Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

OFFICIAL REPORT (Hansard)

Human Transplantation Bill: Briefing by International Experts

9 December 2015

NORTHERN IRELAND ASSEMBLY

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Members present for all or part of the proceedings:
Ms Maeve McLaughlin (Chairperson)
Mr Alex Easton (Deputy Chairperson)
Mrs Pam Cameron
Mrs Jo-Anne Dobson
Mr Kieran McCarthy
Ms Rosaleen McCorley
Mr Fearghal McKinney
Mr Gary Middleton

Witnesses:

Dr Undine Samuel	Eurotransplant International Foundation
Ms Sally Johnson	NHS Blood and Transplant
Ms Patricia Vernon	Welsh Government

The Chairperson (Ms Maeve McLaughlin): Does anybody need to declare an interest?

Mrs Dobson: Yes, Chair, I declare an interest as the proposer of the Bill.

The Chairperson (Ms Maeve McLaughlin): Thank you, Jo-Anne.

We have Patricia Vernon, head of healthcare quality division in the Welsh Government; Ms Sally Johnson, director of organ donation and transplantation from NHS Blood and Transport; and Dr Undine Samuel, medical director from the Eurotransplant International Foundation. You are very welcome. We are pleased to have you here today. We will invite you to make your opening remarks and then open it up to members' comments. Who wants to kick off?

Ms Patricia Vernon (Welsh Government): I will. Thank you, Chairperson. I am a policy civil servant in the Welsh Government in the Department of Health and Social Services, and, for the past four years, I have been involved in supporting Welsh Ministers with the development of the Human Transplantation (Wales) Act 2013 and its implementation. As you will know, the Act came fully into force on 1 December 2015, just over a week ago. It is a key commitment in the Welsh Government's Programme for Government, and it sets out in totality how consent is given to organ donation in Wales for the purposes of transplantation. It makes lawful the concept of deemed consent. That means that any adult living in Wales is regarded as having no objection to organ donation unless they have said otherwise. The Welsh Government believe that this could result in a revolution in consent rates and, potentially, an increase of around 25% in the donation rates. That would equate to around 15 additional donors in Wales per year.

We carried out extensive consultation both at White Paper stage and on a draft Bill before the Bill was introduced in the Assembly. When it was introduced in the Assembly, it underwent substantial and very detailed and robust scrutiny, and several parts were amended as a result. The Act was given Royal Assent on 10 September 2013, but it did not fully come into force at that time. Some elements of it did, most notably the duty on Welsh Ministers to carry out a communications programme with the Welsh public. We have spent the last two years doing just that. We have been communicating in a very sustained way in an effort to make as much information as possible available to the population of Wales. That has included using mass media, television and radio as well as social media, and there has been a focus on different parts of the community, including BAME (black, Asian and minority ethnic) groups, faith groups and people who use different languages etc.

The organ donor register, which is managed on behalf of the four UK countries by NHS Blood and Transplant, has also been redeveloped during that period. As my paper indicates, the work was carried out with contribution from all four UK countries, and we now have a register that we believe is much more robust and much more future-proof. It continues to allow opt-in decisions to be made, so, if a person would like to make an express decision to be a donor, they can still do that and can choose the organs that they wish to donate, but it also allows the opportunity for people to record an opt-out decision should they wish to do that.

The Human Tissue Authority consulted on and developed a code of practice during the past two years, and a suite of regulations was passed by the National Assembly for Wales in relation to excluded materials, appointed representatives and living donors who lack the capacity to consent. The work has been supported throughout by a programme of evaluation. That ranges from a review of the international evidence, which we carried out before the Bill was introduced, some surveys of NHS staff in Wales, work with specialist nurses and clinical leads and a continuous programme of public attitude surveys.

We are very happy to share our experiences with colleagues in other parts of the UK, and I hope that this will add value in some way to some of the discussions are taking place, particularly here. Thank you.

The Chairperson (Ms Maeve McLaughlin): I am just going to let all the witnesses speak before questions. Members should indicate if they want to speak, and if there is a specific sector that wants to answer, we will allow for that as well.

Ms Sally Johnson (NHS Blood and Transplant): I am the director of organ donation and transplantation for NHS Blood and Transplant, which is the organ donor organisation for the UK. Essentially, our role is to operate within whatever legislation each of the four UK nations pass. My role in this, whatever you decide to do, is to operate within that. I am particularly keen to make sure that, whatever decision is made, it will be operationally simple to implement and something that my staff will be able to do without it posing problems for them. It should be clear, but, above all, it should be safe — safe for the staff who operate within the system, for the families who may be giving consent to donation and for the transplant recipients.

I also think it is important that whatever is passed is likely to have the desired effect and increase organ donation, because that is, after all, what we all want, and that it is cost-effective. I mention cost-effectiveness because we have seen a lot of focus on consent and organ donation. We can get many donors, but, if those organs are not utilised, we will not get the transplants that we want. One of the other things that is on the horizon at the moment is new technology that turns previously unusable organs into usable ones, and choices will have to be made about how to use the available funding. That may be a choice that people want to consider alongside whether you do things to increase consent.

You have heard already about donation after circulatory death versus donation after brain death and that more donors, generally, arise from donation after brain death. The consent rates are generally higher in donation after brain death, and that is because there is the opportunity to talk to families after it has been demonstrated that their relative is dead. So you go through brainstem death testing, and, once the family has accepted that their loved one has died, you can talk to them about organ donation.

In circumstances around donation after circulatory death, a decision is made by the clinicians that further treatment is futile and treatment will be withdrawn. Obviously, following that, the individual will die. In order to discuss donation, you have to work with the family to make sure that they understand that there is no hope left for their relative. You then have to talk to them about organ donation and gain their consent to proceed. You then withdraw treatment, and the person dies and becomes a

donor if consent has been given. There are many challenges in that conversation, which is quite different to the conversation after brain death.

