

## FROM THE MINISTER OF HEALTH



Department of  
**Health**

An Roinn Sláinte

Mánnystrie O Poustie

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Dear 

### **Re: Organ and Tissue Donation (Deemed Consent) Bill**

I refer to your letter of 17 November 2021 inviting Departmental officials to a meeting of the Health Committee on Thursday, 25 November 2021, to respond to issues that were raised during oral evidence and in written submissions in relation to the Deemed Consent Bill. I would like to place on record my thanks to the Committee for the attention and time it has afforded to considering this important legislation, particularly in light of the busy timetable this term. I can confirm that the officials attending will be Ryan Wilson, Director of Secondary Care, and Ian Plunkett, Head of the Organ Donation Bill Team. In advance of the meeting, my Department's response to the issues raised is set out below.

### **Family Involvement**

#### Inclusion of family

Donation conversations with families, or a person in a qualifying relationship, are an essential part of the donation process, and are conducted by highly trained and experienced clinicians – usually a Specialist Nurse for Organ Donation (SNOD) – in line with the relevant provisions of the Human Tissue Act 2004 and the associated codes of practice. The Bill will not introduce any change to this requirement but will shift the focus of the donation conversation. In fact, the donation conversation will be necessary for deemed consent to be applied, as this can only come into effect when it is understood by the SNOD that there has been no prior decision given in life.

Therefore, for a person's consent to be deemed, the family, or a person in a qualifying relationship, needs to advise that they are unaware of a prior donation decision. Where



this cannot be ascertained (for example, if no family or person in a qualifying relationship can be found), consent cannot be deemed under the proposed law. In this circumstance, donation will not proceed unless there is knowledge of a prior affirmative decision (for example, a decision recorded on the organ donor register, or ODR).

It will also continue to be necessary for the family give the SNOD vital medical, social and behaviour history that is shared with the transplant centres to assess for suitability and safety. