Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

OFFICIAL REPORT (Hansard)

Human Transplantation Bill: Intensive Care Consultants and Belfast Health and Social Care Trust

6 January 2016

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)
Mr Kieran McCarthy
Ms Rosaleen McCorley
Mr Michael McGimpsey
Mr Daithí McKay
Mr Gary Middleton

Witnesses:

Dr Paul Glover	Belfast Health and Social Care Trust
Dr George Gardiner	Critical Care Network Northern Ireland
Dr John R Darling	Ulster Hospital
Dr T J Trinder	Ulster Hospital

The Chairperson (Ms Maeve McLaughlin): Dr John R Darling, Dr T J Trinder and Dr George Gardiner are consultants in intensive care medicine, and Dr Paul Glover from the Belfast Health and Social Care Trust and regional clinical lead for organ donation. You are very welcome, and thank you for attending today. I invite you to make a presentation, and then we will have members' questions and comments.

Dr Paul Glover (Belfast Health and Social Care Trust): Thank you for inviting us here today. I speak on behalf of the Belfast Health and Social Care Trust, but I am also, as you said, regional clinical lead for organ donation.

I will put the purpose of today's meeting in context. The purpose of the proposed Bill is to increase the number of organ donors in Northern Ireland. Last year, we had 48 local deceased donors, which equated to 26·2 per million population (PMP) and gave us the highest rate of deceased donation in the UK. The rest of the UK had approximately 19 donors per million population. In fact, Northern Ireland has one of the highest international deceased donation rates. Furthermore, while the total number of donors in the UK fell last year, for the first time in 10 years, we saw a continuation here of the upward trend, and we achieved our highest ever number of donors. I am pleased to say that, at this stage, we are already ahead of the number that we had for the same period last year, and it is hoped that we will achieve 50 deceased donors for the first time by the end of March of this year. However, we have not witnessed any overall improvement in the consent rate. It remains at about 60%, which means that four of every 10 families who are approached for consent will not give it.

The increase in donors that we have seen here is really being maintained by the development of donation after circulatory death, and it is likely that any further increase will come from that pool of donors. It is also important to be aware that there are significant variations in consent across the UK: for example, from April to September last year, in the 12 NHS Blood and Transplant (NHSBT) regions, the consent rate for donation after brain stem death varied from 52% to 91%. In fact, three of those regions had a consent rate of greater than 80%.

The biggest obstacle to increasing donor numbers remains consent. While being on the organ donor register (ODR) is highly predictive of a family giving consent, the majority of our donors are, in fact, not on the ODR. Consent and the factors that influence whether families give consent are complex issues, ranging from something as simple as the environment where the consent discussions take place to something much more complex, such as an understanding of the concept of brain death.

Of the 30 families approached in Northern Ireland from April to September past, 20% did not give consent because their relative had already expressed a wish not to become a donor; seven families were not sure whether their relative would have agreed to donation; and a further three were divided over the decision. Those three scenarios accounted for over half of the refusals. Families will give a range of other reasons, such as not wanting the person to suffer any further, the length of the donation process and not wanting surgery to the body.

The Human Transplantation Bill proposes to address the consent issue and increase the number of donors by changing to a system of deemed consent. In essence, any individual who has not expressed a wish not to donate their organs will be assumed to have consented to donation. However, that is not consent as we, as clinicians, would consider it in any other aspect of healthcare, because autonomy is one of the four principles of medical ethics. This model of consent has been adopted in many countries, including, on 1 December, Wales, and appears on the face of it to be the solution to the issue of relatively low consent rates. However, there are issues at multiple levels to be considered.

First, the evidence from the published literature is equivocal on the role that legislation changes have played in affecting consent rates. In virtually all cases, packages of changes were implemented, and it is difficult to tease out which have been the predominant influencers of change. Direct comparisons between countries are difficult because of differences in healthcare systems, population size, community attitudes and where they started from. While Belgium demonstrated a marked increase in its consent rate that was coincident with a change in consent legislation, there are also examples of no significant improvement, such as in Finland after 2010; a decrease, as happened in Chile; and the abandonment of opt-out in Brazil and France. Therefore, the context and culture of the society in which the legislation is introduced are also of relevance. Predominantly white English-speaking countries — the USA excepted — have consistently low consent rates compared with many European countries, and black and Asian minority ethnic groups in the UK have particularly low rates.

Everyone will be familiar with organ donation in Spain. Its donation rate is 36 per million population, and that is led by Rafael Matesanz. The Spanish model is multifaceted. Officially, Spain has a presumed consent system, but Matesanz is very clear that the success there is due to the donation infrastructure and the construction of a positive social climate for donation. Close attention to the mass media and specific communication policies have been instrumental. What Spain has shown is that the highest levels of organ donation can be obtained while respecting the autonomy of the individual and family and without presumed consent. Indeed, on the day on which the legislation was introduced in Wales, Matesanz was quoted on the BBC Wales website as saying that law change was not enough.

Deceased organ donation in Northern Ireland falls exclusively within the speciality of critical care. Without critical care, there would be no deceased donation, and the patients remain our responsibility until the time of the retrieval operation. The previous Public Health Agency (PHA) survey highlighted the fact that the clinicians closest to dying patients who become deceased donors have the greatest concerns about any proposed legislative changes. The concern of many clinicians is that any system of presumed consent might have a negative impact on our extremely precious and sensitive relationships with families, and that must not be dismissed lightly, because we do not wish families to perceive any potential breach of trust.

