worked.

**Q721 Valerie Vaz:** You report directly to the Secretary of State.

***Dame Fiona Caldicott***: Exactly.

**Q722 Valerie Vaz:** For example, is a certificate of destruction of data something in which you would be involved? Are you the one who needs to be assured? If, for example, HSCIC have said they have deleted data, are you the one who needs to be reassured about that?

***Dame Fiona Caldicott:*** Yes.

**Q723 Valerie Vaz:** Do you sign off the certificate of destruction?

***Dame Fiona Caldicott***: Not that, but it is a good question and perhaps one we should address as we think about our broader remit. Where there are issues about which the public have concern—for instance, the destruction of data when it should no longer be retained for its original justifiable purpose—maybe we need to look at that system. That is

an example of what we will be taking on board as we have more resources to fulfil the role.

**Q724 Valerie Vaz:** At the minute who is doing that, and do they need to report anything to you about whether data have been deleted?

***Dame Fiona Caldicott***: As I understand it, that would be a role within HSCIC. They do not report it to us, although there is now quite a lot on their portal about how they address that, which is public information. It is available, but it does not come through our group.

**Q725 Valerie Vaz:** If people have concerns about their data, are you the best person to write to within the NHS?

***Dame Fiona Caldicott***: Goodness—no, not really. It depends on where their concern is located. I did not say in my introduction that my day job, if you like, is that I chair a large hospital teaching trust in the centre of England. If a concern arose about data in relation to our trust practices, I would expect that to come up through the governance arrangement within the provider unit. We may have to report it to the ICO because there is a breach, for instance, but I hope they would not start with me as the national data guardian because I would never be able to open my inbox, frankly. There has to be a system of issues coming up through our existing structures. I hope we will hear from members of the public—we have already had some in the last few months—when they feel they have exhausted all the things that are publicised about bringing forward complaints or concerns about information. We would look at whether we are the best people to try to address it. We had a recent example where it was a matter for the Information Commissioner's Office. We have had a friendly exchange about that, and it is being addressed there. We are going to have to learn how to relate under the new guidance with existing parts of the system. That will be a learning process, but we need to build very constructive working relationships.

**Q726 Valerie Vaz:** When do you see your resource group, job description and remit all in place?

***Dame Fiona Caldicott***: I hope not too long. It may be that once we are into a period of purdah some of this is slowed down, but I hope we can get a lot done before that happens, and not later than the early summer.

**Q727 Chair:** It is rather timely that our report about complaints and raising concerns is being published today. People often do not know where to go in the system to complain. We have recommended a single gateway for just this kind of thing. Where do I take my concern about my personal data? That illustrates the point that it is not clear to anybody at times where issues are dealt with.

***Dame Fiona Caldicott***: We are very much looking forward as part of this development to having a website on which we can put a lot of information of that kind. If this is a problem with your local trust or surgery, you start there and these are the steps you can take if you

are not content. We need to be much more public-facing in helping people find their route through what is a very complicated system.

**Q728 Barbara Keeley:** To come to the 27 questions for the care.data programme board, about which you need to be satisfied before you proceed, the earlier panel thought they were good ones. If we look at Q1, which is, "How do I know my data are safe? How it will be shared, with whom and in what form, and for how long held?" that is the absolute crux of the matter, because it is the past issues we have explored in three sessions in this Committee related to things like data sharing and data reuse agreements. Effectively, the NHS and HSCIC lost control of data. We had examples where things were exported to the cloud by a user in the United States; a company said that even with de-identified data they could link patient episodes and seemingly get round the fact it was meant to be anonymised data; there was lots of concern about commercial uses—the ones I mentioned earlier—insurance company uses, actuarial uses and a comparison website. These are things people never signed up for. You talked about people's concern. I still have a fear about this. What we have in front of us is starting to look better, but what lies beyond it? We have talked about the secure data facility and that usage. How do people know once they have signed up for this in a pathfinder, or they do not opt out, that we do not go back to commercial data uses whereby, in the end, the organisation does not know who the end user is? It is not use by research organisations, the NHS or universities, that people objected to; it is the other uses.

