HOUSE OF COMMONS

Science and Technology Committee

Oral evidence: Blood, tissue and organ screening, HC 990

Monday 28 April 2014

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Written evidence from witnesses:

- British Heart Foundation
- NHS Blood & Transplant (Organ Donation & Transplantation)
- British Transplantation Society
- Transplant 2013

Watch the meeting

Members present: Mr Andrew Miller (Chair); Stephen Metcalfe; Stephen Mosley; Pamela Nash; David Tredinnick

Questions 201-239

Witnesses: **Dr Richard Baker,** Executive Committee Member, British Transplantation Society, **Dr Mike Knapton**, Associate Medical Director (Prevention & Care), British Heart Foundation, **Ed Owen**, Chief Executive, Cystic Fibrosis Trust, and **Keith Rigg**, Chair, Transplant 2013, gave evidence.

Q201 Chair: Can I welcome our witnesses to this afternoon's session? Rather a lot is happening in the House today and people will be coming and going, so forgive the Committee. We are interested in the detail of what you are saying, and everything you say will be carefully read. Perhaps we could start by inviting the four of you formally to introduce yourselves.

Dr Knapton: Good afternoon. My name is Dr Mike Knapton. I am associate medical director at the British Heart Foundation, representing the heart. My professional background is as a GP in Cambridge.

Keith Rigg: Good afternoon. My name is Keith Rigg. I am a transplant surgeon in Nottingham, but today I am representing Transplant 2013. I should also say that I am a non-executive director of NHS Blood and Transplant, and I chair the transplant clinical reference group within NHS specialised commissioning.

Ed Owen: I am Ed Owen, chief executive of the Cystic Fibrosis Trust, which works on behalf of the 10,000 people with cystic fibrosis in the UK, some of whom will need a lung transplant to prolong life.

Dr Baker: My name is Richard Baker. I am a renal consultant from Leeds, and I am here representing the British Transplantation Society.

Q202 Chair: Thank you very much. Perhaps I can start off with a general point. First, what involvement has each of your organisations had in the development of the Government's new strategy "Taking Organ Transplantation to 2020"? Secondly, do you feel that your views have been incorporated?

Dr Knapton: First, the BHF responded to the online survey post-2013 organ donation strategy in September 2012, but we have had no further involvement in the process. Secondly, we have also fed into the consultation and have had a consultation response. Thirdly, we responded to the NHSBT marketing strategy, which we think is an important component of this report.

As to whether our recommendations have been taken on board, I think the answer is: to some extent. For us, the omission that we would like to see there is the notion of a soft opt-out, as is being implemented in Wales.

Keith Rigg: From the Transplant 2013 perspective, we contributed to the online survey, but I was also involved in a number of the workshops. We have a particular interest in trying to raise consents. A number of our recommendations were incorporated within the document, so I am happy that what we had suggested has been included in the strategy.

Ed Owen: The Cystic Fibrosis Trust contributed to the work that led up to the strategy. We feel that it is in the right direction. There are some gaps. In particular, we feel that, on the lung side, there needs to be a national lung allocation system to ensure that there is a better match between organs donated and those that are required. There are other areas which are probably shared by colleagues here. It is a good start, but we think a lot more detail needs to be fleshed out in terms of how it is going to be delivered.

Dr Baker: The British Transplantation Society would say the same. We were consulted, and the chief executive maintains a dialogue with our president on a regular basis. We were happy with most of the conversations. A bit of the devil in the detail needs to be worked out and there are some funding issues that we could discuss, but generally we are behind it.

Q203 Chair: We have some funding issues and some detailed issues. Are these the kinds of weaknesses you would see, or are there more fundamental things you would like to see incorporated in the strategy?

Ed Owen: From the perspective of the Cystic Fibrosis Trust, we were disappointed that there was not a clearer commitment to a national lung allocation system, which is what we think is required on the basis of having a proper national system, so for us that was an omission. It is part of a conversation that we continue to have with NHSBT. We share the issues around soft opt-out that colleagues have raised. We also think there were useful

indications on some of the issues around risk, which are important, so I would give it seven out of 10.

Keith Rigg: It is building on an important bit of work. The previous strategy has delivered a 50% increase in the number of organ donors, although that translates to only a 33% increase in the number of transplants, so there is still a way to go. One of the challenges is that the document says it is to be done within existing funding. There are some challenges as to how you bring about major societal change and also how you deal with the extra activity both within organ donation and transplantation without extra funding. I would perhaps take a different view on the opt-out, which I expect we will come to later, but from my perspective I do not think any significant things have been missed out.

Q204 Chair: Is your point about funding the same, Dr Baker?

Dr Baker: I think Keith knows more about those issues. We had some dialogue with the Cabinet Office about 12 months ago regarding the quite striking results in Scotland. There was an increase in the organ donor register by 10% with a big publicity campaign, which is acknowledged in the document, but at that time there was a problem in releasing funds, which I gather were there within the Cabinet Office, to have a similar programme within England.

We know that, when people are on the organ donor register, 90% of families will say yes, whereas, if they are not, 40% will say yes. There seems to be a clear link between funding and publicity programmes generating an increase in the organ donation register and generating more donors, but that seems to have been blocked. There does not seem ever to have been a campaign. There is a lot in here about working out the best way to do it. There is a document from the Cabinet Office's own advisory group on behavioural insight on ways that you might do it and the principles of how you might do it, but ultimately it will need some sort of funding and a publicity campaign, and that is what we would like to see.

Q205 Chair: Dr Knapton, am I right that the British Heart Foundation chose not to join Transplant 2013, and, if so, why?

Dr Knapton: No. We just weren't asked; it was as simple as that.

Chair: That is very clear.

Dr Knapton: More seriously, the one thing that would trouble us is membership of pharmaceutical companies in the organisation. The BHF is very anxious not to be conflicted, or to be seen to be conflicted, when it comes to its relationship with industry. Lastly, we think we can contribute to the debate as effectively in as out, so on those grounds we stayed out. That is a more serious response to your question.

Q206 Stephen Mosley: One of the things we have seen from the statistics is that family consent to organ donation is low in the UK compared with other countries. We have the example of Spain in our pack. Why is that the case?

Keith Rigg: There are lots of factors. The first is that when somebody dies, and in that situation they can become a deceased donor, it is a very distressing time for the family. NHSBT through the specialist nurses in organ donation record the reason why families say no. I do not have the precise details with me, but I know it is a range. It will include that the family did not know what their loved one would have wanted. It may be a cultural or religious issue; it may be too much time is taken between them making a decision and the organs being removed. There is a multitude of factors.

As my colleague Dr Baker has already said, if somebody is on the organ donor register, over 90% of families will say yes. If families know what their loved ones would have wanted that makes a real difference, whereas it is probably about 40% when they do not. It is multifactorial. There is an issue about translating the views of society in general, where people are very supportive of organ donation and transplantation, into the reality of being on the organ donor register, talking with families and saying yes when the time comes.

Dr Baker: To be fair as well, I think the document is quite sophisticated. It concedes all these points, does it not? It goes through a number of these issues, and to solve this problem will probably take quite a number of different initiatives. I think the document calls it a societal problem, does it not? The trick is how you achieve societal change, which I am sure is not going to be a very easy thing to do.

Dr Knapton: The British Heart Foundation is a member of the Dying Matters Coalition, which is part of what was then Mike Richards' end of life care strategy for England. He very clearly put it that we do not talk enough about death. If we do not talk about it, two things happen. One is that it is not given the policy recognition that it should have in terms of how we care for people when they are dying, which links into organ donation, and, secondly, individuals' wishes, including whether or not organs will be used in the event of their death, do not get aired and therefore their wishes are not respected. The Dying Matters Coalition has been around for five years and is doing quite a lot to support these conversations and create the societal change that has been referenced already.

Q207 Stephen Mosley: Do any of you have any knowledge of how it works in other countries? As I said, we have Spain as an example in the pack. Do they do things differently from us?

Keith Rigg: We are now doing some of the things that Spain did. While Spain has a different culture, one of the key things it felt was important was having what amounts to a donor transplant co-ordinator embedded within each hospital. As part of the organ donation taskforce that reported in 2008, that was one of the recommendations implemented in this country. In all of the major intensive care units in this country, there is now a specialist nurse in organ donation based in that hospital. That has no doubt made a big difference.

There is also evidence to show that, where a specialist nurse in organ donation has been involved in talking to the family members, consent is far more likely to be given compared with where they are not involved. Their role is key, and that is certainly one of the things that have been expanded over the last five years. There is still work to do, but there has certainly been an improvement as a consequence of that. That is probably just one thing that transfers from the Spanish to the English model.

Dr Baker: There is another point about the ITU bed capacity in Spain. There is a lot of pressure on intensive care beds in the UK. If you work out the number of intensive care beds per million of population, it is lower than in Spain. That can create a problem, because there is pressure to get people through and maybe you do not have the time you need to make this process happen in a satisfactory manner.

Dr Knapton: There is some evidence from Norway, which has had an opt-out system, which we are recommending, since 1973. They have got only one single transplant centre, so it is all quite centralised. One of the things they have is a national training programme for health care professionals and national protocols governing donations, so there is more infrastructure around the importance of the conversation that has been referred to at the end of life in the event of someone's death prior to donation. I am sure that the person involved and the nature of that conversation will have a big impact on whether or not the family goes with the wishes of their loved one.

Q208 Stephen Mosley: Could you quickly explain that process? How would the family members be approached in that situation? I am guessing in an ideal world you would be able to do it beforehand, but that is not practical, is it?

Keith Rigg: I do not think any of us are directly involved. My understanding is that, when a potential donor is identified in, say, an intensive care unit, the clinicians or nurses who are looking after that patient will contact the specialist nurse in organ donation, who will either be on the unit already or nearby. The timing of the conversation has to be appropriate. More recently, it is not just one conversation; it is a series of conversations, so the specialist nurse in organ donation will be introduced at an earlier stage as a nurse who has a special interest.

When it becomes apparent that the donor is not going to survive and the necessary tests are done, it will be ascertained whether or not that individual is on the organ donor register. The specialist nurse in organ donation will then tailor their conversation depending on whether or not the loved one was on the organ donor register. They all have specific training, which happens throughout the UK, so that is a model. They are all taught how to break bad news. They spend a lot of time with the families talking through things. For example, if the individual is on the organ donor register and the initial response of the family is to say no, they will often probe the reasons behind that a bit more, so they do not necessarily take no as a first step. That is certainly one of the things that happen in Spain. Perhaps that is a very high-level description of what happens. Unfortunately, none of us has been in that situation for many years, but hopefully that helps to explain it in a little more detail.

Q209 Stephen Mosley: The strategy does focus on this, and it has measures in places to try to increase the donation rate. Do you think those actions are suitable and will result in positive action?

Keith Rigg: One of the pieces of data available is the potential donor audit, which NHS Blood and Transplant run. Therefore, for every person who dies in an intensive care unit, the information around the cause of death—whether they have been approached, whether brain stem death tests have been done and whether consent is obtained—is all recorded.

That is why we are able to have these detailed data of how many people say yes and how many say no. That is the source of those data, which means we can determine why people say no, and so on.

Q210 Stephen Mosley: You referred to ICUs. Is it done in A and E as well?

Keith Rigg: It is most commonly in critical care, but it can be in A and E as well.

Q211 Stephen Mosley: If the donor has given permission beforehand, do you think measures should be put in place to prevent the consent from being overturned by the family?

Keith Rigg: It is a very difficult one. The Human Tissue Act states very clearly that the wishes of the deceased in life should take precedence. The corresponding code of practice from the Human Tissue Authority says that due care should be taken in conversations with the family. If you have a very distressed family, you can question the reasons behind it, but you are not going to say no in that situation and cause added distress. That may have a negative impact not just on that grieving family but also in the wider sphere, but it is an area of debate that people are looking at in more detail at the moment.

Dr Knapton: Our contact at the British Heart Foundation, which is anecdotal rather than evidence, is that, when talking to recipients, the importance of a freely-given gift of an organ is very important to them. If there was some sort of dissent, disagreement or question as to whether or not the organs were freely given, it would have an impact on recipients too.

Q212 Stephen Mosley: The strategy talks about cultural and religious sensitivities and I know you have mentioned it. Are there any particular religions or cultural groups where you do have specific problems?

Dr Baker: The difficult thing is that most of the elders and influential people in these religious groups have come out and said that donation is okay. We have a problem in that black, Asian and minority ethnic groups form just under 30% of people on the waiting list but only 5% of the donors. That is definitely a target area to try to improve. Their refusal rate—I have forgotten it—is also relatively high. Conversations have been had—not by me but by others—with imams, elders of the Jewish faith and other groups. They all agree it is something that can be done, but there seem to be problems in getting it to operate in practice. There are people tackling it.

Ed Owen: It is not an issue on which I claim any great credibility.

Dr Knapton: The only evidence I can draw on is a workshop held at the BHF about two years ago in which we had an imam, a rabbi, a priest and a member of the Sikh community. The question that came up was: what were the religious rules, scriptural or otherwise, around donations either for or against? They said that all religions would consider this to be a gift and therefore it would be part of their religious teaching. The barriers either come from misunderstandings and myths or cultural issues around what happens in the event of someone's death in terms of the timing of the disposal of the dead

body and that sort of thing. There are practical issues about the time involved in terms of taking the body away to retrieve the organs and then the funeral arrangements.

Q213 David Tredinnick: To me, it is common sense that an opt-out system would significantly increase the number of donated organs. Yet the 2008 report of the organ donation taskforce on the potential impact of moving to an opt-out system stated that it could find no compelling evidence. Do you agree with them, or is my simple vision correct?

Ed Owen: Let me start. I have been quiet for a bit, so I can talk now. The Cystic Fibrosis Trust has long supported a soft opt-out. We made the case back in 2008 and we still make the case today. Our view is that it will increase the number of organs donated. I will bow to those who have looked at the evidence in greater detail to give a view on that. While the Cystic Fibrosis Trust supports a soft opt-out and it is right that there is focus on that in terms of increasing the supply of organs donated, the key point is that we also need to get the system that operates now working more effectively. That is really where our focus has been. We support a soft opt-out, but it is important not to see that as some sort of panacea; it is not.

Dr Baker: There is quite a split within the transplant professionals, who I am representing here. If you take a vote, it is a fairly even split between a soft opt-out and opt-in. It sounds very good. One of the disappointing things, which Keith knows a lot more about than I do, is the disappointing results. Where it has taken place, it has not actually yielded results. Most people in the profession would rather wait. The idea of doing it in Wales, seeing how they get on with it under the Welsh policy, is a very good one.

Keith Rigg: Because Transplant 13 has a wide constituent basis it has not taken a position. We recognise there are strong views, and there are those organisations that are very much supportive of it and others who are against it. The initial report did look at it. Their feeling was that there probably was not sufficient evidence, although it is very difficult to say whether it is purely the change in the law that makes the difference or it is all the other bits that go with it. In some European countries it appears to have increased things greatly; in others, such as Chile and Brazil, it results in a fall in the organ donation rate. Therefore, it is complex. There are very strong feelings and we should look at it very carefully. Wales may be a research project. Let's see the result of that. It takes a lot of money to do this. We could argue that the money it would take to do that could equally be used to bring about societal change whereby more people say yes under the current legislation, but there are strong views and the debate needs to continue.

Dr Knapton: I have already said that the British Heart Foundation supports a soft opt-out. We think it will increase the number of organs.

Q214 David Tredinnick: How do you feel about the taskforce comment that an opt-out system would "distract attention away from essential improvements to systems and infrastructure"? It sounds like a spin doctor is speaking.

Dr Knapton: I have discussed soft opt-out with the Bishop of Swansea on their Sunday programme: far from it. It enabled us to have a very sensible discussion about the pros and

cons of a soft opt-out, and, as a result, the issue of transplantation and making your wishes known to your family became a consequence, if you like, of that conversation. Far from it distracting it, it is one of the ways in which you can raise awareness of a soft opt-out.

We have a bit of evidence on cost. Would it cost a lot of money to do it? Our reckoning is that even a small increase in the overall number of organ donors would reap considerable financial benefits to the UK as a whole, although probably not to Wales. We estimate that the associated increases in transplants, even with just one additional donor per year, would have a 10-year return on investment of £8 million because of the cost-effectiveness of transplants versus not transplanting patients and the medical and social costs of that.

Q215 David Tredinnick: Do you think the Government should review their position? We have talked about Wales. Are you happy with the Government's position on presumed consent?

Ed Owen: No.

Dr Knapton: No.[1]

Keith Rigg: Yes.

Dr Baker: I think we should see what happens in Wales.

Dr Knapton: It is to do with the pace of change. Heart transplants are the minority of transplants. Only about 130 or 140 are done. However, given our position, we think it will not do any harm having a soft opt-out and might do some good, and it is cost-effective. Why wouldn't you do it? Why not do it now rather than wait for Wales, because people on the register are dying as we speak at the rate of three per day?

Q216 Pamela Nash: Gentlemen, in the strategy "Taking Organ Transplantation to 2020" risk-averse behaviour by medical professionals is mentioned as one of the factors preventing donated and retrieved organs from being utilised. Can I ask each of you if you agree with that as an assessment? If that is the case, how widespread is this problem? Are the recommendations in the report on how to fix this problem sufficient? Is there anything you would add to those solutions?

Keith Rigg: If I could speak from a professional point of view rather than as a representative of Transplant 2013, there are two aspects to it. One is the risk and benefit strategy, because a deceased donor organ is a second-hand organ—that is how it has to be—whereas, once upon a time, most organ donors were young people dying of head injuries. Now it is increasingly more likely to be an older patient dying of a brain haemorrhage or stroke, so we are dealing with a different donor group. Therefore, we have to be sure that we are able to use those in the most effective way.

[1] The witness later clarified that, the fact that two questions had been combined misrepresented the British Heart Foundation's position. The British Heart Foundation agreed that the Government should review their position, but they were not happy with the Government's position on presumed consent.

If we did not take any risks, a lot more patients would die while waiting. We have to look at how we age-match the donor and recipient and consider what the risks are of not having that transplant; we need to be able to discuss those with the patient and their families so that there is true consent. While we are doing that, there is the opportunity to gain a better evidence base of what is successful. In the last few weeks, there has been a report on the use of organs from donors who have had cancer and what the risks of those are. We know that in certain situations the risks of using an organ from somebody who has had cancer are very low, but it does take a while for everyone to get on board with that. We have to rely on some centres to take the risks, and, as the evidence base builds up, hopefully that means the rest of us, who perhaps are a little more sceptical, can see what the evidence is and change our practice as a consequence.

Q217 Pamela Nash: To be clear, you are saying that you would be sceptical about how widespread this is as an issue or if there is a solution.

Keith Rigg: I recognise that it is an issue. Five or 10 years ago we would not have thought of using organs from somebody who died of a brain tumour, whereas now there is evidence to show that the risk of transmitting that is extremely low, and therefore it is safe to use that for a higher-risk recipient. Things have changed. What is important is that clinicians keep up to date with the evidence so that they do not practise what they were practising 10 years ago but what is current now. There is still work to be done among the transplant community. I address that to myself as much as to my colleagues. We need to look at the evidence and ensure that our practice is based on that.

Ed Owen: It is a very pertinent question. Risk is a big issue. You see inconsistencies across the UK in terms of particular clinical judgments. The concern of the Cystic Fibrosis Trust is that at the moment one in three people with cystic fibrosis on the transplant list—if you can call it a single list; it is not—who are waiting for donated lungs will die before receiving transplanted organs. Yet we also know—I am not making a simplistic read-across here—that only a quarter or a fifth of all the lungs donated are used in transplantation. We have been speaking to the clinical community. We are convinced that a significant number of the lungs that are not being used in transplants could be. It may be we need to push a little, based absolutely on clear clinical judgments, but we are seeing evidence coming through quite clearly that what are called extended criteria lungs, which perhaps would be regarded as sub-optimal under normal criteria, can prolong life. We spend a lot of time speaking to people with cystic fibrosis, because in a sense the people who are really taking risk are those who take the decision to have transplanted lungs. When I sit down with people and ask, "Where do you want the balance of risk to be? These donated lungs that arrive may not be a perfect set of organs, but what is your risk profile?", the answer is, "I'll have them because they will prolong my life." When you see the risk, in terms of the tragic figure of one in three people on the list dying, you get a sense of where we are keen that the risk issue should be pushed.

Dr Baker: I would agree with what Keith said. You have to acknowledge that there is a variation in practice, partly because there is not an evidence base. We are desperately trying to pull in the evidence on what it is like to use kidneys and other abdominal organs from people who have had high-risk behaviours, been exposed to viruses, had cancer and all those sorts of things. For anyone who has done that and had their hands bitten by a

complete disaster, giving someone cancer that kills them within three months when they are meant to be giving them an organ to prolong their life, it is a pretty horrific experience. All of that needs to be collated.

There is now a governance framework for this. There are very public lists, published by NHSBT, of exactly who is accepting organs and what the rates are. When there are outliers, the medical director or head of the specific organ advisory group demands an explanation. I think transparency has gone up and people are called to account if there are outliers in these systems. Would you agree with that? There are mechanisms in place to pull it all together.

Dr Knapton: I am not a transplant surgeon, but I would add to what has already been said that the decision by the team to transplant is a difficult one for them as well as for the family. If the outcome is a 30-day mortality, it will affect that team's audit figures, but it will affect them emotionally as well. They do not wish to see patients die following an intervention of that nature.

On the other hand, those teams also want to see more organs donated. I think the framing of this is a start, but it does not reflect the complexities of risk-averse behaviour; it does not capture it for me. On the one hand, there is the risk-averse behaviour and how that affects the individual in front of the doctor or the surgeon, versus all those others he or she knows about who are waiting. The risk to one and the trade-off with risks to another is quite a difficult thing to do. We at the British Heart Foundation would be very keen to make sure that there was strong clinical leadership in addressing this issue, because you can have inadvertent or unintended consequences if you don't get it right.

Q218 Pamela Nash: When I was looking at the report I was struck that there does not seem to be this issue with hearts. In fact in the year to which it refers, 2012-13, all hearts successfully retrieved were used. Is that a one-off for 2012-13, or is it something the British Heart Foundation is aware of?

Dr Knapton: I was not aware of that, to be honest, but it is not mentioned in here. I do not know how many hearts are retrieved but not donated. I would have to check the data; I do not have that in my head, I'm afraid.

Q219 Pamela Nash: The reason I ask is that I am wondering whether this had an impact on your members.

Dr Knapton: It is certainly the case that less good hearts are being retrieved, because the numbers of young men dying on motorbikes is reduced. That is a cliché; that was where donated organs used to come from, so the quality of organs is changing. It is also changing because the shortage means that clinicians are having to accept sub-optimal organs to transplant to treat patients. There are lots of tensions in this for both the family and the clinician. That is what does not come through here in order to address it properly. I think we should trust the clinicians and families to work on this to make sure we get the balance between audit and dealing with the waiting list and the individual in front of you to optimise the outcomes.

Keith Rigg: NHS Blood and Transplant produces graphs for each of the organs showing where, out of all the potential donors at the beginning, they fall. Although I cannot remember the precise percentage, a heart is able to be retrieved in probably 20% of potential donors; it is above 80% for kidneys; it is in between for livers; and it is probably towards the bottom for lungs as well. There is still room to improve that and learn from one another. There is more detail under this that needs to be looked at.

Q220 Pamela Nash: Can I move to the screening procedures used to look at individual retrieved organs? In your view how suitable are they at the moment? Among your organisations are there any concerns that organs that might transport disease are getting through? On the other hand, are they too rigorous and we are losing the opportunity to use organs for fear of disease being passed on?

Dr Baker: There are erudite bodies in place to help us with this. We have SaBTO. I forget what it stands for.

Keith Rigg: It is the Advisory Committee on the Safety of Blood, Tissues and Organs.

Dr Baker: That gives us advice on checking for viruses. All organs are already checked for all the main viruses and various other things, but I do not think they are particularly restrictive. There are cases where we have had disasters, even within the last couple of years, of three organs all transmitting effectively a fatal illness. So you have to start with a cautious approach and maybe liberalise it. We have become a little more liberal about hepatitis. Some countries use organs from HIV donors for HIV recipients. We have not done that in this country, but that may be somewhere we can go. They are not massive numerically, but they are the sorts of things that happen and we have to be cautious.

Q221 Pamela Nash: This might be beyond your expertise. Has the use of donated organs from people living with HIV been considered in the UK?

Dr Baker: I think it has been considered. It has not been done. It has been done a lot in South Africa, as you might imagine, because of different issues there, but it is something you could consider.

Q222 Pamela Nash: It is estimated that there are now 100,000 people in the UK with HIV, so it might be something that we start to look at. Do any of the other witnesses have concerns about the current procedures to screen for disease, or are you happy with them?

Dr Knapton: We have not had any concerns raised through our contacts with patients with regard to heart transplantation, which is a small number of transplants, but the key for me would be that any risks either way would be discussed as part of the consent procedure with the patient in advance of any intervention. With people on the waiting list, you have time to do that properly so that people understand what risks they might be subjecting themselves to.

Keith Rigg: There are a lot of donor as well as recipient factors. For somebody who is waiting for a kidney transplant and can be maintained on dialysis, you may not want to

take the same degree of risk, whereas for somebody who is waiting for a heart, lung or liver there are no other options. I think it all has to be taken into account.

I think the screening procedures are adequate. The SaBTO guidelines are guidelines. There are some absolutes within that, but there are others where it says you should discuss it with your recipient, and there may be situations where you would want to do that. One new virus that we have become more aware of is West Nile. SaBTO has produced some recent guidelines for that. I do not think we have seen that in this country. The SaBTO guidelines talk about a large cohort of blood donors who have been in endemic areas and there has been no transmission of that. It is a matter of balancing these things and for the experts to continue to be vigilant.

Q223 Pamela Nash: Since you mentioned West Nile virus, do you think it was the right decision to add that to the illnesses that completely rule out someone from donating?

Keith Rigg: Yes, because it can't be treated—and certainly there have been cases in other countries of recipients who have died once they have had it. It is important that we are aware of it. Although it has not happened in this country yet, as people travel more frequently it may be something that we are confronted with in the future.

Q224 Pamela Nash: Are there any other illnesses of that sort on the horizon that might be added to that list, or anything that you think should be added to it?

Keith Rigg: I am not sure it is my area of expertise to say so.

Pamela Nash: Fair enough, but you are here.

Ed Owen: To make a point that goes beyond screening, there is the issue about extended criteria. Lung transplantation has been governed by international criteria set 20 or 30 years ago. Clinicians are pushing that with extended criteria lungs. Traditionally, lungs from people over 55, or with a strong smoking history, were not used. It is clear from research—obviously, it has to be based on a clinical judgment about the particular set of organs donated—that there is no decrease in life expectancy when using extended criteria lungs, which push beyond the criteria that were set 20 or 30 years ago. Part of the problem goes back to the point about inconsistency. It is most important that we get the evidence base and make sure it is properly and consistently rolled out across the system. One of our concerns is that it is relatively inconsistent at the moment, and that is why it requires the buy-in of the professional community and other organisations working together to make sure there is a more consistent approach in this respect.

Keith Rigg: Looking at the UK strategy, there are four strands, and two of them are around donor hospitals and recipient centres. A lot of that is reducing variation and working to best practice so that we make the most of the opportunity we have, to endeavour to ensure that we have all the donors we can and not only transplant to all the people we are able to but to keep those organs lasting for as long as possible. There are a number of multiple strands which have been highlighted within the strategy, but there needs to be a lot more work done at local and national level fully to work those out.

Q225 Stephen Metcalfe: Good afternoon. We have already touched a little on how organs are allocated. There seem to be different systems depending on the organ itself, so there are local and national allocation policies, and a hybrid somewhere in the middle. Do you consider that the policies as they stand at the moment, bearing in mind they should all be about patient outcomes, are fair and consistent, or is there room for looking at them?

Ed Owen: If I can answer that first, I suspect I am an outrider in this group. Obviously, our focus is on lungs. Starting from first principles, is it the case that the existing system ensures that those most in need get the lungs that become available? No. We are clear that that is not the case because, in truth, we have local allocation systems, not a national one. It is our strong view that in order to ensure there is that connection with need, and also, by the way, to ensure that the criteria recognise the long-term worth of a transplant, we look at the rates of survival in particular areas. Cystic fibrosis is one of those areas where the survival rate of transplantation is good and high. How do we move to a system whereby that connection can be made? Our view is that it is a national system. As I said in my opening remarks, we are disappointed that NHSBT did not commit itself to that.

I recognise some of the arguments used in response, but there are other systems. The US has introduced a national allocation based on a scoring system which balances the criteria of need with what the transplant would produce for a particular patient. We think there are very strong arguments for moving in that direction. We call on NHSBT to examine it. It is moving in the right direction, so we are likely to move to a system of national allocation for urgent cases in England for lung transplantation. That is a start, but it will deal with only a very small number. We think there is now a very strong case to move to a national scheme for the whole system.

Q226 Stephen Metcalfe: Speaking about your specific area of interest—lungs for cystic fibrosis sufferers—why do you think they have not moved to a national system? If you have identified that this would improve patient outcomes, why not do it?

Ed Owen: These issues are complex.

Stephen Metcalfe: Help us understand.

Ed Owen: Our focus, inevitably, is on the fact that one in three people are dying on the waiting list and how we can move that down, which tends to be the driver for moving toward a national system. The argument of NHSBT goes that you do not want to come up with unintended consequences, so you move to reduce the one-in-three risk but start to reduce the length of life for people who have received transplants. I do not minimise those risks. This is going to take a lot of work, but we start from that principle. We do not see that there is any other way ultimately of getting to where we want to be, which is that you have a system that matches those most in need, who can most benefit, with the lungs that become available—and that is a national system.

Dr Baker: With abdominal organs, there is the issue of time. We have more time to facilitate moving things round the country. The national allocation system particularly for donation-after-brain-death kidneys is probably the most advanced. That is a full national system. It is obviously a scarce resource, so you have to balance the needs of the

individual patient you are looking after and the utilitarian consideration of what is best for society. That allocation system has to balance those things. I and most of the members of the British Transplantation Society think it is pretty fair. It is constantly reviewed. For example, children get a lot of points. Various other groups might wait longer and are given points to help, and that is regularly reviewed. I think the system is pretty good. We need to move for other kidneys that are donated after cardiac death. We are hopefully moving to a national system some time this year, or maybe early next year, but that needs to happen as well.

Q227 Stephen Metcalfe: Mr Rigg, you were trying to get in.

Keith Rigg: No; I was going to say exactly the same thing. I will save time and not repeat it.

Dr Knapton: Our position on the system around allocation, notwithstanding all the trade-offs and difficulties in it, is pretty good. The only additional point I would make is that, as I understand it, NHSBT allocates donated hearts, but the transplant centres, of which there are six or seven across the UK—there is one in Scotland and the rest are in England—select the patient, so there needs to be a degree of understanding and trust, frankly, between the retrieval team and the donor team to make sure you get an organ that is satisfactory. That trust needs to be protected and built up so that, when a heart from Devon gets transplanted in Newcastle, the Newcastle team knows that the people retrieving the organ in Devon are getting it right.

Q228 Stephen Metcalfe: That would be an argument for keeping a system local, because the teams are likely to be geographically more—

Dr Knapton: It needs to be national, so the selection of the patient to receive the organ should be for the local team, but the distribution of the donated organ should be done nationally.

Q229 Stephen Metcalfe: That requires the recovery team to be working to the same standards, guidelines or whatever across the whole country.

Dr Knapton: Exactly, yes.

Q230 Stephen Metcalfe: Are you saying that is not happening at the moment?

Dr Knapton: No; I think it is happening, but it needs to be carefully protected, and the relationships that exist between the retrieval and transplant teams need to be protected.

Ed Owen: Any national system would obviously take into account geography. For instance, timing is critical to get the lungs that are donated to the relevant transplant centre. Geography is going to play a part in any scoring index, if you like, which creates that system, because, inevitably, there are practical issues that you are concerned with, but that would be within a national allocation system.

Q231 Stephen Metcalfe: In a perfect world, would it be your overriding desire that all organs that are donated, where practical, are allocated on a national basis so that those most in need receive the organs before anyone else and it is a more equitable system? Would that be an overriding principle, and then you add the caveats of time constraints, geography and so on?

Ed Owen: Could I add an additional caveat to that? Yes, it is about need, but we obviously want to ensure that a calculation is made about the longer-term outcomes of transplants, so that the list scoring recognises that certain people benefit from transplants differentially from others. We think that is important because, if you don't have that, you create some of the perverse outcomes we talked about before.

Keith Rigg: One of the other recommendations of the taskforce in 2008 was the establishment of a national organ retrieval service. That has been in place. There are seven teams around the UK who do all of the retrievals, but because the activity has grown with a 50% increase over the first five years—it is now up to 63%—those teams are going out not just to their own area but neighbouring areas, which is partly why the cost is going up, to try to ensure that these organs are retrieved in a timely fashion. There is a robust system whereby those involved are trained to national standard. There are national retrieval standards. I think that some of those initial thoughts—Mike is right; there has been concern—are less than they used to be.

Q232 Stephen Metcalfe: As to those who would submit that the current system of allocation is unfair and there are inequities in it, in your collective view, although there is room for improvement, you would challenge that. You do not think it is unfair.

Keith Rigg: No, I do not.

Dr Knapton: No, I do not.

Ed Owen: Do I think it is deliberately unfair? No, but the consequence of having a locally-based system means that an ultimately fair outcome is not achieved. If I say it is unfair, I am implying there is a deliberate intent to do that. That is certainly not the case, and it is a system that works on the basis of professionals working very hard in the system, but it is our strong view that we need to move to a fairer system which we believe can be achieved only through a national system.

Q233 Stephen Metcalfe: I think you said the direction of travel is starting to head that way.

Ed Owen: Yes. I am not here to speak for NHSBT, and in the strategy NHSBT does not commit itself specifically to the creation of a national system for lung allocation. We strongly feel that there should be. That is an issue of continued debate, and we will continue to make that case. We made the case in the report "Hope for more" that we published in February. I am pleased to say that the relevant health Minister in a debate in the Commons only a few weeks ago agreed to raise with the particular advisory group advising NHSBT on its future policy in this area that a national allocation system should

be looked at, and we strongly hope that it will see the sense of that and make recommendations accordingly.

Stephen Metcalfe: Thank you very much.

Q234 David Tredinnick: Do you think it is desirable that there is an age barrier to donation? I understand that infants under two months do not donate organs in the UK, unlike other countries. Is that a satisfactory situation?

Keith Rigg: I think it is an area that needs to be looked at. The Academy of Medical Royal Colleges came up with a code of practice for the diagnosis and confirmation of death. I think they last reported in 2011. That age of patients was deliberately excluded from that. In light of recent publicity, perhaps it is now time to revisit that. That would result in a small increase in organs, perhaps particularly for those requiring hearts but not necessarily all organs. Hearts and small bowel, for example, would benefit from that age group donating.

Dr Knapton: In principle, you would want to retrieve organs from any age if it were possible to do so. This was not an issue I came across. I did a little bit of investigating. There are technical issues about the diagnosis of brain stem death in very young babies and neonates. Our position would be that, in principle, yes, but I suspect there will be some technical issues about retrieving organs from, sadly, neonatal deaths, on which I am not in a position to give evidence today. I think that is a very specialised area.

Q235 David Tredinnick: A recent study conducted at Great Ormond Street Hospital cited national guidelines as a barrier to donation after brain death in infants and neonates. Do you think there are any other barriers to donation in this group?

Keith Rigg: The absolute contraindications to donation are published on the NHSBT website, and actually there are very few absolute contraindications. I think they have been agreed among the transplant community. Probably most of us would not go to those extremes. I think there are some absolute contraindications. There are a lot more relative contraindications, some of which we have touched on today, but it is open.

Q236 David Tredinnick: Do you include in those contraindications donation after circulatory death in infants and neonates, which I understand does not currently take place?

Keith Rigg: Because we are not allowed to do it, it is not included within that.

Dr Baker: There are clinicians doing organ transplants from that age group to see whether it can work. There are problems because the organs are very small for adults and so on, but it is an area that people are looking into. As I understand it, there is no brain death in the very young, so it would have to be donation after circulatory death, would it not? Therefore, people are using DCD donors to see whether these organs can be useful. It has been estimated that it could be a useful pool of organs, but it is clearly a very sensitive area, and we need to prove that they can be useful.

David Tredinnick: Thank you very much.

Q237 Chair: For clarity, in conclusion, I understand that the 2020 strategy was intended to start last September with a series of operational plans. What is the status of these plans, and what other progress has there been towards implementing the strategy?

Keith Rigg: In terms of results, we are still under the momentum of the previous strategy. As I said earlier, there was a 50% increase in donors by April 2013. By April 2014 that was 63% from the baseline year, so the numbers are increasing. With my NHSBT hat on—I am aware that a lot of work is being done within the different areas to do this—it is clear that not everything can be done in year one; it is a seven-year strategy. I am not sure that progress has been communicated as effectively within the stakeholders as needs to be done. Perhaps that is something I can take back because it is important that all of us know what is happening.

Dr Baker: I think we are still in the honeymoon. We have seen what the bold intentions are, but we are waiting for the detail really.

Dr Knapton: In response to the consultation, we have welcomed the chapter on measuring success and the targets that have been set. That gives us a firm basis against which to measure progress. However, implementation of this does have some co-dependencies on other strategies within the NHS, and that does not come out. Do you want me to stop?

Q238 Chair: No. I am just trying to understand what you are all saying. Are you really saying that nothing has started yet and we are still in the honeymoon, which I think was the phrase?

Ed Owen: From our perspective, an advisory group has been set up to look at cardiovascular issues and various allocation systems. Our issue is more that the strategy is a good start. We want to make sure—I hope you will get the point I am making—that, from the strategy to implementation, we as a patient interest group are properly involved in the process of discussion which leads to recommendations. If I can mention that particular advisory group, we welcome the fact that they are introducing lay members to the advisory group, which has been overwhelmingly populated with clinical professionals. We would like to see that widened to ensure that groups like us that can represent patient experience are properly involved. I suspect that is probably something all of us want to see across the piece.

Keith Rigg: There is a stakeholder group set up with patient groups already as well to look at some ideas as to how these societal changes can be brought about, because there is no simple answer to that. If there was, it would have been done already.

Dr Knapton: I misunderstood the question. I am not in a position at the moment to say whether anything has or has not been done because I have not seen the first annual report, as it were, but I have confidence that things are being done in terms of the conversations I have had. I cannot present evidence as to what progress in detail has been made, but I have no concerns that progress is not being made. Of course, it is continuity as well. What was said by Elisabeth Buggins in 2008 has been largely successful, and I see this as a continuation of that with additional recommendations, particularly around family refusal.

Q239 Chair: This is obviously a very complex subject with enormous human and scientific challenges associated with it. Of the strategy's recommendations, to which would you ask the Government to give the highest priority?

Ed Owen: We welcome the fact that there is strong emphasis in the strategy on making the system now work more effectively. While we regret the fact that there is not a commitment to the soft opt-out system in terms of legislative change, we think that the focus on making the system as it works now more effective is of paramount importance, so we welcome that. We look forward to a continued and robust further discussion with NHSBT on the particular issues about which we have concerns.

Keith Rigg: With regard to the challenges to the Government, the main thing is how we change the current consent rates of families saying yes from 57% to 80%. That is a societal change in which the Government have a clear role. Alongside that, we need to find ways of funding this increase in activity, because that cannot be done within the existing capacity.

Dr Knapton: Ducking the question would be to say that any one of these in and of itself will not do the job, so you need to do them all. In terms of the trajectory, we have a very good national system which was put in place following the Elisabeth Buggins report in 2008. Perhaps we now need to balance that with a cultural and societal change in terms of the wish that it becomes a cultural norm that the gift of life by donation of an organ in the event of someone's tragic death will help not only the recipient, funnily enough, but, in my surgery for families who have donated, it is a consoling thought that the death was not in vain.

I go to the Transplant Games every year, which were held in Sheffield last year. The biggest ovation goes to either the living donors or the bereaved relatives of donors. I cannot remember how many there were, but a significant number turned up. If you ever needed a moment to understand why this matters at a human level, that was it. There were people playing sports as a result of their transplants, who had an opportunity to say thank you to the donors. I think the donors' families got something back from that, which acted as a form of consolation, having lost a loved one to whatever it was.

Chair: That is a very powerful point on which to finish. Thank you, gentlemen, for your evidence this afternoon. If there are further points that come up after you have read the transcript and considered what other people have put in, or additional comments you would like to make, please feel free to do so. Thank you very much for your attendance.