Moving on to the specifics of the Bill, we feel that society's attitudes to organ donation must change if there is to be a sustained improvement in donation rates and for donation to be seen as the norm. Clause 1 is fundamental to that. Any legislative change will fail, if it is not robustly underpinned by an appropriately resourced and maintained educational and awareness programme.

Specific points in the proposed Bill give cause for concern. The words "organ donation", which represent the greatest gift that can be given, are not specifically mentioned, and it is disappointing that that gift is not acknowledged. As a general point, it is unclear from my reading of the document where the donor after circulatory death whose consent was not in place prior to death fits into the proposed legislation. Such an individual will still be alive when consent is obtained, although, in the vast majority of cases, he or she is unlikely to be able to give consent at that stage.

The greatest areas of concern relate to clause 4. First, in principle, the role of the family as described undermines the deeming of consent. The fact that a relative or friend of long standing must affirm that the person would not have objected to the transplantation activity is likely to reduce the number of donors because the absence of information to affirm will result in the donation process being halted. That weakens the extent to which an individual's consent is deemed. However, this highlights what many see as the fundamental process that will increase organ donation in Northern Ireland, namely, discussing our wishes with our family so that they know what decision to take in the event of our death. That should be independent of whatever organ donation consent process is in place.

There are other real issues for those of us closest to these patients and their families. What would happen in the situation of a family or friend disagreeing with the deceased's wishes? Can a family override such wishes, as is currently tolerated with patients on the organ donor register? What would be the consequences if a specialist nurse did not pursue donation in such circumstances? The primacy of the family's wishes must be accepted; otherwise, trust in the donation system will be greatly undermined, and trust is a crucial issue because of the unique circumstances surrounding deceased organ donation. It is essential that an appropriately constructed code of practice accompanies any legislative change.

In the proposed legislation, there is an onus on the individual, while alive, to register an objection to donation. However, the possibility will always remain that individuals may not be aware of this onus or be in a position to register an objection. A recent survey in Wales suggested that only 70% of the population was aware of the legislative changes. Thus, the assumption can never be made that failure to object equates with consent in each and every case, and the potential would exist for organ retrieval to occur in the case of someone who never wished it to happen. If the ultimate outcome is the introduction of an alternative consent system to the current system, a different model, such as mandated choice, may provide greater safeguards. Furthermore, in relation to clause 8(2), there are concerns about deemed consent for transplantation from living donors who lack capacity.

The ideals behind the Bill are acknowledged. Organ donation is something that we in critical care ensure is part of routine end-of-life care when appropriate. As clinicians, we not only manage the patients to become organ donors but treat the patients who need transplants. Sadly, we are also involved in the care of those who do not get the transplant that they need. We welcome all measures that will positively influence our work to increase donor numbers.

It is also important to recognise that the optimum model for consent is far from a black-and-white issue. The international evidence on the benefit of opt-out or whatever terminology you wish to use is inconclusive. However, as Wales has already gone down that road, there is an opportunity to observe the impact that their legislation will have, learn from their experience and reconsider whether this is what is required for Northern Ireland society. Undoubtedly, the concerns and reservations held by many clinicians here will be held by colleagues in Wales, and it would be useful to draw on their experiences of the change.

Irrespective of the legislation proposed, we must all work to change societal attitudes to organ donation. I hope that the Committee will consider in its deliberations the points that I have raised.

The Chairperson (Ms Maeve McLaughlin): Thank you very much. Before I open the session to comments and questions, I just want to be clear that what I am hearing and reading is, quite bluntly, that there is no evidence that deemed consent saves lives.

Dr Glover: There is no clear evidence that deemed consent will change lives. It appears from the headline figures that the consent model, particularly opt-out, increases donor numbers. However, when you go into the detail of factors that affect donor numbers and consent, it appears that legislation on its own is not the crucial factor. It is important to consider the nature of the society in which the legislation exists. For deemed consent to exist, we are assuming that we live in a society that accepts organ donation as the norm. That is a question that we all have to answer: is that the type of society

that Northern Ireland is at this time? If you read the literature, you will not find a clear yes or no answer on the impacts and benefits of deemed consent legislation.

The Chairperson (Ms Maeve McLaughlin): From your direct expertise, is presumed consent clearer or better?

Dr Glover: The weakness of presumed consent is the presumption that the person wanted to become an organ donor. Virtually all presumed consent models operate with the proviso that the family are approached and are the final decision-makers.That is the model that exists here. There are few countries in which the opinions and wishes of the family are not respected. There would be a hugely detrimental effect on organ donation, irrespective of the model, if the family's wishes were ignored and the donation happened irrespective of them.

The Chairperson (Ms Maeve McLaughlin): I am trying to tease this out to ensure that we are robust in our work on this. Is it correct to say that presumed consent would be clearer if it was set alongside a priority for the family's wishes?

Dr Glover: The biggest predictive factor for what the family will decide is whether they know the deceased's wishes. The system that we have — the organ donor register — is one way of indicating the deceased's wishes, but even more powerful than the organ donor register is whether families have had the conversation. If families know the deceased's wishes, it relieves them of the burden of having to make that decision. We know, from our own and international experience, that, if families are asked to make a decision in the absence of knowledge of the deceased's wishes, they are more likely not to give consent. It is much easier to give consent when it affects us as individuals, but, in making a decision that relates to a family member in the absence of information, the default position is more likely to be not to give consent.

The Chairperson (Ms Maeve McLaughlin): Frankly, you could ask whether there is a need for legislation.

Dr Glover: You could ask that question.

The Chairperson (Ms Maeve McLaughlin): What are your views on that?

Dr Glover: Personally, I think that the legislation is not the most relevant factor: the most relevant factor is changing society's attitudes to organ donation. That should not happen because the law has changed and we have adopted a top-down approach; it should happen through a bottom-up approach, whereby we accept organ donation as something that normally happens at the end of life.

There is evidence of great local variation in Northern Ireland in the rates of people on the organ donor register. There is evidence from the old council set-up of a great range in the rates of population in council areas who were on the organ donor register. Something at a local level is influencing communities to sign on the organ donor register and discuss organ donation. Local stories are very important, and that is how we will change how individuals perceive organ donation.

The Chairperson (Ms Maeve McLaughlin): I was looking through some of the figures. Without wishing to be parochial, I see that the areas with the highest number of persons on an organ donation register are in my constituency: city side followed by the Waterside. That is interesting because the area with the highest number of transplant recipients is in north Belfast. I am not sure, so I am asking you whether the dynamics around that should be the critical piece of work. The figures are stark, with over 20,000 people on the register in one part of the city.

Dr Glover: That is an important question: what has happened in your area that has not happened in other areas? Why do your constituents see organ donation differently from those in other areas? We do not have the answers, but knowing the successful factors in your area will provide us with the information that we need to make progress across Northern Ireland.

The Chairperson (Ms Maeve McLaughlin): Will you expand on your comment on the issue of mandated choice?

Dr Glover: There are potential weaknesses and flaws with presumed consent. We are making the presumption that, if an individual has not indicated their wishes, they have made a decision. As I said

in my presentation, a recent survey in Wales indicated that maybe upwards of 30% of people were unaware of the legislative changes, so that 30% have not opted out. Within that 30% there will, undoubtedly, be individuals who do not wish to become an organ donor, but, if they have not indicated their wishes, there remains a possibility that, in the event of their death, they could become an organ donor, although that was not their wish. The proposed presumed consent model is not fail-safe and does not provide complete certainty on what an individual's indicative wishes were. I do not propose this as the way that we should go, but, potentially, a system whereby individuals are expected to make a decision one way or the other and that decision is widely known is more likely to ensure that as many members of the population as possible indicate their wishes. This is all about knowing what the deceased's wishes were, and that is the driver of change.

The Chairperson (Ms Maeve McLaughlin): You are saying that mandated choice is around wanting to know what a person's wishes were, so individuals are expected to make a decision. Has that worked anywhere else through legislation? Has that been part of any other legislative changes?

Dr Glover: I am not aware that it has been, but maybe someone else is.

Dr T J Trinder (Ulster Hospital): I am not aware of it having been used elsewhere. It was considered but not pursued during the Welsh consultation period.

Dr John R Darling (Ulster Hospital): It was considered in 2008 when Gordon Brown and the UK Government were looking at this. One issue was that they thought that it might interfere with individuals' human rights, in that they were being asked to make the decision when 50 people per million would be affected by it. The other things were the cost and the way of introducing it. At that time, it was seen as impractical to have a mandated register, although, with new technology, it could, I guess, be revisited at this time.

The Chairperson (Ms Maeve McLaughlin): You mentioned trust: is it your view that the Bill, as drafted, changes the relationship between the patient, the medical professional and even the state? Clearly, trust is an issue. If issues such as deemed consent are flawed or not clear, might that have implications even for the number of people who would voluntarily come forward?

Dr Glover: You are right: trust is crucial to the success of any model. The Public Health Agency's attitude survey highlighted medical distrust as one of the factors that had an impact on whether families gave consent. In particular, there was a notion that someone on the organ donor register would continue to be treated only for the purpose of obtaining organs. Our particular concern is about donors after circulatory death. These are patients from whom we withdraw treatment once medical staff and the family agree that ongoing treatment is no longer of benefit to them, and then we consider donation — at that stage. If families somehow felt that clinicians were withdrawing treatment because we perceived an individual to be a suitable organ donor, while there is no rationale to it, that perceived breach of trust could have significant implications. While we say that there is no rationale to it, it is still a perception that the public have, as was highlighted in the PHA survey.

The Chairperson (Ms Maeve McLaughlin): You touched on that. There seems to be, from the annual report on transplantation — I am referring to transplantation from donors who are deceased — a dependency here on donor rates in England. I presume that the intention in this legislation is to examine donation rates here in the North. I am not sure if that is even considered or mentioned in the legislation. Suffice it to say, we depend on donor rates in England.

Dr Glover: The region is ultimately a net exporter of organs from deceased donors. There is some local benefit to those awaiting kidney transplants if we have a donor after circulatory death. If that patient meets the specific requirement of the local transplant unit, one of the two kidneys from such a donor will remain in Northern Ireland and be transplanted into a local patient. The rest of the organs go into the national organ allocation scheme. There is no particular benefit to Northern Ireland patients from Northern Ireland donors. We benefit from overall donation numbers in the UK as a whole.

The Chairperson (Ms Maeve McLaughlin): I have two more quick questions. You mentioned Spain, which is often heralded as an example of a positive impact. I cannot remember the terms that you used, but you said that there were a number of caveats or different scenarios in play. Can you expand on that?

Dr Glover: The Spanish model has been replicated closely in Croatia and Portugal, which have two of the highest rates of organ donation in the world. There are several features of the Spanish model. First, there are transplant coordinators in all the hospitals. That differs slightly from the set-up in the UK, as these transplant coordinators are doctors. There is an organisation in the hospitals at regional and national levels. There is an overall body that coordinates the system. There are appropriate legal and ethical frameworks. There is significant education of all medical and nursing staff involved in looking after donors. There is quality assurance of the donation processes. In particular, what they have found in Spain is that advertising has a very high benefit-to-cost ratio. Access to the media and using the media to disseminate information have been crucial. That has been one of the key features. They also significantly reimburse the hospitals from which the donors appear. In Matesanz's writings on the Spanish model, he does not talk about consent. Those six or seven aspects come together, and the model has been replicated in Croatia and Portugal.