You can create this careful bubble round the pilot, but I still have a concern about what lies beyond that. You can say to people, "This is what we are going to do, and this is what you do in the pilots," and everybody feels happy, and then their data have gone. At the last session Kingsley Manning and Sir Nick Partridge sat before us and admitted that the data had gone, even that they had no authority to tell a commercial organisation to delete it. We have had that in the past. How can you be assured, with those very sensible questions, that it will not run out of control again?

***Dame Fiona Caldicott***: As I understand it, the sorts of problems that you discussed with Mr Manning and his team were to do with the previous incarnation of the information centre, as opposed to the new Health and Social Care Information Centre. I think the reassurance comes within the way in which the Care Act has been drafted and the sections of it which talk about the use of data for health and social care purposes. There is now a very clear expectation that the end user can use data only for those purposes.

**Q729 Barbara Keeley:** But there are no regulations. We were assured at the meeting with Kingsley Manning last July that there would be regulations in September. We are now told they might come in February for operation in the autumn, so effectively the processes that relate to signing up the companies. We have had a letter from HSCIC. They are still talking to the same people who had data that ran out of control, and in some cases they are reapplying. How can you, with these very sensible questions, which are the right ones, be assured when there is another arm not operating under regulations passed by Parliament—the regulatory position is very much out of order—and signing people up when it is not at all clear on what basis they are doing that? We do not know; this Committee cannot check.

***Dame Fiona Caldicott***: We have to ask the questions once the Act is in place and make sure that the way in which it is written and the regulations, notes and all the things that go

with it make absolutely clear that these things must not happen and, if they do, there will be sanctions. As I understand it, that is still being drafted.

**Q730 Barbara Keeley:** But that is concerning. I have to tell you that as of today we are concerned to find that out. We have not got long in Parliament. The process, the forms we have been sent and all of this is going on, yet there are not proper regulations around them. In terms of where data are stored, in what form and for how long it is held and by whom, can you be sure that beyond the secure data facility we will not end up in a situation where companies have things on their PCs, or end up in the cloud in the United States? Can we be sure of that?

***Dame Fiona Caldicott***: Sitting here today, I cannot be, but you raise a series of very important questions which we will have to make sure we can address through our new role. If the Committee can make some comment on what it would like to see in the regulations relating to this, that would be really helpful.

**Q731 Barbara Keeley:** I am sure we could.

***Dame Fiona Caldicott***: Part of the difficulty is the rate at which work can be done. Members of the public are clearly very concerned about that, and it is a very good aspect where we would like to see those regulations drafted for all of us to comment on as quickly as possible.

**Q732 Barbara Keeley:** I am sure we could do that. Another of your questions was about what data will be extracted. I raised this point earlier. As a member of this Committee, I was concerned that students were accessing GPs' handwritten notes, which is possibly where patients have shared their most sensitive feelings and thoughts with a GP. Can your pathfinders or other patients be assured that we will stick with coded data and there will not be use of GP records of that very sensitive information, as happened in the past, without proper authorisation?

***Dame Fiona Caldicott***: As I understand it, that is absolutely the case. That would be breaking rules, and it is not going to happen.

***Tim Kelsey***: That is absolutely not going to happen. The GP practices that have volunteered are very conscious of it. We will very shortly be sending the responses to those CCGs and the programme board to Dame Fiona's standards. We have collectively looked at them very carefully. The CCG practices are completely committed to meeting the standards that have been set, which do not in any way, shape or form condone that kind of behaviour.

**Q733 Barbara Keeley:** Can we be assured that what was happening has stopped? Has the project involving students accessing GPs' handwritten records stopped?

***Tim Kelsey***: I am not familiar with that.

**Q734 Barbara Keeley:** We raised it in a previous session. We can let you know what it is, but we need an assurance that it has stopped.

***Dame Fiona Caldicott***: As far as I know, that is not happening because no data are leaving GP practices at the moment.

