Northern Ireland Assembly

Committee for Health, Social Services and Public Safety

# OFFICIAL REPORT (Hansard)

## Human Transplantation Bill: Human Tissue Authority

6 January 2016

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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:**
Mr Allan Marriott-Smith Human Tissue Authority

**The Chairperson (Ms Maeve McLaughlin):** We have Mr Allan Marriot-Smith, who is the chief executive of the Human Tissue Authority (HTA). You are very welcome to the Committee. I invite you to make your opening presentation, and we will then open the meeting to comments from members.

**Mr Allan Marriott-Smith (Human Tissue Authority):** Thank you, Chair, and good morning. Thank you for inviting me to give evidence on behalf of the HTA; I welcome the opportunity to do so.

As a statutory regulator, the HTA's role is to provide advice and guidance to the Assembly and this Committee, rather than to support or oppose the proposals that are being made. The HTA is a small organisation of around 50 staff, and it was set up in 2005 following inquiries into hospitals where organs had been removed and stored without permission. The HTA was created to ensure that tissues and organs are used safely, ethically and with proper consent. Ten years on, the HTA licenses over 850 premises across six sectors that remove, store and use human tissue for a range of purposes, including research, transplantation, medical treatment, post-mortem examination, education and public display. We also assess applications for living organ donations to proceed lawfully from around 1,200 donor and recipient pairs each year.

Central to our approach and role is the provision of advice and guidance on how practitioners should interpret human tissue legislation so that they act within the law. One of the key mechanisms for doing that is our codes of practice. We publish nine codes of practice under our Human Tissue Act 2004, which is our founding legislation. The first of those deals with consent as a fundamental principle in the use of organs, tissues and cells for a range of purposes and with the practical implications of the law in this area. We ensure that appropriate and valid consent is in place when organs and tissues are donated from deceased and living people for the purposes of transplantation. We also publish a code of practice on the Human Transplantation (Wales) Act 2013 that provides information to practitioners in Wales on consent to organ donation following the introduction of deemed consent in Wales in December 2015.

Of specific interest to the Committee are our duties under the Human Tissue Act 2004 and how they relate to duties proposed for us in the Human Transplantation Bill. The Bill places explicit duties on the HTA to ensure that a code of practice to deal with your Human Transplantation Bill, once it becomes law, is covered to deal in particular with advising practitioners on when consent can be deemed and with provision for us to superintend compliance with the requirements imposed by your Bill. In effect, that means that, once the law goes live, people will look to us to explain what it means and to interpret it. Those are very similar roles to those set out for us in the Human Transplantation (Wales) Act. We worked very closely with the Welsh Government during the development of their legislation, writing and consulting on a code of practice that explains to practitioners how to interpret the law. Through that work, we have developed experience that we are happy to share with the Committee. Since 1 December 2015, we have also had responsibility for superintending the Welsh Act.

It is worth emphasising that your Bill also creates a statutory basis for new forms of consent in Northern Ireland. Those are deemed and expressed consent. While the Bill makes amendments on consent to the Human Tissue Act 2004, other aspects of the law that relate to organ transplantation will remain unchanged. Most notably, picking up on a couple of points raised at the Committee in earlier evidence sessions, the trafficking offences created by the 2004 Act will be left to stand unchanged and the requirements for living organ donation to proceed legally are unaltered.

Having said that, we believe there are some key issues that require further consideration, as set out in our written consultation response. I would like to highlight two of those, if I may. The first is about affirming deemed consent. One of the main differences between the Welsh legislation and this Bill is that deemed consent is effective only if a person in a qualifying relationship affirms that the deceased would not have objected to transplantation. We are concerned about how "affirmed" may be interpreted. In England, if the deceased's wishes are unknown, a person in a qualifying relationship is asked to make a decision on behalf of the deceased person. We have yet to seek legal advice on that, but it appears to us that asking a qualifying person to affirm that a potential donor would not have objected to the transplant activity could be counterproductive to the aims of the Bill. Put more simply, if a person in a qualifying relationship has never discussed organ donation with the donor, they would not be in a position to either affirm or refute whether a person would have objected to donation. If that interpretation is correct, consent could not be deemed.

The second issue to flag up is around communications. In our view, communication will be vital to ensure the legitimacy of deemed consent. Without it, Northern Irish residents may not know what action to pursue or whether they wish their consent to be deemed or not to be deemed. The current law requires valid and appropriate consent. The giving of valid consent is a positive act. Valid consent is freely given by someone who is appropriately informed and has a mental capacity to give that consent. Appropriate consent relates to who is able to give the consent, and it places primacy on the wishes of the individual during their life.

Deemed consent will no longer necessarily require a positive act. Therefore, if the primacy of the individual's choice is to be maintained, each Northern Irish citizen needs not just to understand what it means to opt in or opt out but to have the information to understand what it means to take no action. That is also broadly the view taken by the Nuffield Council on Bioethics and one that was made to us during the consultation on the Welsh code of practice. We are pleased to see a commitment in the Bill to inform the public about deemed consent at least once a year. We believe that those campaigns will be essential in ensuring that every person living in Northern Ireland is aware of the proposed system and how it will affect them. In particular, the communications campaign may wish to look at hard-to-reach groups, those moving into the country and those in Northern Ireland who are coming up to their eighteenth birthday.

Thank you again for the chance to give evidence. I am obviously more than happy to take any questions you have.

**The Chairperson (Ms Maeve McLaughlin):** Thank you very much for that. There are a number of points that you referred to and that we have reflected on, but I will just raise three of them. The first is on clause 1, and I suppose it is a huge part of the conversation on public awareness and the duty on the Department of Health around education and public awareness. You said that the explanatory note said that there would be a limited cost associated with that: are you challenging that assertion?

**Mr Marriott-Smith:** It is not so much a challenge on the limited cost; I suppose it is more a point of interpretation of what "limited cost" means and the Committee having an awareness of the likely cost of reaching members of the community. I am not saying that it will be a lower or a higher cost; I am

not putting a figure on it. All I am saying is that the Committee would need to be cognizant of the likely costs of trying to reach the whole population, including hard-to-reach groups. Whether that is limited I do not know. Having a fair assessment of what that cost is likely to be is the point that we are trying to make.

**The Chairperson (Ms Maeve McLaughlin):** So it is more about the assessment of that cost.

**Mr Marriott-Smith:** Yes.

**The Chairperson (Ms Maeve McLaughlin):** OK.

You talked about deemed consent only addressing solid organs. I think that would come under clause 2. Is that different to what is proposed in the legislation? In this draft legislation, is there potential scope for the transplantation of other relevant material?

**Mr Marriott-Smith:** The Bill sets out the right to deem consent for relevant material. "Relevant material" is defined as anything that contains human cells, so the Bill could cover more than solid organs. The Bill also provides for Ministers to make provisions to rule out certain types of material from the provisions of deemed consent, but those are not in the Bill. The Welsh parallel, for example, would be that, when the regulations that support the Welsh Act were set out, they ruled out novel transplantations — for example, face or hand transplants — but it is not until the regulations are set that they are ruled out. The Bill is framed in terms of relevant material.

**The Chairperson (Ms Maeve McLaughlin):** It is quite significant, suffice it to say, that we are not talking about deemed consent just for solid organs but there is scope within the legislation for —

**Mr Marriott-Smith:** That is what this Bill provides for, which is in parallel with the Welsh legislation. Although your policy intent is predominantly on organ donation, the framing of it sets deemed consent as a possibility for the transplantation of relevant material. It does not define "organs".

**The Chairperson (Ms Maeve McLaughlin):** From your point of view in the authority, what are the implications of that?

**Mr Marriott-Smith:** I suppose the implications will not hit us as an authority until Ministers have decided what is within and without the scope of the material that is covered by the Bill and for which consent can be deemed. From our perspective, the biggest issue that you would need to face is legitimacy. These are points that were raised to us in the consultation. There were concerns about the scope, particularly for novel transplantations. It is about legitimacy and acceptability to the wider public who think that human material beyond organs might be covered by the scope of what is proposed here. From a regulatory perspective, we would cover whatever is —

**The Chairperson (Ms Maeve McLaughlin):** Does there not need to be a very definition of other relevant material in the legislation?

**Mr Marriott-Smith:** "Relevant material" is defined in the Bill, as are organs, but it does not indicate what relevant material is considered novel and, therefore, what consent cannot be deemed for and what it can. That is the bit that will be set out in regulations.

**The Chairperson (Ms Maeve McLaughlin):** In relation to a lot of the conversation on deemed consent, specifically clause 4, you pointed out that consent and seeking consent are very complex matters that obviously involve clear communication. There is almost the suggestion that it is important that any move to deemed consent does not add further complexity. Can you expand on that?

**Mr Marriott-Smith:** I suppose the point that we are trying to get across is that inaction by an individual to either register and opt in or opt out or to appoint a representative on the organ donor register will act as consent. People really need to understand that that is the implication of taking no action. That is important for the legitimacy of the system. If an individual dies in circumstances where their consent can be deemed and the family say, "Well, they had no idea about this law; it had not reached them", that adds a layer of complexity that does not exist at the moment to the process of family involvement. More widely, a potential worst-case scenario would be where someone's organs are donated through deemed consent but it is subsequently established that they had objected or written evidence is provided that says that they had objected. That could be in a will, say. That has potential problems

for legitimacy and support for the system publicly if those sorts of stories get traction in the media, for example.

**The Chairperson (Ms Maeve McLaughlin):** Potentially, that would undermine trust, which is central.

**Mr Marriott-Smith:** Yes.

**The Chairperson (Ms Maeve McLaughlin):** I am mindful of what you say about communication, particularly in the Welsh scenario, where huge sections of the population were not aware of the legislation.

**Mr Marriott-Smith:** I have not heard evidence, to be honest, that large chunks of the Welsh population have not heard about the legislation; in fact, I think that the Welsh Assembly's evidence suggests something different, but I cannot go any further than that. Again, it goes back to trust and legitimacy. It is not that it makes it illegal: consent can be deemed whether the individual knew about the legislation or not. The Welsh Act has and your Bill will put in place the situation where consent can be deemed if an opinion has not been expressed. It is a wider point about trust in the system. It does not make it illegal just because the individual did not know about it, but the extent to which you can describe an organ taken in those circumstances as either "consent" or "donation" is the point that is open to question.

**Ms McCorley:** Go raibh maith agat, a Chathaoirligh. Thank you very much for your presentation. What I am hearing is that the Bill will add further complexity to how things currently sit legislatively in the event of families and relatives having to consider organ donation.

**Mr Marriott-Smith:** I am not saying it definitively will, but it has the potential to, which is why there is a need to get across to people what the legislation means. I think it can be managed, and the Welsh experience seems to be that getting the message across about what the new law means has been extremely well managed. What I note is that, in the discussion with families, there is potential for an additional layer of difficulty that did not exist before.

**Ms McCorley:** In practical terms, what do you think will change if the Bill were to proceed and become law? What would the impact be?

**Mr Marriott-Smith:** I defer to the point that, as a regulator, I do not take a view — it is difficult for me to do that — on whether the Bill will have an impact that will increase donation rates, leave them stable or reduce them. There are several different models, and I suppose the answer is this: as policymakers, what do you think the root causes are for potential donations not translating into actual donation and transplantation? Those are things that the Bill needs to address. Without hedging quite so much, there is mixed evidence about the impact of deemed consent where it has been introduced. There are different views about different models and about whether mandated choice versus deemed consent will have an impact. There are questions about whether education is the key and about having discussions with the family. All those lead to different responses, and I would not make a judgement. Part of our role in superintending is to try to make an assessment after the fact of what has happened.

**Ms McCorley:** Do you believe there is a benefit in watching how the Welsh legislation progresses and seeing what the outcome is there?

**Mr Marriott-Smith:** We will do that, and it is our intention that, as part of the superintending role, baseline information will be provided pre and post the introduction of the law to get an estimate of its impact. That is something that we will work on closely with the Welsh Government and NHS Blood and Transplant (NHSTB). Whether you should wait is, again, a decision for you as legislators and policymakers.

**The Chairperson (Ms Maeve McLaughlin):** OK, thanks. Unless anybody else has indicated —

**Mr McCarthy:** Just before you go, can you tell me what was your reaction and input to what was going on in Wales? Did you have a consultation there or give any advice or anything like that?

**Mr Marriott-Smith:** Yes, we worked closely with officials in Wales on the development of the code of practice, and we consulted on the code we developed for them. They produced the Bill, as you have done, and we then produced the code of practice that says to practitioners, "This is how you should interpret the Bill from our perspective". We then ran a public consultation on that, although most of the responses were from practitioners, to address where they still did not understand what the law expected of them. That is the model I would expect us to follow in this situation if the Bill became law.

**Mr McKay:** Given your involvement with and input to the Welsh experience, were you happy with the Welsh Government's end product, or were there suggestions that you made that the Welsh Assembly did not take on board?

**Mr Marriott-Smith:** The point that is worth making is that, by the time we came to write the code of practice and to consult on it, the law had been passed. We can write a code of practice based only on what the law says, not what we would like it to say. When we consulted on the code there were questions from practitioners that said, "We'd like to see more on this", and our response was, "We cannot give you more, because it is not in the Bill". The plea I would make is for us to be involved earlier, before the Bill passes, so that we can say which areas you are likely to run into interpretation issues in. I have a couple of examples. It could include things like the definitions of people who are "ordinarily resident" and the treatment of people who you might not consider ordinarily resident, such as students, members of the armed forces or prisoners. Those are policy decisions, but we had to interpret afterwards, because the Bill was silent on the definition of "ordinarily resident". If we are involved earlier, we could point out where practitioners might say, "I do not understand what the Bill says".

**Mr McKay:** Obviously, you are before us at Committee Stage. Was there not a parallel process in the Welsh Assembly where you came in to give your views to help to amend the Bill before it got to that stage?

**Mr Marriott-Smith:** No, our involvement in it was much later. We were involved only when the Bill was further developed.

**The Chairperson (Ms Maeve McLaughlin):** That was reflected in what the consultants who were here earlier said about the need for them to be central to any development of a code of practice. You are saying that your process for the code of practice came after the legislation and that there were issues that could not be altered at that stage.

**Mr Marriott-Smith:** Yes.

**The Chairperson (Ms Maeve McLaughlin):** OK. Thank you for your time. It has been extremely useful. We are reflecting on all of this, and we appreciate you taking the time to give us your expertise today.

**Mr Marriott-Smith:** It was a pleasure. Thank you.