HTA response to call for evidence
Human Transplantation Bill

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Northern Ireland Assembly's Committee for Health, Social Services & Public Safety's call for evidence on the Human Transplantation Bill.

2. As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), and superintending the Human Transplantation (Wales) Act 2013, the HTA ensures that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.

3. As part of our superintending role in Wales, we have published a Code of Practice on the Human Transplantation (Wales) Act 2013 and three pieces of supporting guidance which aim to offer practical support to professionals working in organ donation in Wales. This Code of Practice was consulted on in 2013.

4. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Northern Ireland Assembly. It is the role of the HTA to provide advice and guidance as required. While we have not yet sought legal advice on the detail of this Bill, this response provides our opinion about the provisions of the Bill for consideration by the Committee.

The proposal's in the Human Transplantation Bill

5. The Bill introduces the concepts of deemed and express consent. Express consent is identical to the active consent requirement of the HT Act. It is, in the first instance, the consent of the person themselves in life. If that does not exist, the consent of an appointed representative, and, if there is not a representative, then the consent of a person in a qualifying relationship to the donor.

6. Deemed consent (Section 4) will mean that if an adult has died and has not made his or her views on transplantation known, then the person is deemed to have consented to transplantation. However, deemed consent is not effective unless it is affirmed by a 'qualifying person' (defined in Section 10).

7. Operationally, this system seems not to differ significantly from that which operates at present, in the sense that the NHS Organ Donation Register will be consulted and a conversation will then be held with the family. What will change is that when the deceased has not expressed a decision in life, a person in a qualifying relationship will need to affirm that the deceased would not have objected to transplantation.

8. When an adult resident who had the capacity to consent dies in Northern Ireland, and has expressed either a wish to be considered as an organ donor, or their wish not to be an organ donor, this will be acted upon, if possible. The ability to record a yes or no

decision already exists and is facilitated by the NHS Organ Donation Register across the UK, although this is not the only way it is possible for a person to express their wishes.

HTA response to the sections of the Bill

Section 1: Duty to promote transplantation

9. The HTA notes the commitment in the Bill to promote a campaign informing the public about deemed consent at least once a year. However, we are concerned that paragraph 15 of the Explanatory and Financial Memorandum states 'there will be a limited cost associated with the new duty to run a promotional campaign in support of transplantation'.

10. Communication will be vital in ensuring that every person living in Northern Ireland is aware of the proposed system and how it will affect them. In order for the individual's decision to remain paramount they must be aware of the action they are required to take, if any, to make their views known.

11. Without proper communication an individual may not be in receipt of the information they require to know what their silence on the matter of organ donation after their death will be considered to mean. If the focus on this continuous communications campaign is lost, then there is a significant risk that people will not be properly informed, leading to the whole system being undermined.

12. Communication with all Northern Ireland residents will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English, and also those living in deprived areas.

13. It will be important to develop a communication plan which ensures people who move to Northern Ireland are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, express their wishes.

14. The HTA considers that the planned communication with every Northern Irish resident six months prior to their eighteenth birthday will also be important to ensure that there is time for these young people to make an active decision prior to deemed consent applying to them.

15. The HTA is happy to work with the Northern Ireland Assembly to provide advice on the communications activity for the proposed system.

Section 2: Authorisation of transplantation activities

HTA licensing

16. Under the HT Act, a licence is required for storage of tissue (included at S.2 (2)(a)and(c) of the Bill). Under Section 1 of the HT Act, consent is required for each of these storage

activities and as such a licensed establishment must demonstrate that consent is in place as part of the HTA's licensing requirements.

17. Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012, a licence is required for the removal or implantation of an organ (included at S.2 (2)(b)and(d) of the Bill). A licence granted by the HTA under these Regulations also requires that HT Act consent is in place.

18. The Northern Ireland Assembly and the Department of Health will need to ensure that between the three pieces of legislation, the licensing requirements for these activities are unaffected by the move to deemed consent.

Relevant material

19. Section 2 of the Bill refers to 'relevant material' rather than just organs. Relevant material is defined at Section 17 of the Bill and means 'material, other than gametes, which consists of or includes human cells'. Relevant material does not include 'embryos outside the human body' or 'hair and nails from the body of a living person'.

20. At present the Northern Ireland Assembly plans for deemed consent only address solid organs. However, the Bill provides scope for the transplantation of any relevant material to be lawful with deemed consent. The Bill provides powers to set limits on what constitutes relevant material by way of Regulations. In our experience, there is public sensitivity around certain transplants e.g. novel transplants which mean that careful consideration needs to be given to inclusions and exclusions.

Import and export

21. Under Section 2 (3) (a) and (b), the Northern Ireland Assembly will need to consider how it amends the HT Act to allow material donated under deemed consent provisions in Northern Ireland to be used in the rest of the UK.

22. It will also be important that there is clear and timely communication that the consent requirements of the HT Act in regard to removal of material for the purpose of transplantation remain in place in England and likewise for the HT (Scotland) Act in Scotland.