***Tim Kelsey***: I do not think it was at care.data.

***Dame Fiona Caldicott***: Not at care.data.

**Q735 Barbara Keeley:** In the letter that we got from HSCIC there was further discussion about this issue. HSCIC were not able to stop and insist on data being deleted. My colleague Valerie Vaz has already asked about data deletions. We have been told that the actuarial company Milliman is trying to apply to continue its data-sharing agreement. It seems to me we are at a point where, if it is not approved by the data access advisory group and it is not in place by May, it will need to destroy the data held. That gets round HSCIC's legal problem. It seems, certainly to me and maybe to other members, that that is the outcome the public would want to see. Is this not the point at which to grasp the nettle and say, "Well, they won't do it when we ask them? So let's allow their agreement to lapse and we will look at the future"? People are still very unhappy that 13 million HES records went out to an actuarial company. It should never have happened. I understand that HSCIC did not have the power to stop it, but the power is now in their hands to do it. That would seem to be a very wise thing to do.

***Dame Fiona Caldicott***: Yes.

**Q736 Chair:** Is that what you will be recommending?

***Dame Fiona Caldicott***: Yes.

**Q737 Chair:** Can I come to the issue of regulations? We know there was a consultation last summer on the data collection, processing and release, but the results of the consultation or the regulation wording have not been published. Can you give us any update on that? Have you been given any new information about where we are in that process? I understand you have made it clear that the pathfinders cannot go ahead until that is in place.

***Dame Fiona Caldicott***: Are we talking now about the regulations to do with safe havens?

**Chair:** Yes.

***Dame Fiona Caldicott***: As I understand it, there was a wide range of responses from "There should be only one" through to "There can be 50". There has been a lot of thought about whether a solution could be put in place to meet the generality of responses in advance of sorting out what it is that commissioners need to fulfil their role. The NIB paper refers to the fact that, increasingly, any identified data should go only with the consent of the individual, but it is taking time to work that through. I think it is likely that there will be some sort of statement before long—I believe within February—which gives an indication of the response to the consultation.

**Q738 Chair:** Are you yourself clear that you will not be authorising the pathfinders to go ahead until all of that is in place?

***Dame Fiona Caldicott***: Absolutely, as far as the pathfinders are concerned. That is why this report is so important. Mr Kelsey knows what we expect. We have asked the questions, set the tests and we may want to look at the evidence. We are not just going to accept, "We've done that." We are looking forward to the responses.

**Q739 Chair:** The public can be satisfied that you are on the case, if you like, and this will not be going ahead until then.

***Dame Fiona Caldicott***: Absolutely.

**Q740 Chair:** Turning to sanctions and financial penalties that have been referred to earlier, is it your view that there should also be criminal sanctions, including the option of custodial sentences, for those who maliciously try to re-identify or use data?

***Dame Fiona Caldicott***: I can see why people think that is a good idea. My hesitation in saying it is a very good idea is about the impact of the information commissioner's sanctions on the culture of health and social care. There have been some very large fines. I know money is not important to big corporate organisations, but within the health service those fines have made a real difference to some of the organisations that had big fines to pay. I would argue it has had an even more important effect on the attitude of people to the question of sharing information. I am rather ambivalent about it. I can see why people might want such extreme sanctions. In the end, Parliament will have to decide whether that is appropriate, but I worry that it will have quite an adverse effect on people's confidence to act in the patient's interests when it comes to sharing information.

**Q741 Chair:** You are worried about the unintended consequences.

***Dame Fiona Caldicott***: I am, but that is not to say I could not be persuaded, particularly on the advice of lawyers, that in the end this thing has to be there, even if it is never needed to be used, to achieve the ends Parliament wants.

***Tim Kelsey***: As the Committee knows from previous conversations, I have been a campaigner for transparency for many years in public services. It is inevitable that we will move to a custodial sentence for deliberate re-identification. That is an issue I have raised. It would be helpful to some extent, bearing in mind what Dame Fiona said about a careful investigation of how that could be constructed without the promotion of unexpected consequences. I do not see how, in a society that is becoming as digital as we are and as public services grasp the opportunities, as well as the challenge of that, we do not move to that position over time.