It is important to recognise that, although we hear lots of things about the UK's consent rate being poor, it is poor if you look at it in total, but I believe that we can show that our rate of consent to donation after circulatory death is very good. It is just that we have a very different model of end-of-life care from that in many other parts of the world, and it is significantly different from that in Spain. In Spain, they have very few donors after circulatory death; nearly all their donors are donors after brain death. That, to some extent, explains some of the consent rates. There is a longer period to have discussion, the relative is already dead when you have it and you get more organs per donor in those circumstances.

The ultimate aim, of course, of all this is not more donors; it is more transplants. We need to be cautious because, when we compare donation rates, as people tend to, that does not take into account different rates of organ utilisation. The UK has a high rate of utilisation. We generally find that about 5% of the donated organs cannot be used at the end of the day, which is significantly lower than the figure in Spain. It is important that people recognise that getting more consent will not necessarily lead to more transplants.

Moving on to the issue of consent, our research shows that it is more likely that people will give consent if families have discussed the issue before death. We also know that people who join the organ donor register and give express consent expect to donate and expect their families to support that decision, even if they have not told them, which they often have not.

Organ donation relies very heavily on trust, and you have heard from some of our clinical colleagues about how important it is to have the trust of the public, families and clinicians. That must be an important consideration in any legislation. Families are critical to the process. They will always sit at the heart of the process, because, without them, we will not know a lot about people's lives. Things about someone's personal and social behaviour help us to assess whether their organs are likely to be risky to transplant. We need families at the heart of all of this.

I was heartened to see how similar the Bill was to the Human Transplantation (Wales) Act 2013, which has already come into operation. In delivering an operational service, not ending up with four different lots of legislation makes it a lot easier for us to train our staff to operate on-call advice etc.

I have a couple of questions, particularly questions about asking a family to confirm that there is no objection and about how you define what an objection is. Is an objection somebody saying, "You wouldn't want my organs, cause I've spent too much time in the pub", or is it a considered conversation with the family, where, having had a really good discussion, people decide that they do not want to be organ donors? We experience all of those levels of objection, from the flippant comment to the very thought-through one. It is important to be clear about what the test is.

The other area that might bear further thought is the role of deemed consent from living adults where the donor lacks capacity. My feedback from clinicians has been that it is something that they have concerns about. If you had siblings and one of them had learning difficulties and lacked the capacity to give consent, would it be appropriate for that person to donate to their sibling if the other one had kidney failure? Those are the kinds of questions that people have raised with me. That is all that I wanted to say in relation to that.

The Chairperson (Ms Maeve McLaughlin): Thank you very much.

Dr Undine Samuel (Eurotransplant International Foundation): Thank you very much for inviting me. It is a great honour for me to be here. I will give you a little information about myself. I am the medical director of Eurotransplant, but in my former life I was a urologist and used to transplant kidneys. I procured kidneys and other organs. Then, I changed a little and went over to the German donation organisation, where my task as a transplant coordinator was to talk to the relatives about organ donation. In Germany, only donation after brain death is allowed, so I only have experiences of that kind of talk, but with consent it is almost the same. I have also had great experience with organ procurement.

Now I am responsible for organ allocation for eight European countries. Those countries all have different forms of consent. Most of them have presumed consent. Germany changed in 2012 to a so-called informed consent, which is a little like what is in your Bill and makes it necessary that you inform society of what transplantation and organ loss mean, what donation means and what the implications

are for the relatives and the families left behind. That has to be done every two years via the insurers. In Germany, it was seen as necessary to keep the public informed because otherwise relatives would not be able to give consent or know what consent means. I think that the most important thing when we talk about consent is that we have to inform the family in a very transparent way, give them the pros and maybe the cons if they did not have a yes or no from the deceased person and, when they have given consent, inform them of what happens if a donation cannot take place and what happens afterwards. That transparency would also create trust in the system because they would know that they will get all the information that they need.

Presumed consent is sometimes much easier for the one who asks for the donation, because then the question is "Do you know about an objection?" and not "Do you know how she or he thought about it?". That is something completely different. Most of the time, that is the argument for why presumed consent seems to be the best thing for everybody. Normally, in this case, my answer is not "Spain". It was mentioned that Spain had presumed consent in former times but did not have higher organ donation rates. They changed the system, more or less. When you build a house, you cannot build a house with one wall. You need more walls. Consent is a very important wall, but you need more than that. For example, information, as you have in the Bill, is one very important wall. What I also think is very positive — well, "positive" might not be the right word here — is that you have it in your Bill that you want to be informed every five years of what has happened in the last years and have ideas of what maybe should be changed for the future so that society can be sure that you are taking everything into consideration and are not just saying, "Let us work with the Bill" and that is it. You will keep track and keep society near to the people who work in the system. That is vital.

What struck me a bit about the Bill is that I never read the word "donation"; it always talks about "transplantation activities". The word "donation" itself is not in the Bill. When I first read the Bill, what came to my mind was "Well, 'transplantation activities' may be the words for 'donation' in Northern Ireland".

Another thing that we are sometimes addressed with is the question of organ trafficking, such as when organs are donated from living donors. Maybe you would bring your living donor from another country with you and say that it is your relative, the son of your brother or whatever. Society should make a very strong statement in every transplantation Bill that organ trafficking is something that is condemned. The question is whether the statement should be made in this Bill that Northern Ireland society will do everything to promote and support organ donation in this country and that it condemns organ trafficking.

We all know that not every transplantation has a good outcome. Part of getting consent is telling the relatives what the outcome might be and being very open in your conversation. All eight countries that I now have the honour to represent, more or less, although they have presumed consent, always talk to the relatives. There is no country where organ donation is just done without keeping the relatives informed. If you have a country where there is presumed consent and relatives say, "No, we do not want to do this. We cannot do this. We cannot cope with this situation" and the situation is not solved in really good, quiet talks, organ donation is not done, because it might harm overall organ donation and how it is seen in society. We have learned that that means that we have to be prepared to have another information policy in the country to keep society informed of what organ donation and transplantation are all about and what it means for patients on the waiting list. We also might become patients on the waiting list. We do not know, so how would we feel about that? I strongly agree with you that information is vital. Without good information, you cannot get a consent rate that grows higher and higher.

The Chairperson (Ms Maeve McLaughlin): OK, thank you all for that. Congratulations on the Act being passed in Wales, and I am pleased to have the opportunity to discuss it so early. In the Welsh scenario, you indicated that it is envisaged that there will be an increase of 25%, which is 15 additional donors a year. How do you reach that figure?

Ms Vernon: We arrived at that figure after a review of the international evidence. We reviewed a number of papers — the established research — that had already been reviewed by York University, plus new research, which was slightly more experimental. The figure was arrived at by taking all those into consideration and applying them to Wales and our consent rate at the time. We anticipate an increase of between 25% and 30%.

The Chairperson (Ms Maeve McLaughlin): NHS Blood and Transplant flagged up the issue of how you define objection and deemed consent from a living adult who may lack capacity. How did Wales address those issues?

Ms Vernon: The Welsh Act, in the same way as the Northern Ireland Bill, replicates in many ways some of the provisions of the Human Tissue Act 2004. It is similar to the way that it is worded etc. There is a provision in the Human Tissue Act that covers living donors who lack the capacity to consent. In order to make our legislation stand-alone legislation that sets in one place all the provisions for consent to donation, it was included in our Act.

Subsequently, Ministers made regulations that set out that the only circumstances in which the consent of a living donor who lacks capacity could be deemed is if it is in their best interests. There would have to be a process to establish whether it was indeed in that person's best interests. In practice, a court of law would first have to rule on the matter. It would then go to a specialist panel at the Human Tissue Authority, which would look at the case.

Although I very much take the point that Sally made that clinicians do not feel comfortable with the issue, theoretically that situation could arise. It is important to have a process that everyone would understand. Certainly, a best-interest test would have to apply.

The Chairperson (Ms Maeve McLaughlin): In the research briefing, reference was made to an authorising person. Is that specific to Scotland, or is it in the Welsh legislation that an authorising person would be specified as a medical or healthcare professional?

Ms Vernon: That is in just the Scottish Bill.

The Chairperson (Ms Maeve McLaughlin): OK. What would happen under the new legislation if a deceased person had agreed to donation expressly or through deemed consent, but, for some reason, some family members did not want to proceed? Is it a case of a family having to be, for want of another term, upset before the wish is granted? What would happen under current legislation?

Ms Vernon: The law sets up what would be lawful in a situation, so it would be lawful to deem the consent of the individual concerned so long as they were not one of the excepted criteria. That, however, does not make organ donation inevitable, compulsory or automatic in any way, because, as colleagues have said, it very much takes place in the context of a conversation with families. There is no measure or test about how upset that family needs to be. A very skilled conversation is carried out by a specialist who has been trained to understand what the family's objections might be to organ donation. Even though it might be lawful to proceed with organ donation because you have consent — either expressed by the individual or deemed — it still has to be carried out in the context of that conversation and very carefully taken through. No law provides for that, because that is a practical issue, which I am sure Sally will want to say a bit more about.

The Chairperson (Ms Maeve McLaughlin): This is, obviously, around sensitivity to a family. In your experience, how has that been reflected in legislation? Given what you say about how difficult that is to measure, is it something that needs to be specific in the Bill? The need for sensitivity towards the family, how you measure that and how you monitor or progress that are coming up increasingly as issues.

Ms Vernon: That was discussed when our Bill was going through the National Assembly for Wales, but I think it was felt that, to a great degree, taking a family through the conversation is a matter of judgement and skill. The law can only set out what is lawful; everything else becomes a matter of sensitivity and judgement, and it is difficult to put a measure of that in an Act. I think it was discussed and acknowledged that it was certainly an issue, because it is a very sensitive time for the families who are being approached.

Ms Johnson: It may be helpful if I explain how our nurses would frame a conversation. Under the current law in Northern Ireland, if you were on the organ donor register, our nurses would go to your family and tell them that you were on the organ donor register and wished to become a donor if the circumstances arose. They would ask the family whether they knew that and ask them to help the nurses make that final wish a reality. If you were not on the organ donor register — if you had not recorded a wish to donate — we would ask the family to make the decision on your behalf. They do not have to make it on the basis of what the dying person's wish was, but, under the law, their

responsibility is to take that decision for them, unless, as you have been able to do since June, you have recorded a decision not be a donor, in which case we would simply be telling the family that you had recorded that decision and, unless they knew that the person had changed their mind in the intervening four months, in this case, we would not be talking any more about it.

In Wales, we explain that everybody has four choices. They have a choice to decide to be an organ donor; a choice to appoint a representative, who could be a family member or somebody else, to make the decision on their behalf; a choice to decide not to donate and to record that decision; or the choice to decide that they are happy to be a donor but do not want to join the organ donor register, in which case their consent will be deemed. Each of those four states is equally valid. If somebody had chosen to take no action, we would say to the family, "The law in Wales is that, if they have not recorded a decision not to donate, their consent is deemed, and, unless you can demonstrate clearly that they recorded an objection, the expectation is that they would go on to be a donor".Clearly, that is a very simplified way of describing a very complex and sensitive conversation, but that is how you would frame it from a starting point in order to make sure that the family understood where their range of decision-making is. In the case of a very upset family, we would not push to comply with what the law allows. We would want a good outcome for the family because they are grieving, and it is important to get it right for them. Equally, it is important to get it right for confidence in the organ donation system as a whole. This is a delicate matter, which is why I think that you can legislate for deemed consent, but there is a difference between legislating and enforcing. We need the family to be happy with the outcome, and we need their expertise and knowledge of their dying relative to tell us about the person's lifestyle and other things that might affect organ safety. Those things will always be central to that discussion.