The Chairperson (Ms Maeve McLaughlin): Finally, if legislation is not the most relevant factor — you made the point about societal views on organ donation and transplantation — is it the case that, if legislation were to proceed in this guise, the biggest challenge is clause 4 as drafted and that, if clause 4 was amended or removed in favour of a process involving either presumed consent, which, I suggest on the basis of what you have said, there are issues with, or mandated choice, that would make for better legislation?

Dr Glover: The way in which clause 4 is drafted has the potential to, in fact, decrease donor numbers. It undermines the whole concept of deeming consent if, ultimately, the family has the final say. The individual's wishes are potentially of secondary importance.

The Chairperson (Ms Maeve McLaughlin): That is extremely useful and very clear. Thank you for that.

Mr Easton: Happy new year. You do not mind if I call you Paul, do you?

Dr Glover: No, not at all.

Mr Easton: You have raised some points that I want to pick up on. If I reword them back to you and they are not correct, let me know.

Compared with other areas, transplantation rates in Northern Ireland are pretty good: is that fair?

Dr Glover: Rates of donation?

Mr Easton: Yes.

Dr Glover: The rates of donation are the highest in the UK and internationally are top or close to the top of the list.

Mr Easton: I think that it was suggested that the Bill would not necessarily increase rates and it was more about using the media and getting awareness and stuff like that out. If that were used more effectively, do you think that there would be a need for the Bill?

Dr Glover: I believe that the Bill in isolation would fail. It would have to be underpinned by education and awareness. If the legislation were to be introduced, we would have to have society talking about organ donation, people considering what their wishes were, making that decision and having the conversation with their family — signing on the organ donor register and making their wishes known. Without the education and awareness, there would be significant issues. The Public Health Agency survey highlighted a significant lack of knowledge and information on many matters concerning donation: those would have to be addressed.

Mr Easton: Do you feel that we should wait to see how it develops in Wales before proceeding?

Dr Glover: I feel strongly that that is the approach that should be taken. The international evidence is unclear, but we now have, in some ways, an experiment close at hand. The Welsh population is similar in many ways to our population. As I said, the society in which it is expected to operate is crucial to the success of any legislation. If we are able to observe what happens in Wales, we can

look at what they do well. Undoubtedly, there will be mistakes. We can learn from the mistakes and reconsider. I think that some of my colleagues here also have views on the Welsh model.

Dr Trinder: If the Committee agrees, I would prefer to save that element because I will deal with it in my presentation.

The Chairperson (Ms Maeve McLaughlin): That is OK.

Mr Easton: My last question — I am not sure whether I have picked this up right — is about the potential for some organ donations to happen even though the person may not have given consent.

Dr Glover: Yes. Consider the specific scenario where a person did not wish to become an organ donor in the event of their death but for whatever reason — there is the possibility that they were unaware that they had to register their wishes — had not registered their wishes and had never discussed them with their family. If, in the event of their death, their family is approached and gives consent, ultimately, those organs would be removed from a person who would never have wished organ donation to take place. That is one of the potential flaws in any presumed consent model.

Mr Easton: OK. There are some serious points there.

Mr McCarthy: Thank you very much for your presentation. Much of my concern has been answered. However, I must say that your last response to Alex that, in your opinion, the Bill will fail — I think that that is what you said — will be most disappointing to the sponsor of the Bill, who is a member of the Committee. She is obviously not here at the moment, but she is dedicated to trying her best to ensure that more organs are donated for the purpose of saving lives, so that will be a disappointment.

Paul, in your presentation, you said that you were disappointed that something was not contained in the Bill. I cannot remember exactly what it was: can you recall? The sponsor of the Bill has always said that she is prepared to listen, talk, discuss, amend etc: have you or any of your colleagues taken up the opportunity to discuss with the sponsor of the Bill your concern and what you say you are disappointed with?

Dr Glover: I think that you are referring to me saying that the words "organ donation" are not specifically mentioned in the document.

Mr McCarthy: Yes.

Dr Glover: It is disappointing that the gift of life is not specifically acknowledged in the Bill. This is a huge sacrifice that people make. Donors make a huge contribution to society, and it would be appropriate that that is acknowledged in the Bill in some way.

Mr McCarthy: So there is scope for that to be put right between you and the sponsor of the Bill. At least that would be one aspect of moving the thing forward. Would you be happy to discuss it with Jo-Anne Dobson to try to overcome that?

Dr Glover: Yes, we would be prepared to do that —

Mr McCarthy: OK.

Dr Glover: — to see if there was some way of having that acknowledgement and using the words "organ donation". Ultimately, although the Bill is very transplantation-focused, transplantation can occur only if organ donation has happened.

Mr McCarthy: Yes, and that is the whole ethos of her endeavours. You probably know that she has experienced this in her family and that, as a follow-on from that experience, she wants to help other people. What you are saying to the Committee is that you are happy and would be prepared to work with Jo-Anne Dobson to move things forward positively so that the end result is beneficial.

Dr Glover: We acknowledge the ideals behind the Bill and would certainly welcome any move that would have a positive impact on organ donation in Northern Ireland.

Mr McCarthy: OK. That is fine. Thank you.

Ms McCorley: Go raibh maith agat, a Chathaoirligh. Thanks very much for the presentation. A lot of the questions that I had have been answered. The current rate of donation where consent is given is 60%.

Dr Glover: Yes, currently, the consent rate is about 60%.

Ms McCorley: OK. Can you give me a wee bit more information to track how long it took to get to that rate and how long it has been at that rate? I am trying to get a sense of the chances of moving it higher.

Dr Glover: Essentially, the consent rate has remained unchanged for quite a number of years.

Ms McCorley: How many?

Dr Glover: It has always been in and around that figure in Northern Ireland. The consent rate has not changed. All the changes in the infrastructure and organisation of organ donation in Northern Ireland happened from 2008 onwards. That is when the infrastructure, the clinical leads and the specialist nurses were all put in place. Despite that, consent rates have not changed, although we have more than doubled our donor number. There is something causing a block here. I personally think that it in some way reflects upon our society. I have given you some of the reasons why families do not give consent. The two biggest are that either the deceased had clearly expressed a wish not to become a donor or the families did not know what the deceased's wishes were. That takes me back to the point that I have been making about awareness and families knowing what the wishes were.

At the end of the day, our purpose is to ensure that the families make the right choice for themselves. We are not saying that organ donation is right for every family and is what we expect of every family, but it is about getting our society to reflect on organ donation and consider that it is something that we should do at the end of life.

Ms McCorley: Given that the rates have not changed over that number of years, we need to do something differently. Just continuing in the same way will not make it happen. Do you believe that the Bill can change that in any significant way?

Dr Glover: As I said previously, I do not think that the Bill on its own will change anything significantly. Any Bill will have to be — as they have done in Wales — accompanied by a prolonged, widespread education and awareness process, not a one-off process. It has to continue happening, because it is about changing society. It is not about saying, "This is the law; therefore, this is what we must do"; it is about the positivity regarding organ donation coming from society up and individuals saying that they wish to become an organ donor in the event of their death, irrespective of the legislation.

Ms McCorley: What do you think is the best way to get that going? Initially, it is about trying to encourage people to have the conversations — I think that is the basis of it — and then let people know what their views are. What do you think is the best way? Is it a dedicated, resourced team set up just to do that, not leaving it to a doctor who already has his own role? What do you think?

Dr Glover: Essentially, it has to happen outwith the medical profession. It is about local individuals. The story of someone who had a family member who became an organ donor is a very powerful one, and that may well impact on what we have seen in the north-west, with very high rates of people going on the organ donor register. That will change how people view and consider organ donation much more than seeing an advertisement on the back of a bus. It is making it personal and taking it home. It has to be driven not by the medical profession but by influential members of society. In particular, donor families have a role to play. Obviously, it is not always easy for families to tell their story, but that is potentially a very powerful tool.

I do not believe that there will be a quick fix. Education, getting into the schools — young children are powerful influencers of parents, their friendship groups and so on. What is lacking in Northern Ireland is any significant organ donation education in the school system.

Ms McCorley: So you would be supportive of a campaign through schools.

Dr Glover: Yes, very much so.

Mr Middleton: Thanks, Paul, for your evidence this morning. It has been very useful. I have just two small points to make.

You mentioned the international evidence and the fact that it is actually quite unclear at this time. I have said before that I believe that we need to take note of all the other areas that have implemented legislation. You mentioned that France and Brazil had abandoned the opt-out system: do you have any information on the reasons why they did that? Are you aware of any education programmes that they had in place? You mentioned society's attitudes as well. I will just ask my second question as well and then you can answer. Do you have any concerns about the time frame that we, as a Committee, have agreed to? Obviously, we are looking at this being in front of the Assembly in the next couple of weeks. Given what you have said, how do you feel that sits with the time frame?

Dr Glover: I will go back to the first part of your question. It was an unmitigated disaster in Brazil, and the legislation was repealed within a year. They had no education or awareness programme in place; it was just introduced. Doctors were threatened with being sent to jail if organ donation did not take place. The public were unprepared for it, and there was a backlash. I am not so clear on the issues in France.

On the timescale, the international evidence on the benefits of consent models is unclear. We are in a position to witness what is unfolding in Wales and how things may develop there. We do not know whether the Welsh model will work. You run the risk of jumping in quickly after Wales and ending up with a system that may have acquired significant cost but has no additional benefit. You may find that the legislative changes in Wales have made a significant improvement, and then people will say, "This has worked in Wales. We could introduce something very similar here". It may deal with that uncertainty about whether legislation will work in our society. As I have said, you cannot just lift what has happened internationally and say that it will work in Northern Ireland; we have very different attitudes to death, the whole death process and the burial process. It is very different here even from England. Our deceased are buried within three days, whereas, in England, you wait a lot longer. Again, that came through in the PHA attitudes survey: the ritual of death is very important to our society here.

Mr Middleton: OK. Thank you.

Ms McCorley: I have one question. In relation to clause 4, could you say that the Bill may, in some circumstances, be a negative in cases where a relative cannot honestly say because they do not know?

Dr Glover: As clause 4 stands, if a relative cannot positively affirm, you cannot move on to the next step. If a relative —

Ms McCorley: They might have given consent, but they are genuinely challenged by the fact that they just do not know.

Dr Glover: As the Bill stands, unless a relative can positively affirm, donation cannot take place. That wording would have to be significantly restructured if the Bill is to move forward.

The Chairperson (Ms Maeve McLaughlin): I will move on to your good self, Dr Trinder, because I know that you want to make a number of observations. I think that you wanted to come in on the back of this part, so I will open it up to you at this point.