If I may clarify an earlier point for the record, the programme board for care.data has absolutely agreed that the CAG regulations need to have been approved before the programme continues, but the accredited safe haven regulations we have just been talking about are not relevant to care.data because we are using the information centre as the safe

haven. There are two families of regulation, and the CAG regulations need to be laid before Parliament before we can continue. That is a given.

**Q742 Chair:** Thank you for clarifying that important difference. Perhaps I may pick up a couple of points raised by the previous panel, which I think are important ones. The point about delays to research is quite worrying. Is that something that concerns both of you? Is it something you are looking at? How genuine—

***Tim Kelsey***: It was not just delays to research but delays to perfectly legitimate commissioning purposes as well. In fact the entire system suffered very badly. The reason for that was exposure of the fact that the decision-making processes being operated at that time were not fit for purpose, so in a sense that should have been exposed many years ago. It was not. Care.data at that moment—

**Q743 Chair:** Can I just stop you there? When you say it should have been exposed, were you not the person responsible for overseeing it? Shouldn't NHS England have been aware that there was a kind of sloppiness and we went from one extreme to something else?

***Tim Kelsey***: I took this job only two and half years ago. Care.data exposed it very rapidly.

**Q744 Chair:** That is a fair point.

***Tim Kelsey***: The situation is improving, but it has been bad all round. We have been working with the information centre to get those processes sorted out on behalf of commissioners around the country as well as researchers.

**Q745 Chair:** Are you confident that progress is being made?

***Tim Kelsey***: Yes.

**Q746 Chair:** The final point I want to ask you about relates to the kind of data that is going to be extracted. We still do not know the list of drugs to be extracted. There is also a controversy around whether mental health data should be extracted. If we do not have information about mental health issues, we will not be able to commission adequately for it, so there is a real danger—almost a form of stigmatisation—if we do not extract that. Clearly, people need to be confident about the confidentiality issues. Are you concerned? Do you think we need to review that?

***Tim Kelsey***: No. When this programme was designed—it was done in collaboration with clinicians and commissioners, who led the design process—it was decided at the beginning that this would be principally for commissioning. A variety of fields—Sam has pointed this out on many occasions, and I share that view—were not included in the original specification for care.data. In the pathfinder phase it has been decided that the original specification will be what is tested, mainly because we are trying to test public information and to some extent the data, but this is really about understanding the new standard for fair processing. When and if we move to a subsequent stage, as a precondition

we are going to run a consultation to establish precisely and most beneficially what fields of primary care data we should be extracting. For my money, that must include fields relevant to mental health which are not already included—some are—and areas of treatment like HIV and others, which were left off the original list of specified fields.

**Q747 Valerie Vaz:** On sanctions, you used the word "deliberate", which is obviously going to be hard to prove. You can always blame someone lower down the scale, but there is a lot of legislation around where you can look at something in the public interest—for example, directors' disqualification. Dame Fiona, my last question is to you. If someone wants to write to you, what is your address?

***Dame Fiona Caldicott***: fiona.caldicott@dh.gsi.gov.uk.

**Q748 Valerie Vaz:** That is an e-mail address. What about a postal address?

***Dame Fiona Caldicott***: That is quite tricky at the moment. Post gets lost, but I think we could give you an address in Leeds where the team is based. I will do that.

**Valerie Vaz:** Thank you.

**Q749 Chair:** In closing, are there any issues that we have not asked you about that you feel are very important to put on the public record regarding either of your roles or the care.data programme?

***Dame Fiona Caldicott***: The welcoming of the cross-party view about a statutory footing for the national data guardian would be really helpful; the expediting of the relevant regulations about the matters you have shown a lot of interest in would be useful in reassuring the public; and I refer to support for the work we are trying to do to make sure the public are well informed. I mention the website again. An issue in the Department of Health is having a website that we as an independent body can use and that is approved. It is interesting that this Government, who are so keen on transparency do not have rules that always enable transparency to be adhered to, but perhaps I should not say that in this setting. It has been a great problem for us.