Mrs Dobson: Thank you all for your briefing. I will start with you, Sally, if you do not mind. It was lovely to meet you and your team earlier this year. For me, it was a surreal experience to go into the room where the call would have come for my son's kidney, and I will never forget the feeling that I got there. Well done on the recent updates to the register that took place in the summertime. I am sure that that took many months of planning to get off the ground.

In your presentation, you said that the legislation could result in an additional 36 transplants a year on the basis of 14 extra donors. Will you talk us through those estimates and the increased cost of transplants? Equally, we will hear from our Assembly researcher later about the increased savings for our health service here and the wider economy, not to mention the benefits for patients.

Ms Johnson: I am not an expert on the statistical modelling that came up with those figures. I think that you have received a paper from us previously — the Bill team certainly has — to explain how they were arrived at. We used the same modelling as we did for Wales, which basically makes assumptions about the levels of consent you might achieve, the size of your donor pool and, therefore, how many donors you might end up with. We then translate that using our standard normal organ utilisation rates to give the number of transplants that you would end up with. Obviously, you have to take into account your starting point in this country, which is already a pretty high rate of organ donation. The challenge for us is more the size of the donor pool than anything else. People often do not appreciate that there are only some 5,000 people in the UK who die in circumstances in which they can become an organ donor, and, as 1,300 already go on to donate and some who do not donate will not have useable organs, the actual numbers for us to convert into consent are relatively small. Does that answer your question?

Mrs Dobson: Yes, it does. I jotted down a few of the phrases that you used. You said:

"I was heartened to see how similar the Bill is to the [Welsh] Act".

I could not agree more with your comment that:

"Families are critical to the process. They will always sit at the heart of the process".

That is the essence of what we are trying to do.

I know that, when we met previously, you placed a lot of emphasis on the role of advocates carrying out the wishes of their loved ones. Could you outline your thoughts on how advocates could help in preserving the gift freely given?

Ms Johnson: Do you mean appointed representatives?

Mrs Dobson: Yes.

Ms Johnson: Appointed representatives are an interesting option. So far, 18 people in the UK have nominated and signed up an appointed representative. It is not easy to do, because you cannot just write their name and address on the organ donor register. They have to be properly witnessed and so on, otherwise we cannot hold their details. I am reasonably confident in saying that, to date, not a single member of my staff has approached a family where there has been an appointed representative.

I do not know whether people feel that they do not need to take advantage of it. It has been in the Act since the Human Tissue Act was passed, although there was no method of recording the names until the new register came into place. We have no experience of whether that makes any difference, whether appointing a representative removes the burden from a family in making a decision — it can be burdensome — or whether it might leave a family feeling, if you had appointed somebody else, that there was a conflict between the appointed representative and the family members. The reality, however, is that there is often quite a lot of conflict within families, never mind with appointed representatives.

Mrs Dobson: That is very interesting.

Ms Vernon: Can I add something on that point that might be useful?

Mrs Dobson: Of course.

Ms Vernon: When we were consulting on our Bill, there was quite a bit of discussion on appointed representatives. Several members of faith communities felt that a provision on appointed representatives might be useful for them, because, on the question of organ donation, people might like to consult their faith leader. As Sally said, even though, in reality, a very small number of people have actually appointed representatives since the organ donor register was amended to allow for a record to be made, those are the sorts of scenarios that people painted for us where it might be a useful tool.

Mrs Dobson: May I ask you a few questions, Patricia? I want to say from the start that you beat us to it: Wales got there first. I congratulate you on that. Will you pass on my congratulations to Mark Drakeford and everyone in the team? We had an organ donation event here yesterday to encourage people to have the conversation. From speaking to so many representatives from our wonderful charities in Northern Ireland, I know that they have nothing but admiration and praise for your work in making Wales the first region to introduce this — well done. We would like to have got there first, but, as I say, you beat us to it.

Your briefing refers to:

> *"a revolution in public attitudes and behaviour".*

Will you talk us through the provision in the Welsh Act for an education programme and public awareness campaign? In this Bill, clause 1 is about education, which is undoubtedly crucial. What form would a campaign take, for example? You spoke about the media and Twitter. Will you take us through how that has panned out in Wales?

Ms Vernon: Similar to your Bill, our Act contains a duty on Welsh Ministers to make sure that information is provided to the public, particularly the circumstances in which consent could be deemed. There is a special emphasis on making sure that people are provided with that information and every reasonable effort is made to put such information before the Welsh public. It also contains a duty to conduct a public information campaign annually after that and to lay a summary of the activities that were conducted before the National Assembly for the first five years of the operation of the new law. In my paper, there are links to the two annual reports that we have laid before the Assembly so far. In the last two years, there has been an extensive and intensive amount of public awareness.

Mrs Dobson: In the lead-up to the Bill.

Ms Vernon: In the lead-up to the Bill, as you would imagine and expect. We built that up gradually. You could not have gone in immediately with a lot of very intense messages, because it might have lost its impact after a while. It was built up gradually, and the messages changed to keep them fresh and so on.

Mrs Dobson: I enjoyed the Twitter countdown: two days to go, one day. It was very good.

Ms Vernon: Yes, we had some recognisable themes, motifs and logos, with the hope that people would start to recognise the campaign flavour. We have also had a lot of different types of media activity, ranging from roadshows to flash mobs. There have been all sorts of things to try to keep people's interest fresh. We tracked public awareness of all that work, and awareness of the change in the law is now at something like 72%. When the Welsh public are asked whether they have seen something before, 72% say that they have. There is quite a high level of awareness.

Now that the Act is in force, the obligation on us does not stop there, and we will need to continue to make sure that people are aware that this is the law in Wales. A number of activities will continue over the next year and each year after that. One key thing that we will do is to write to every person who is just about to reach their eighteenth birthday. NHS systems in Wales will generate a letter to remind the rising 18s that the system will apply to them when they reach the age of 18. That is one example of what we do.

Mrs Dobson: It has been excellent to watch it unfold. Your countdown reminds me of a New Year's Eve countdown — a new dawn, in effect. I commend you on the education and social media, which have been very impressive.

When Wales started out on this journey in 2012, public support in favour of the Bill stood at 49%, and, in June 2015, it stood at 67%, which is a considerable increase. In Northern Ireland, we are at approximately 62% in favour. Given that your Bill was brought in by the Government rather than by a Back-Bench MLA, as is the case here, what led to the rise in public support?

Ms Vernon: There has been a lot of media coverage. ITV Wales has made a big effort to make people aware of the change. We reviewed one piece of research that seemed to suggest that, the more people knew about the change, the more supportive they tended to be. As awareness has grown, support for the change has gradually grown. The number of people who are against it or do not know what they think has started to go down. We have seen gains in that way.

Mrs Dobson: So you have seen a change in public support, coupled with the Welsh Government getting fully behind it since 2012, when they decided to go with it. The Welsh Government have thrown their weight behind it, and you have been fortunate that they brought it in.

As you said, international evidence shows a clear link between opt-out countries and increased organ donation rates: have you looked at the system in Belgium since it was introduced in 1986?

Ms Vernon: I should say that our review of international evidence suggests that there is an association between the countries with assumed consent-type systems and an increased donation rate. I could not go as far as to say that that is the cause of the increase in the donation rate, but, taking all other things into account, it certainly appears to be a contributory factor. We have been in touch with colleagues in Belgium. The lead clinician in Belgium, Luc Colenbie —

Mrs Dobson: I also met him, and he was impressive.

Ms Vernon: — spoke at our conference in Wales in September. There are some interesting lessons to be learned. Belgium brought in its system 20-odd years ago, and a lot of things are different now. There are interesting things to look at in Belgium, and we kept tabs on that.

Mrs Dobson: Given that your experience in Wales is also about effecting cultural change, do you agree that education and legislation go hand in hand?

Ms Vernon: It is not necessarily possible to separate the two. In order to deem consent validly, people need to be informed about it, but you will also have the situation of it working the other way round. People being informed about it might affect the donation rate. They are very much two inseparable pieces of the jigsaw.

Mrs Dobson: I am conscious that I do not want to hog all the questions. Thank you very much.

Mr Easton: Thank you for your presentation. It was very impressive. Dr Samuel, you talked about organ trafficking. Should there be something in the Bill to make that illegal? Were you referring to people being paid to donate one of their kidneys?

Dr Samuel: There should be a sentence or statement in the Bill saying that society in Northern Ireland is against organ trafficking and condemns it. It should be a part of any transplantation Act. This Bill also refers to consent for living donors. Organ trafficking is with living donors, not deceased donors. That should be part of this Bill because the Declaration of Istanbul is signed by so many states. The Eurotransplant website has a disclaimer that we condemn it. The easiest way to do it is to have one sentence in your Bill.

Mr Easton: Is it in the Welsh Act?

Ms Vernon: No.

Ms Johnson: NHS Blood and Transplant is a signatory to the Declaration of Istanbul, and, unlike Eurotransplant, it is on our website. We have always felt pretty confident that, although people might try to traffic for the purpose of organ transplantation, regulation in this country is very tight. We are pretty confident that the process that the Human Tissue Authority goes through would weed out anyone who was doing that. We found that people were more likely to go abroad as transplant tourists than to bring living donors to this country.

Mr Easton: Is there evidence of that?

Ms Johnson: Do you mean is there evidence of people going abroad?

Mr Easton: Yes.

Ms Johnson: Yes, there is.

Mr Easton: The figures show that, for the size of the population in Wales, there is quite a low opt-out rate. Around one million people were left on the theoretical list. To inform and educate the public in Wales, do all those people get a letter to say that they are on the list and there is an option to opt out if they want to? Is that how it works?

Ms Vernon: Over one million people in Wales were already on the organ donor register. Their decisions are still on the register, although, if they wanted to, they could change their mind and alter that decision. The options are that they could change it to an opt-out or remove their name from the register and have their consent deemed. They will have the card or letter that NHS Blood and Transplant sent them. However, if people are registering a new decision from 15 June, when the new organ donor register opened, everybody gets a letter confirming their decision from NHS Blood and Transplant. There is a definite record that you are on the register.

Mr Easton: Potentially, there are one million people. As people get older, they die, unfortunately, for various reasons. How do you cope with the number of people whom you have to ask about their family members' organs?

Ms Johnson: The numbers are tiny. In the UK as a whole, half a million people die every year, but only some 5,000 die in circumstances in which they can be an organ donor. They are nearly all in accident and emergency or intensive care departments. We train staff in those departments to identify when somebody who is dying could be a donor; that is the key first step. If you do not get your clinicians to identify potential donors, it does not matter how good your legislation is, because you will not be able to get any organ donors. That is the key point.

If they are potential donors, they will need to be brainstem death tested or a conversation will need to be had with their families about the futility of further treatment and the withdrawal of treatment. Only after that has happened is there a conversation about whether they should become an organ donor. The numbers are quite small. If it is helpful to the Committee, I can look at the potential donor

numbers for Northern Ireland specifically. You are talking tiny numbers: some hospitals will have fewer than 10 potential organ donors a year.

Mr Easton: That surprises me.

Ms Johnson: That is why it is really difficult to get large numbers of transplants; people generally do not appreciate how difficult it is to be an organ donor. Never mind the consent issue, it is difficult to die in the right circumstances. The more we improve people's health, whether that is through public health measures or better care in intensive care, the more the number of potential donors shrinks. That is the case every year.

Ms Vernon: As none of us knows the manner in which we will die, it is important that as many of us as possible think about what our organ donation decision would be. That is why the issue of consent is important. Most of the consent will never be used, because most of us will never be in that position. However, it is still important to know what the decision would be if you were ever in the position.