Section 3-8: relating to consent

Affirming deemed consent

23. The Bill notes in Section 4 (2) (a) (b) and (c) that deemed consent is only effective if a person in a qualifying relationship affirms that the deceased would not have objected to transplantation. We are concerned about this wording as it assumes that the person in the qualifying relationship knows the wishes of the deceased. If they do not, they cannot affirm the decision, and it would appear to us that consent could not be deemed. In England, if the deceased's wishes are unknown, a person in a qualifying relationship can provide consent for donation.

24. As the organisation tasked with developing a Code of Practice which will provide professionals with practical guidance on the Bill, we are concerned that if our interpretation proves to be correct when legal advice is sought, then our advice would be counter productive to the policy aims of the Bill. We would be happy to explore these concerns further with officials.

Expression of wishes

25. Establishing whether consent is in place and seeking consent are complex matters and involve communication with people in a period of high emotion. It is important that any move to a system of deemed consent does not add further complexity and that everyone involved in the process is informed fully of their role and responsibilities.

26. The current NHS Organ Donation Register which allows UK residents to both opt-in and opt-out of organ donation is important to support the wishes of the deceased in life. This must be both easy to access and readily available.

27. However, the NHS Organ Donation Register will not, in law, be the sole mechanism by which wishes could be expressed. A person could opt-out orally or in writing in a variety of ways. For example, expressing a desire to opt-out in a Will appears to us to be legitimate. Alternatively, if the family said that the deceased had orally expressed the desire not to donate, this also seems to us legitimate.

28. One of the tests for express consent is 'the person has died and a decision of the person to consent, or not to consent, was in force immediately before the person's death'.

29. While express consent to donate might not be identified under the current system (resulting in no donation going ahead), the consequences of failing to identify an express wish not to donate under a system of deemed consent (and the donation proceeding) seem to be of a different magnitude ethically and legally.

Section 11-13: relating to offences

30. Under Section 13, consideration should be given to who should make a referral to the Director of Public Prosecutions for Northern Ireland.

31. From the HTA's experience there is merit in policies and procedures being in place from an early stage in order that all involved understand their responsibilities when an offence may have been committed. The Northern Ireland Assembly may choose not to include this level of detail in the primary legislation; however, it should be available in good time for the launch on 31 May 2018.

Sections 14-17: which make general provision

Annual report on transplantation

32. The Bill sets up a mechanism for post-legislative scrutiny. The Department must produce a report once a year on transplantation activities. This will be an important way of assessing the impact of the Act and ensuing there are no unintended consequences. HTA suggests that this report seeks to highlight both successes and challenges. If the

impact is a drop in the number of organs being donated, steps should be taken rapidly to understand the root causes.

Areas for further consideration

33. The HTA believes that there are areas which require further consideration prior to the implementation of the proposed system.

The role of the HTA in the new system

34. Once it becomes law, the Bill will place a number of explicit and implied duties on the HTA. In addition to the requirement to produce a Code of Practice, the HTA is also placed under a duty to superintend the Act. We understand this to mean the provision of advice and guidance on how the legislation should be interpreted. It would be helpful to have early conversations with Northern Ireland Officials about each of these areas.

35. While the HTA has not yet had the opportunity to undertake a full analysis of the impact of the Bill, it has undertaken a similar role in Wales. As in Wales, there a number of possible risks to the implementation of the provisions from a regulatory perspective. These relate to the HTA's role in advising on the practical circumstances under which consent can be deemed.

36. The HTA currently provides advice on the conditions which need to be fulfilled for consent to be valid. As in Wales, the condition that consent should be active will be removed under certain circumstances as a result of the Bill.

37. A further condition is that consent should be informed. For deemed consent to have legitimacy, people affected by it must clearly understand the circumstances under which their consent will be deemed. We provide more detailed views on this in paragraphs 9-15. Widespread understanding among people living in Northern Ireland, over time, is a pre-requisite to being able to advise on specific circumstances under which consent can be deemed. By extension, any reduction in this understanding may limit our ability to provide such advice.

38. While our experience (in partnership with NHS Blood and Transplant (NHSBT)) will allow us to develop a Code of Practice, there may be a number of operational challenges, for example timing of the production of a Code. We will work with officials in Northern Ireland and colleagues in NHSBT to address these issues.

Donation systems across the UK

39. Following the passage of this Bill, the HT Act will govern consent requirements for organs donation in England, the Human Transplant Act (Wales) Act will govern consent requirements for transplantation in Wales, and The Human Transplant Act (Northern Ireland) will govern the consent requirements for transplantation in Northern Ireland. Each piece of legislation has its differences.

40. The Government, Devolved Assemblies, NHSBT and HTA need to give consideration to each of these pieces of legislation to make sure that the three systems do not conflict or cause confusion. For example, different systems may result in challenges for the training of staff that come from other areas of the UK.

For further information please contact Jenna Khalfan, Head of Communications at the Human Tissue Authority. E: jenna.khalfan@hta.gov.uk, T: 02072691958