**Q750 Chair:** That is the reason I am asking you, because these are things we need to raise and flag up as a result of this hearing.

***Dame Fiona Caldicott***: The difficulty of having a functioning website with which the public can interact with us has impaired the development of our work and profile.

**Q751 Chair:** It is particularly difficult when we have heard, as you say, that post goes astray. We need to have a system where the public can contact you to keep abreast of these issues.

***Dame Fiona Caldicott***: Absolutely; that would be really helpful..

**Q752 Chair:** Thank you very much for raising that.

***Tim Kelsey***: I hope that I have been able to promote to the Committee the evidence that there has been a genuine commitment to co-production and co-creation in the redesign of the care.data programme, and that there are no artificial time limits. We will continue to redesign it as necessary to meet not just Dame Fiona's requirements but the broader requirements that the advisory group, programme board and others have.

One of the most important characteristics of a properly co-produced and co-designed project is that it is transparent. Can I clarify one thing on that? The programme board agreed last week to publish its programme board papers. Those will be published very shortly. We already publish the care.data advisory group papers. Sam was raising the issue of programme board publications. If people have issues around transparency and want to learn more about the programme or see the papers, we are completely happy to share those sorts of things with people. People should contact me if they worry that there is a hidden agenda, because there genuinely is not. We are committed to transparency for this project.

**Q753 Rosie Cooper:** Could we start with the minutes that we heard about? I don't know what they are, but that would be a pretty good start, would it not?

***Tim Kelsey***: They are being published. The programme board took that decision on the advice of the advisory group—I do not know whether Sam was at the meeting—some weeks ago. That was a commitment we made a while back.

**Q754 Chair:** Would you agree with Professor Mathers's comment that you were at the last chance saloon? If we do not get it right this time, it would be extraordinarily serious.

***Tim Kelsey***: I do not know whether members of the Committee are aware that, for example, we have just prioritised the treatment of kidney disease as NHS England, and are going to incentivise a very different approach to it in the NHS. At the moment about 3 million people a year suffer very badly from chronic kidney disease, mainly because we cannot support GP practices to prefer an earlier diagnosis of their condition. That is because we cannot link the data. The importance of this is so great that we will not commit to any deployment or rolling-out unless we and independent authorities are absolutely satisfied that we are in the right place. All I can say is that in a sense it is the last chance saloon, but we will never get to that point because we will not roll this out unless we are completely satisfied that we have got the programme right.

**Q755 Barbara Keeley:** I know you keep going on about the good reasons for doing this. The reason that problem exists and you are in the last chance saloon, which I think was a good comment and I think you are, is because of the sloppiness, the commercial uses, and people out there who did not respect patient data—the hospital episode data they had—and were cavalier with it. The people to blame for the delays are not this Committee for asking questions, or anybody else for being concerned about it, but the people inside HSCIC who were sloppy and those who were cavalier in their use of data, saying they could link data and put up examples which alarmed people. That got into the national press and caused this. The questioning and the reassurance that can come from what we do with you is not to blame.

Those people in the past were to blame. We should all look at that and ask why it happened. It happened because of that.

***Tim Kelsey***: I have not been a career civil servant or public servant. I think it is very difficult for public services. To be honest, we were in a very bad situation last year. For patient benefit we all collectively have to learn. I do not think it is about blame; it is about setting a new standard. We now have that new standard. Dame Fiona has done a very important piece of work. It is a demanding new standard, and I welcome the productive, constructive criticism and comments of this Committee.

**Q756 Rosie Cooper:** It is about fair blame. You cannot look at the havoc, upset and worry experienced by people and say, "Oh, it's all gone." There has to be accountability for it. I do not believe in blaming people, but I do believe in fair blame. This was a mess. Dame Fiona, with your reputation I deeply respect you, and I think you can bring the very steady hand to this that will save it.

***Dame Fiona Caldicott***: Thank you very much.

**Chair:** I think there is a difference between blame, responsibility and insight. Thank you both very much for coming this afternoon. We appreciate your time.