Ms Johnson: The people who join the organ donor register tend not to be the people who die in circumstances where they can become an organ donor. You are more likely to join the register if you are well educated, better off and tend to have better health. If you do not join the register and live a more chaotic lifestyle, you are more likely, inevitably, to die unexpectedly, possibly younger than you would otherwise have expected, and to be able to be a donor. That is the very group that does not have the conversation.

Dr Samuel: In Germany years ago, a very thorough examination was done. Germany does not permit donation after cardiac death (DCD); there is only donation after brain death. They concluded that around 0·8% of patients who die in hospital were potential organ donors. I say "potential": that does not mean that they will become organ donors once they are brain dead. The number is very small, and, with such a small number, if you miss two thirds because, for example, the hospital staff are not aware of the situation, are not informed or are under too much stress and do not get support in the hospital, that is a huge problem. Consent rates outside the hospital among the relatives do not change a lot. You have to think about the staff who work in the hospital, who also have to give consent and support to organ donation in the hospital. That is also very important.

Mr McCarthy: As we go along, I am getting more confused — more intrigued, perhaps. I have three questions. If they apply to you, maybe you will answer them. There was a reference to donation rates and being unable to use some organs. What is that all about?

Ms Johnson: Why do we not use all the organs that we get consent for?

Mr McCarthy: Exactly.

Ms Johnson: Some of them, when they are examined, turn out not to be safe to be used. We do donor characterisation. Before a person has their organs removed for transplantation, we gather 590 separate pieces of information about the dying person to see whether their organs will be safe to be used.That is one of the tasks of my specialist nurses. That information is sent to the transplant centre, and they will be asked to consider an organ from that person. We provide the blood group, the tissue type, the lifestyle that they have had and how they died — a whole raft of information. The transplant unit then looks at the people on its waiting list and at whether the organs from that donor would be suitable for its recipients. If it thinks that they would, we will then remove the organs.

In the process of removal, we may find things that nobody knew about. We may already have consent, but we may be proceeding to remove the organs and discover that there was cancer or something else wrong with the donor that makes the organs unusable. That might rule those out. There are also circumstances in which the organs look OK when they are removed, but when you get them to the transplant surgeon he might examine them further and say that it is too great a risk and not use them. That is quite a small number of cases in this country, but as we have increased our numbers of donors after circulatory death and are using older and older donors than we have in the past — those are what are called extended criteria donors — the organs are much riskier to use and there is a higher rate of them being unable to be used. That is why you have a number of organs that we have consent for but never get transplanted. We try to keep it as low as possible, but it is never zero.

Mr McCarthy: OK. You also mentioned your nurses going to the families. On the back of what you have just said, surely it must be devastating if a family has gone through the consent and agreement processes, only to be told that the organs cannot be used.

Ms Johnson: It is, but we always tell them beforehand that there is a risk that they may not be used. There is also a risk if consent for donation is given for a patient after circulatory death, and then treatment is finished for those patients and they are allowed to die. As they die, their organs deteriorate. Unless they die within three hours of the point at which treatment is withdrawn, the organs will not be safe to use. We have to explain that. We take families through all the potential scenarios and ask what they would want to happen if that happened and whether they would want the organs to be used for research etc. None of it is done without the family having a really thorough understanding of the potential outcomes.

Mr McCarthy: Finally, we are talking about the UK. You are the UK representative, which includes Northern Ireland. There are 60-odd million people in the UK. I do not know what the waiting list is for organ recipients.

Ms Johnson: It is about 6,600 at the moment.

Mr McCarthy: That is from a population of 67-odd million. Why is there such a waiting list? We heard from somebody who has been waiting years and years for an organ.

Ms Johnson: There are a number of reasons. Some people will wait a long time because getting an organ that matches their characteristics is very rare. You might have somebody who is 100% sensitised and has a rare blood group and, in 10 years, there may be two or three offers of an organ for them — and they may not be at the top of the list. There is a rarity issue, and if we only get 1,300 or 1,400 donors a year and have 6,000 people waiting, even though they can give more than one kidney — kidneys are the biggest area of waiting — we cannot match the demand. However, I do not think that there is a country in the world that can match demand. If every organ could be used, I suspect that you would transplant more people. In Northern Ireland, it is very positive that the numbers waiting are falling and the numbers on dialysis have also fallen. Across the UK, the treatment for 50% of people with renal failure is a transplant rather than dialysis. That is much higher than it used to be. What we are trying to do, really, is to make sure that anyone who could benefit from a transplant gets one, but it is a constant battle to find enough organs.

Mr McCarthy: Finally, I am somewhat disappointed when you say that, of the people who have signed the organ donor register, many will probably not be used, because I would be one of them. Are you telling me that after all my generosity in giving my body, at the end of the day you are going to say that you do not want it?

Ms Johnson: Well, you may be lucky enough to die in your sleep at home.

Mr McCarthy: Hopefully.

Ms Johnson: Absolutely. You cannot be an organ donor then.

Mr McCarthy: Gosh, there we go. *[Laughter.]* End of story. Really?

Ms Johnson: It is not that we are not grateful. The reason that we want people to join the register is that if you are one of the unlucky people who dies suddenly in circumstances where you could be a donor, it makes life so much easier for your family, because they know what you want. It just takes all the anxiety away.

Mr McCarthy: But no one knows.

Ms Johnson: I am afraid that it is a very odd lottery.

Mr McCarthy: Good luck in your work, because it is vital, and there is a lady there who has benefited enormously and is living proof of the work that you do. Good luck to you all.

Ms McCorley: Go raibh maith agat, a Chathaoirligh. Thank you very much for the briefings today. It is a fascinating subject, if it was not so tragic in ways. It is tragic, and it is good. It is difficult discussing circumstances that are tragic for somebody, and the sensitivity required to deal with that is — I cannot imagine the skill that it takes to deal with that, but I take my hat off to the people who do that.

Just on the last point that Kieran was talking about there, where people are donor-card holders but still the likelihood is that your organs will never be used. Does it often happen, or would it ever happen, that someone is a cardholder but their family members object?