Dr Trinder: The first thing that I want to say in response to that question is that clause 4 as it stands is ambiguous. It is open to more than one interpretation, and that is another reason why it is not really fit for purpose at the moment.

I am an intensive care consultant who has been engaged for more than 20 years in obtaining consent for organ donation, and I have seen the pleasing increase in donation rates that Dr Glover has described. Even though refusal rates have not changed, the number of organs donated has increased.I am most grateful for the invitation to appear before the Committee. I am sure we all want to do what is best for patients, both potential organ donors and potential organ recipients. In my speciality — the specialty in which all of us are involved — decisions often have to be made on

patients' best interests when they are too ill to contribute to the decision-making. The best interests determination is usually made by clinicians, liaising closely with family. The trust of the family members in the healthcare team looking after their loved one is absolutely crucial in such a situation.

Because of my past role as a Northern Ireland clinical lead in the UK transplant donor liaison scheme and subsequent work, I have been termed an "organ donor champion" by those who like to use that kind of terminology. I continue to champion organ donation in hospital and beyond. Although I do not doubt the good motives of those behind the proposed legislation, I view it as unhelpful and potentially harmful.

I will address a number of key points. First, informed consent is a cornerstone of medical practice and is central to the Human Tissue Act 2004. Deemed consent is very different. For the sake of clarity, I perceive deemed consent to be no different from presumed consent. There is no distinction, because for consent to be deemed it must be presumed, and I consider "presumed consent" to be a clearer term. Because that it is very different from informed consent, the 2004 Act had to be amended in Wales. We should have compelling and extraordinary reasons, backed by evidence, to distort usual consent practice in this one area and to alter the law on consent. A Bill that introduces presumed or deemed consent could have a detrimental effect, undermining confidence and trust in healthcare teams and in organ donation in general. I have explained that in detail in my written submission. Those promoting presumed or deemed consent, whilst they no doubt have the best motives, have often made large assumptions that have not been made explicit and may be ill founded. I also have concerns about the validity of surveys conducted to gauge the views of the public. I am happy to take questions on those concerns if the Committee so desires, but in the interest of time I will move on.

I am informed by the clinicians involved in the Welsh consultation that, in Wales, the Government proceeded with legislation contrary to the views of specialists in the field. I hope that Northern Ireland does not follow that example. It is vital that Committee members heed the concerns of those of us who are involved in decisions to terminate life support and who have, for many years, also been engaged in discussions with family members on organ donation. As I address the issues, I encourage you to imagine yourselves in the shoes of a soon-to-be-bereaved family. Often, there will have been a sudden catastrophic event, so think about what they will be going through and the powerful emotions they will have, particularly as cessation of life support is proposed and organ donation is discussed.

I am particularly concerned about how intensive care staff can be perceived to have a conflict of interest, especially in the context of organ donation after circulatory death. In such circumstances, we withdraw life support from patients who, at that point, are still alive. If families were to find that their objections to organ donation were not heeded, facilitated by new legislation, it might generate feelings that the decision to withdraw life support was influenced by a desire to harvest organs. My colleague has already referred to that risk.

The main obstacle to donation has indeed been family objection, and my understanding is that the aim of the Bill is to circumvent that obstacle. If I have misunderstood that aim, the proposed deemed consent legislation would be impotent. Dr Douglas touched on that in his written response. Since the issue of family objection is such a core one, I hope that the Committee will allow me a little more than the suggested time allocation of five minutes so that I can address it. That will save the Committee time in the long run.

There is an absence of clarity in the Northern Ireland Bill on how situations will be handled where families object to donation, particularly when the patients have not demonstrated their views — for example, when they have not had a conversation with family in which they have expressed their wishes. The Bill mentions a code of practice for that situation, but that does not appear to have been made available as part of the consultation. The Northern Ireland Bill's intent seems to coincide with that of the Welsh legislation, so, on the basis of the Welsh code of practice, which is available, and recognising that the major obstacle to donation is family refusal, I have inferred in my written response that the Northern Ireland code of practice will make it possible to override family views when the patient has not had a conversation with family.

Clause 4(2)(b), in particular, is the focus of concern. It is open to alternative interpretations, and that is evidenced by the written responses to the consultation. If the Human Tissue Authority (HTA) Welsh code of practice was to be adopted, clause 4(2)(b) could be taken to mean that the family would be considered to have effectively affirmed consent if they could not provide sufficient evidence to an NHS Blood and Transplant employee that the patient had expressed a view against donation. Another possible interpretation of clause 4(2)(b), as drafted, has been mentioned. That possible interpretation is that the family will effectively have a veto on donation if they are free not to affirm deemed consent.

I believe that that interpretation is what prompted the first of Dr Douglas's points of concern from a nephrology perspective. As he pointed out, that interpretation would rob the Bill of its force. I think that is the reason my colleague suggested for why the Bill could fail. The Human Tissue Authority has indicated in paragraph 24 of its response that, if it were to draw up a code of practice for the Northern Ireland Bill in line with that interpretation, it:

"would be counter productive to the policy aims of the Bill."

In my view, there is little doubt, with either of those two interpretations, that there is no credible argument for new legislation, unless the intent is to override family objection to donation.

On the basis of many years of discussing this issue with families, I think that many families are presenting an instinctive view of their loved one's wishes in a situation where the patient has not had that conversation. We trust them to do that, very commonly, when withdrawing or withholding life support in other circumstances, such as when the patient's survival may depend on the decision that that relative instinct is affecting. Why would we choose to exclude that instinct in this situation? I certainly trust the family's instinct regarding their loved one's views in the middle of the real-life situation more than I trust surveys conducted in an entirely different setting, particularly when there is uncertainty regarding the quality of information given in the survey and the skills of those conducting the surveys.

In summary, I urge the Committee and the Assembly not to legislate on the basis of an assumption that MLAs know individual patients' wishes from surveys better than family members' instincts regarding their loved ones' wishes. Notwithstanding the good intentions of Mrs Dobson and others, I consider that it would be most imprudent to proceed with presumed consent legislation in Northern Ireland when clinicians in the specialty of intensive care have expressed serious concerns here and across the rest of the UK, alongside concerns expressed by two royal colleges. Indeed, the UK Government's organ donation task force advised against it. I urge members not to dismiss the insight and advice of the architect of Spain's success in organ donation, Dr Matesanz, who has responded to the Northern Ireland consultation and has been arguing that presumed consent legislation is not the appropriate course.

Finally, it is our collective view that spending finite resources on infrastructure and, particularly, education and engagement with the community is preferable to legislative change. However, if the Assembly is determined to legislate without evidence, those of us at this table advocate mandated choice as a better and ethically superior route to presuming a patient's consent and legislating for that presumption. Mandated choice was also viewed favourably by the Welsh public in the public debates held by the Welsh Government, but that option does not seem to have been given serious consideration to date in Northern Ireland. Thank you very much.

The Chairperson (Ms Maeve McLaughlin): Thank you. Do you want to make any comments, and then we will open it to questions, or are you comfortable enough with what has been said to date?

Dr Darling: My submission, in which I really make three points, has basically been covered by most of the other speakers. I am a consultant in intensive care. I sit on the council of the Royal College of Anaesthetists in London and, to some extent, represent the views of intensive care doctors throughout the UK as well as those in Northern Ireland.

First of all, I feel that the Human Transplantation Bill is fair. However, it does not emphasise, as Paul said, the words "donor" or "donation" and does not recognise extensively enough the gift that families and friends of donors make at a time of great distress for them. I want to make the point that I find that a lot of bereaved families find a lot of comfort in the idea that they have given a gift to society, and that sometimes brings benefit to other members of society and gives them a lot of comfort. If we make it a duty rather than a gift — if we pressurise or coerce them in any way — there is a danger that we might alienate them. If, as in the Welsh code of practice, we set out at the outset that the function is to veto their ability to object or to reduce their ability to object to organ donation in any way, that may alienate this group of the population. I think that that is really what happened in Brazil. Brazil had a very hard line on opt-out. The populace in general rejected that, and it meant that the whole system fell apart and had to be repealed.

I also agree with the others that clause 4(2) and, in particular, paragraph (b) are unclear. In the case of a potential donor where relatives cannot affirm that the person would not have objected, deemed consent is not effective and, therefore, transplantation cannot go ahead in the way that it could under

the present system. That might reduce the number of organs available for donation and transplantation, which is exactly the opposite of the reason for the Bill.

I also support and think that we can do an awful lot more on education and promotion of organ donation. If a person is not on the organ donation register, there is a 43% chance throughout the UK of consent to organ donation when the relatives are asked. If they are on it, that doubles to 87%. If everybody were on the register, the number of instances of consent being given by relatives would double. Mandated choice or some sort of register of mandated choice — it has been looked at in other countries but not introduced — would be the ideal.

Dr George Gardiner (Critical Care Network Northern Ireland): Chair, in the interests of time, I feel that I should make a few points. First, my colleagues are all experts in this area. Personally, I agree with everything that they have said. My evidence, however, is on behalf of the Critical Care Network Northern Ireland (CCaNNI). Just to explain, the Critical Care Network is an operational clinical network for intensive care medicine. It includes nine intensive care units in the Province and the doctors, nurses, allied health professionals and managers who have responsibility for critical care. I represent the 60 or so consultants in intensive care medicine who deliver the medical component of that care. Alongside the nurses, allied health professionals and others, we form the medical teams who deliver that high-quality care to those who need it, and it is we who provide the end-of-life care. We are crucially involved in decision-making surrounding the end of life, through communication and negotiation with patients and their families. It is we who must make decisions about how and when to change treatment priorities from cure to comfort care and then to organ optimisation, should that be the wish of the patient and their relatives. I must emphasise that overall clinical responsibility lies with us, and I speak on behalf of 60 consultants and hundreds of nurses and colleagues.

What I have to say echoes what my colleagues have said, but I say it simply to emphasise that this is a corporate view; I have consulted as widely as possible within the time frame available. The points that I raise are ones that I am confident have broad support. All of us are supporters of organ donation. We all seek to achieve improvements at every stage of the process, but I have to inform you that there is significant concern among my colleagues. We cannot predict the effect that the change in legislation would have, and there is little evidence to guide us. We are essentially trialling a new intervention that may have a positive, negative or neutral effect. Meanwhile, in Wales — a similar nation — that experiment, if you like, is already in progress. We should at least await the results. If I had a great idea about changing practice in my intensive care unit and I went ahead, if it worked, you would hail me as an innovator; if it had no effect, the trust would wonder why I spent the money; if it had a negative effect, I would be censured. If I did that while a similar experiment was already ongoing, serious concerns would be raised. I suppose that is what we are embarking on. We do not have a great deal of evidence, and we are about to change legislation without really knowing what the effect will be, while, to a certain degree, the experiment is already under way.

We have concerns, already expressed, about clause 4. That area needs rigorous definition to avoid uncertainty at the time when our patients and their relatives are most vulnerable. I cannot emphasise enough the complex relationship that we have with patients and their families, one that relies even more than most doctor-patient relationships on openness, trust and communication. Anything that undermines that or shifts the balance in this relationship at the most stressful of times will compromise the achievements in organ donation over the last decade.

We are concerned about the requirement for a code of practice. The Welsh code of practice provides real obstacles to its delivery at the bedside, and, as a network of medical experts, we feel that it will be essential for us to be involved in producing a code of practice, if it is the wish of the Assembly to proceed with new legislation. In general, public and specialist medical opinion is moving towards greater care and complexity in informed consent. To move to presumed consent seems, therefore, to be moving in a completely different direction from society. We also agree that public education, engagement, training and education infrastructure are much more likely to deliver results and that, if an investment was to be made, it would be most efficiently made in that area rather than in legislative change.

Thank you for the opportunity to express the network view. The Critical Care Network stands ready to assist the Committee in whatever way is required in future deliberations.

The Chairperson (Ms Maeve McLaughlin): Thank you.

I have touched on some of the points in Dr Trinder's paper previously, but I will remark on the very clear language that has been used in relation to the legislation being unhelpful and potentially

damaging. We all need to recognise those stark words. Again, I go back to the issue around mandated choice. I asked earlier about what examples there were and where. If we are saying that there is no clear evidence of deemed or presumed consent having a negative, positive or neutral impact, what is the evidence around mandated choice?

Dr Trinder: To begin with, mandated choice is easy to understand. The fact that it has not been deployed elsewhere, to our knowledge, should not be regarded as a reason not to consider it seriously. I gather it was floated in the Welsh consultation. The central issue is one of principle and the potential erosion of the core principle of informed consent that this legislation seeks to alter. Mandated choice preserves informed consent to a much greater extent, and we consider it to be ethically superior because we are not presuming the wishes of individual patients on the basis of surveys that have been conducted in an entirely different setting. We would know what the wishes of the patients were by having a mandated entry, one way or the other, on the organ donor register. I am not expert in suggesting how that would proceed practically, but I can imagine that, as it is at present when registering for a driving licence or other things, one could make one's wishes known regarding the organ donor register, and that could become a requirement, in theory, when wanting to access services. The result of that would be that we would no longer be presuming patients' wishes with the risk of getting those wishes wrong and retrieving organs against their wishes.

The Chairperson (Ms Maeve McLaughlin): There are options or views around not legislating or proceeding with legislation. If the Assembly were to agree to proceed with the legislation, would an amendment to remove clause 4 — the issue about mandated choice being built into the legislation — provide us with better legislation, or is it completely new legislation?

Dr Trinder: I will respond to that, if I may — in the first instance, anyway. I perceive that something akin to clause 4 is core to any legislation with the intent of the Bill. The problem is that, if we have a code of practice accompanying the Bill that is akin to the Welsh model, we will be in a situation where, if the patient has not had the conversation, the instincts of the patients' relatives regarding the patients' likely wishes will be set aside and consent can be deemed, as in the Welsh model, against the wishes of family, if the family is unable to present sufficient evidence that the patient had expressed a wish not to donate.

The other problem with clause 4, as it stands, is that it could also be taken to mean that relatives will have a veto on the donation. If that is the case, as has been pointed out by the HTA in its response, it will undermine the entire purpose of the Bill. My perception is that clause 4 cannot be fixed because, as I stated in my presentation, there is no credible argument, with either interpretation, for new legislation, unless the intent is to override family objection to donation.If we wish to override family objection to donation, clause 4(2)(b) should remain and it should be clarified that it does not give families a veto. That is all that I have to say on that.

Dr G Gardiner: May I say that, at an operational level, it is incredible that a family's wishes would ever be ignored? We may discuss them, but we would not ignore them. I do not think that anyone is asking us to ignore the wishes of the family. There is no legislation that could be put in place that a clinician on the front line would adhere to that would go against the wishes of a family. It is simply beyond the bounds of possibility that a patient would be taken for donation against the wishes of their family at that time.

The Chairperson (Ms Maeve McLaughlin): Is there an indication that what is proposed would allow that? One of the issues of concern is that families would have a veto.

Dr Trinder: There are dual issues of concern. One interpretation is that families would have a veto. That would render the Bill impotent in its desired objective of overcoming relatives' refusal. The other interpretation is that families would be denied a veto. If the code of practice, which, as I understand it, has yet to be drafted for Northern Ireland, mirrors the Welsh legislation, in effect we would create legislatively the opportunity to override families' wishes unless they could provide enough evidence to satisfy an NHS Blood and Transplant employee.

The Chairperson (Ms Maeve McLaughlin): Finally, a lot has been said about societal views, obviously, and about developing this work almost on the basis of surveys. It seemed to be quite critical — maybe that is too strong a word, but it was certainly challenging some of the robust evidence coming from the survey process. Is that accurate?

Dr Trinder: I have certainly challenged on the basis that there may well be assumptions underpinning surveys that are not founded and have certainly not been made explicit. I would be happy to address that if you wish.

Dr Glover: That fits in with what we see. Again, in the Public Health Agency survey, 86% of the population said that they supported organ donation, yet we still have only 60% of families consenting. There is a disparity between what people will say in a survey and the decision that they will take at this emotional and difficult time.

I go back to the earlier phase of the conversation: all the issues or concerns about family veto and family override would be eliminated if the wishes of the deceased were known and the family were not being asked to make a decision.

The Chairperson (Ms Maeve McLaughlin): Ultimately, on an issue like this, people would want to do the right thing in responding to such a question or survey, but that may not translate.

Can I thank you all, gentlemen? It has been extremely useful. We will certainly reflect on all that we heard today. Please keep up the good work. Thank you.