



# Blood and Transplant

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The Health Committee Clerk  
Room 419  
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1<sup>st</sup> September 2021

Dear Sir/Madam

As Director of Organ and Tissue Donation and Transplantation, and on behalf of NHS Blood and Transplant (NHSBT), I am pleased to provide our submission in response to Committee for Health's call for evidence on the Organ and Tissue donation (Deemed Consent) Bill.

NHSBT welcomes the development of the Organ Donation Deemed Consent Bill for Northern Ireland. We would also like to offer our thanks to the Department of Health in Northern Ireland for the close, collaborative working during the Bill's progress. We believe that, in time, more lives will be saved or improved as a result of this Bill. There is clear public support for the introduction of this Bill with nearly two thousand responses to the public consultation in January 2021, the majority positive and in favour of a law change that seeks to improve consent rates in deceased organ donation.

### **1. Comments on the Bill**

NHSBT is the organisation responsible for delivering deceased organ donation across all of the UK, which includes the employment of Specialist Nurses for Organ Donation. The Bill in its current form aligns closely to the Acts in effect in Wales and England. As such, the training and operational delivery will benefit from experience in those countries as well as seeing a consistent model for consent across England, Wales and Northern Ireland, all countries that are legislated under the Human Tissue Act 2004, which this Bill seeks to amend.

There are significant benefits to be realised from this Bill outside of the expected increase in consent rate and subsequent life-saving transplants. As we have seen with countries that have recently changed their consent system, engagement from minority groups and communities increases as they seek to understand how the law change will affect them, it provides new opportunities to promote organ donation and increase engagement and awareness of the subject.

If the Bill changes significantly from its current form and the consent model varies from those already in place in the UK, this will likely increase the cost for implementation as it will require

a new training model to be built, tested and delivered, bespoke I.T. changes, development of new NHSBT processes and a different model for engagement.

The Bill identifies important safeguards to protect certain Northern Ireland residents, again aligning with those set out in Wales and England e.g. deemed consent cannot apply to under 18's, those not ordinarily resident in Northern Ireland for 12 months prior to their death and those who lack the capacity to understand the legislation for a significant period prior to death. Maintaining the safeguards will allow for a tested model of training and implementation, however changing these safeguards significantly will result in increased the time and costs for training, marketing and engagement.

The explanatory and financial memorandum indicates the importance of a comprehensive marketing campaign to inform the general public of the upcoming changes, how it may affect them and how to record a donation decision (opt-in or opt-out). NHSBT supports this plan and recommends that a 12-month marketing campaign is allocated to ensure every opportunity is afforded to properly inform the public. Promotion and marketing campaigns in other UK countries of 12 months in length have demonstrated, through public surveys, awareness of the upcoming law changes greater than 70% of the population. This is an essential component of the law change as it gives assurance that the law can be implemented safely knowing the general public have been provided with adequate opportunities to record a donation decision, or indeed understand what happens if they don't record a decision.

Finally, consideration should be given to commission a longitudinal study to assess the impact of the change in legislation across the healthcare system and general public. It is recommended that this is conducted by an independent body to assure impartiality. NHSBT will continue to monitor key donation metrics, including consent rate and this data would be able to support any longitudinal study.

## **2. Reassurance regarding NHS Blood and Transplant/ organ donation process**

It is important to provide reassurances regarding NHS Blood and Transplant's current and future processes. In preparation for legislation changes in other UK countries, NHS Blood and Transplant have worked closely with faith representatives, patient groups and clinical teams to seek views on what changes might be needed to implement the new legislation, should the Bill be successful.

### **i. Role of the family**

The public and subsections of the community have been very clear that it is vital that the family should be involved in the discussion regarding organ donation and the next of kin of potential donors will always be approached to discuss the option of donation. If the family is not present when the patient first enters hospital, the NHS goes to great lengths to find them. This starts when the ambulance crews first arrive at the scene and continues until the next of kin can be found. If necessary, the police are asked for their help and other records, such as passport applications, are checked to identify next of kin. Where there is no family, others are approached – such as friends of long-standing.

This family discussion is vital for three reasons.

First, and most importantly, it is simply the right thing to do. Families will be consulted regarding the potential for organ donation, as they have been regarding every other stage of their loved one's care.

Secondly, NHSBT needs to speak to families to determine whether their loved one would have wanted to donate. For those who have recorded a decision on the Organ Donor Register, the Specialist Nurse will inform that family of what their loved one had decided and confirm their loved one's decision. For those who had not recorded a decision and in whom 'deemed consent' would apply, the family is asked for their views on whether their loved one would not have wanted to donate.

Thirdly, Specialist Nurses for Organ Donation need information from the family regarding past medical and lifestyle history. Without this information, it is much more difficult to determine whether it would be safe for any retrieved organs to be transplanted.

Specialist Nurses are very highly trained and manage these discussions in a professional, sensitive and caring way. They ensure that, as far as possible, the family are given sufficient time to consider organ donation and any steps required to facilitate the donation. If necessary, the discussion is delayed so that all the necessary family members can take part. NHS Blood and Transplant data shows that family consent rates are higher if a Specialist Nurse is involved in the family approach. In the UK in 2019/20, when a SNOD was not present for the approach to the family to discuss organ donation, Donors after Brain Death (DBD) and Donors after Circulatory Death (DCD) consent rates were 43% and 24%, respectively, compared with DBD and DCD consent rates of 73% and 69%, respectively, when a SNOD was present. Families are also aided by knowing whether their loved one had recorded a decision on the Organ Donor Register. The consent rate is over 92% if the family know that their loved one had recorded a decision to donate on the Organ Donor Register.

#### **ii. Faith or Beliefs**

The family will also always be asked for their views on whether there should be any special considerations that should be taken in to account to support the donation process. In particular, the family is always asked whether their loved one had any faith or beliefs that should be taken in to account and whether they would like to speak to a faith leader or counsellor. To support this further the NHS Organ Donor Register now includes a section for registrants to record that their faith is important to them and they would like the Specialist Nurse to discuss with the family how to proceed with donation in line with the donor's faith and beliefs.

#### **iii. Safeguarding**

NHS Blood and Transplant has safeguards in place to ensure that no organs or tissues are removed for any purpose without consent. There are strict policies and protocols in place, with many checks throughout the donation, retrieval and transplant process. The consent is checked on multiple occasions, by several different medical, nursing and support teams. NHS Blood and Transplant is audited and inspected on this aspect by the Human Tissue Authority.

### **3. Human Tissue Authority**

It is recommended the Human Tissue Authority should be engaged early in the legislative process to write (or amend) a code of practice for clinicians which will cover a range of scenarios the clinical teams may have to navigate. A Code of Practice exists for both Wales and England and is considered an essential document to accompany the law.

There is a significant risk of the law being wrongly interpreted in the clinical setting if a Code of Practice is not provided, resulting in a potentially unlawful act being committed inadvertently and the erosion of public trust in the new system.

### **4. Secondary Legislation / Regulation**

NHSBT acknowledges there is a need for secondary legislation and regulation to identify either those organs and tissue that can be retrieved under deemed consent or those organs or tissues excluded from deemed consent. Other UK countries where opt-out legislation has been implemented have taken the decision to itemise in regulation all organs and tissues not included under deemed consent, which amounts to a lengthy list of material. For Northern Ireland, consideration should be given for regulations to include those organ and tissues only included under deemed consent.

In the explanatory and Financial memorandum 'commentary on clauses' – clause 1 notes that "consent will not be deemed where the transplantation is of a novel nature". We welcome this and recommend the same provision is made for research. Consent cannot be deemed in Wales or England for the purpose of research and following this example will provide a safe and consistent delivery model. Public consultations from all four UK nations has highlighted the public concern that organs and tissues for research should only be lawful by expressed consent of the family. Public trust in a new consent system relies on them knowing that organs and tissues cannot be removed for any purpose without the appropriate consent in place.

### **5. Financial Effect of the Bill**

We recognise the recurring cost of the Bill to be a reasonable estimate based on our experience with Wales, England and Scotland. There will of course need to be a one-off implementation cost which in large part will be driven by the engagement and marketing activity that will direct the public to use the Organ Donor Register (ODR) website, the National Contact Centre for inbound queries and any other public facing services provided by NHSBT.

The introduction of deemed legislation is expected to increase the number of consents and subsequent donors and will also increase donor activity more broadly. To accommodate this uplift in activity and ensure that whenever donation is a possibility the family will always get the opportunity to speak to a Specialist Nurse for Organ Donation, additional Specialist Nurses will need to be recruited. Without the adequate staffing to support an increase in activity, opportunities for life saving transplants will be lost.

Additionally, an increase in donation activity will have an 'upstream' effect on other NHS services and resources. Specifically, organ donors are primarily identified in the Intensive Care Unit and where consent is gained for donation to proceed, will stay there for up to 48 hours, which will draw further on those services as well as the requirement to use theatre space and retrieval surgeons to conduct the organ donation operation.

Finally, it is anticipated that the change in legislation will increase the availability of organs from donors after circulatory death, from whom currently fewer organs can be successfully transplanted. Organ usage from these donors can be dramatically increased if the retrieval teams are able to use novel technologies that preserve the organs. For example, between February 2015 and July 2018, the introduction of machine perfusion for hearts led to 66 additional hearts being available for transplant. Service evaluations for the use of abdominal organ machine perfusion is also demonstrating significant increases in the number and quality of organs that can be donated. Utilising these new technologies is the only way we can ensure that no potential for a safe transplanted organ is missed.

Of course, all these have cost implications. NHS Blood and Transplant, along with the rest of the NHS, is doing everything it can to improve cost-efficiency and make the most of its available resources. However, it is not possible to deliver against the Government's aim of more donors and more transplants without additional investment across all these areas, it is therefore important to liaise with Commissioners at this early stage, to ensure there is capacity in the system to manage the anticipated increase in organs, noting that organs cross UK borders and England and Scotland have recently introduced their own opt out legislation and the number of organs available are expected to continue to increase over the coming years.

## **6. Conclusion**

NHSBT have worked closely and collaboratively with Northern Ireland Department of Health colleagues through the public consultation process and in support of the passage of the Bill to date. We will continue to provide our expertise and experience as the Bill continues through the Assembly and if Royal Assent is provided, the support will continue through the implementation process and be ready to deliver the change and work under a new consent system in Northern Ireland.

NHSBT would have no issue for this written evidence submission to be made publicly available by the Assembly Committee. Equally, NHSBT are most willing to attend and provide oral evidence should the Committee require. Given the intrinsic nature of our role in organ donation and transplantation, we have several subject matter experts within our organisation which the Committee may benefit hearing from. I would be happy to co-ordinate any representative attendance accordingly, should this be of interest.

Yours sincerely,



**Anthony Clarkson**  
**Director of Organ and Tissue Donation and Transplantation**  
**NHS Blood and Transplant**