Ms Johnson: About 100 people in the UK every year are on the organ donor register, and their families on the day feel unable to support their decision. It is usually because they have not told their family that they have joined the register. You already have the shock of coping with the loss of your relative. Then you find out that they were on the organ donor register, and you knew nothing about it. What people often say to us is, "Well, they cannot have been that serious if they did not tell me". When we ask people why they do not tell their families that they have joined the organ donor register, they say, "Well, I did not tell them because I did not want to upset them". It is a real challenge. We want everybody to talk about this just in case, so that people do know what they want and it does not come as an awful surprise.

Ms McCorley: I can see that. Did I hear correctly earlier? Did someone mention previously unusable organs turned into usable organs?

Ms Johnson: Yes. There is new technology. Perhaps the best example is that we do not generally transplant hearts from people who have died following circulatory death. The heart stops beating; blood stops pumping. We do not use the heart — we use other organs. We have now, with the use of a very clever machine which replicates as far as possible what it is like for the heart inside the body, transplanted 13 hearts from people following circulatory death. One of them was waterskiing within a month of his heart transplant. I met one of them recently who had a transplant in October and looks fantastic. New technology is making a real difference in cases where surgeons would previously have said, "That is too high-risk. I could not take an organ from that person". I am sure that Undine will be able to back me up on this. That is the kind of thing that transplant surgeons are really excited about. There is the possibility in the future of being able to take organs where we have got consent and actually use them.

Dr Samuel: Or even make them better, in the machine, through the machine and through the new techniques. That is also what is done, not so much with the heart, but with the lungs. We put the organ in a machine — a very big box with oxygen and everything — and you can watch the organ and treat the organ in this box and try to make it a little better, because, for example, brain death is a big stress for every organ. Giving this organ a little bit more rest of only a few hours, not a day, might give you the chance to decide whether this organ is still transplantable or not. Sometimes it looks not so good, but you think that it might get better, so the beginning of a new therapy, more or less, might give you the opportunity to watch this organ work over a few hours and then take a very solid decision that, yes, this organ can have the possibility to help the patient. We should never forget that transplantation is a chance, with a little bit of an uncertain outcome. We will never know exactly whether this organ will work perfectly or whether it will not work any longer or will work for only a few weeks. This is a chance for the patient, and every doctor will take very seriously the decision on whether this organ is a transplantable organ or not.

Ms McCorley: You said that you deal with transplantation in eight European countries.

Dr Samuel: Eurotransplant does organ allocation in eight European countries: Belgium, the Netherlands, Germany, Luxembourg, Austria, Slovenia, Croatia and Hungary. That means that we have a cross-border organ exchange and the possibility that we work together.

Ms McCorley: That is eight cooperating nations, then.

Dr Samuel: More or less. You have those eight countries. For example, if Northern Ireland were part of Eurotransplant and had an organ donor, you would report the organ donor to us and the organs that were consented. We would then look first at the overall high urgency list in all Eurotransplant member states, because the cooperation is to find for the highly urgent patients on the waiting list the best suitable organ, including from outside your country. That offers your patient the possibility to get

transplanted faster. After that is done, you have approved combined organ transplantations, where patients need not only one organ but two or three organs. They are high-immunised patients. Then you go to the patients who are on the country-specific waiting list. If there is no suitable recipient for the organ under the extended criteria, for example, you then offer this organ to all the other countries that are in your community, so to speak. Eurotransplant tries everything so that not one organ that could maybe be transplanted cannot be transplanted. As Patricia mentioned, it is a difficult task because you always have to have in your mind whether you are going to harm the patient — the recipient of the organ. Is this organ still transplantable? There is also the time that it takes getting it from country to the other country. That adds the so-called cold ischaemia time outside the body. It is a very responsible decision that you have to make.

Ms McCorley: Are there similar rates of donation among those eight nations?

Dr Samuel: All the transplant Acts more or less concern not just consent; that is different. Also, brain death confirmation is a little bit different. Donation is allowed after cardiac death in some countries and not in others. In Germany, for example, it is not allowed. Eurotransplant has to take note of that, and organs from a donor who has donated after cardiac death are not allowed to be offered to German patients on the waiting list. Within our system, these are business rules, and we take care of that. There are differences in the transplant Acts.

Ms McCorley: What are the differences in the percentage of the population who are voluntary donors — people who are cardholders, let us say? Is that similar between the countries?

Dr Samuel: No. There are very big differences. For example, we think that, this year, Croatia will have 35 donors per million population. It will maybe even exceed Spain. I do not know the numbers from Spain. Germany, on the contrary, has around 10·8. In 2012, there was a big discussion in Germany, so the organ donation rates dropped dramatically. Also, the numbers of patients on the waiting list are different. There are around 10,000 patients on the waiting list in Germany. In Eurotransplant, overall, in all the eight countries, there are 14,000 patients. So there are 10,000 in one country alone. Organ donation rates; patients on the waiting list; what can be transplanted — there are big differences. One country — I will not say which — does not accept so many organs, because it can cherry-pick. It has more offers, so it tries to get the best organs for its patients on the waiting list. The other organs are then maybe transplanted in another country. That is also a positive thing, because through that organ getting transplanted in another country, the other country learns what is possible, because we have the outcome of the patient who received that organ. So, for the whole community, this is — well, "positive" might not be the right word for that, but we learn from it. You should always bear in mind that a transplantation should not be a greater risk for the patient on the waiting list than the normal risk in getting on the waiting list. We should not add a further risk in being too optimistic with an organ that maybe it is not useful or suitable for transplantation.

Ms McCorley: Overall, we can see that the aim is to increase the pool of voluntary donors. On a final point, Sally, you said earlier that the people who make the best donors — my terminology is probably not great. The people who are most likely to be able to donate — that might be a better way of putting it — are the least likely to be cardholders, because educated or healthier people tend to register and, I think you said, people who live more chaotic lifestyles do not. Should there be education campaigns targeted towards people who might be more likely to be better donors?

Ms Johnson: We started doing that in England, and, in particular, we targeted people over the age of 50 who commonly say to us, "You wouldn't want my organs; I'm too old", not realising that the average age of a donor is over 50. A lot of it is about trying to counteract those myths. A number of people have said, "You wouldn't want my lungs; I'm a smoker", but 40% of lungs that get transplanted come from somebody who smoked. If you need a lung transplant, you would be better taking one from a smoker than waiting for one from someone who has not smoked, because you will not live to get one, probably. As you have heard, it is a real balancing act. That is why you have got to get everybody to think about it, say yes and be proud to donate, if they can.

Ms Vernon: We have been tracking public awareness in Wales through our communications campaign. One of the benefits of doing that is that it has allowed us to target different areas of Wales where awareness was lower or people were not discussing the subject. We have been able to take specific action and target those areas of Wales with more information and different types of information. That has been one benefit of part of the work that was put in place to support our new law.

Mr McKinney: I apologise for not being in for the start of your presentation. I welcome you here and thank you for your contributions. How did consultants and those at the front end view the Welsh legislation initially? Had they difficulties with what was being proposed?

Ms Vernon: The BMA in Wales has always supported a move to the opt-out system. Perhaps, to begin with, some of our clinical colleagues were a bit more sceptical about whether it would work, and perhaps some of them remain so. There are a couple of things to say. We did some research with NHS staff in Wales. There was considerable support for the law change, but it depended on the staff group. It varied amongst the different staff groups. As we have gone on with the work, we have worked very closely with colleagues in NHSBT and the organ donation committees in Wales, and we have seen people become more and more comfortable with the idea, and thinking, "Yes, it probably can work". I am sure that Sally will want to add something, but I take the message from the clinical teams now that they are approaching this with some confidence. They feel equipped to deal with it. At first, perhaps, concerns were expressed, but that has diminished as we have gone along and more information has been made available.

Mr McKinney: Were those concerns similar to some that we have been hearing — that it might lead to a diminution in the amount of people? If that was the case, what did you do or what are you doing to assuage those concerns?

Ms Vernon: Similar concerns were probably raised at the time that our Bill was going through. We tried to involve the people who directly work within the organ donation world and made sure that everybody was involved in the developments, particularly the training and all that side of things. I do not think there is any evidence that it has resulted in any decrease in the organ donation rate per se. In fact, I think that this year our organ donation rates are keeping up quite well. So we probably did some have similar concerns raised, but they have grown less as time has gone on.

Ms Johnson: Initially, there was apprehension and fear that it might not help or it might be a distraction. It was a steady process, and there was a lot of engagement from clinicians all the way through so that they understood what might happen and were able to say, "Well, I don't think that would work" or "I've got some concerns about this". Taking the clinicians with the Welsh Government was positive.

Mr McKinney: We have a conflict around deemed consent and family. We want to arrive at a balance, but a balance that works and not just satisfies individual constituencies. It has to work to be effective. With regard to deemed consent and family, did you explore fully and actively giving the family the biggest voice and then arrived at deemed consent, or did you exclude it? Can you shape that for me?

Ms Vernon: That was one of the most important bits of the discussions around our Bill when it was going through. Our Minister actively sought out views on that. We crafted an amendment, which is in the Act. It is based very much on the views of the deceased; those are paramount. The views of the deceased reign supreme. That includes the ability of the person when they were alive to choose to do nothing and have their consent deemed. That is an important factor.

We are not necessarily asking the family to affirm anything. We are starting from the default position that consent is deemed unless any of the other scenarios apply. You will have noticed that our Act has one clause covering consent from adults. Unless their express consent is given — it is exactly the same sort of table as is in the Northern Ireland Bill — then consent is deemed to be given, unless, in addition, the family can say that they know that the person did not want to be a donor.

There is a reasonable person test in the Welsh Act as well. That provides for a conversation to be had about how the family knows the considered view of the deceased. That was our position, and that was how we arrived at it. There was a lot of discussion and meetings convened with a number of stakeholders, and that was the position that was arrived at and that people felt comfortable with.

Mr McKinney: The thing that struck me most was the tiny numbers contribution. We are having such a huge debate about something that is tiny numbers. Is it right to have this debate to this extent, given the tiny numbers, or would it be wrong not to have the debate?

Ms Johnson: That is an interesting question. If I was one of the people waiting, I would hope that you had the debate, even if you did not pass the law. I would hope that you had the debate so that everybody talked about it and more people said yes.

Ms Vernon: I agree with Sally. Also, there is a responsibility towards the people waiting to view it from their point of view. There is a huge emphasis on what it means for the donor and their family, and that is absolutely right. There is an equal responsibility towards those waiting, and dying while they are waiting. That is very much where we came from during discussions about our Bill.

Ms Johnson: It is interesting that families who do not know what their relative wanted tend to default to no, because they think it is safer to say no. What deemed consent does is say, "Look, your relative effectively made this decision to become a donor but didn't make a very strong decision, because they didn't register express consent. Equally, they didn't make a decision not to be a donor, so they appear to be happy to be a donor, unless they've told you something else". It takes away some of the difficulty for the family about making that decision. If you can make it easier for the family on that day, and make them proud about the decision that their relative has made, whether express or deemed, you should end up with a family that feels proud of the outcome, and more people alive through transplantation.

Mr McKinney: Also, those you are asking may or may not have opted out or in, so they may understand that discussion more clearly.

Ms Johnson: Yes.

Mr McKinney: Thank you very much.

The Chairperson (Ms Maeve McLaughlin): OK, folks, that was really useful. We will certainly be reflecting on and learning from what we have heard. I was particularly interested in the whole notion of family sensitivity and deemed consent and some of the ways that you have advanced that. Thank you for taking the time. I certainly appreciate it. Thank you very much.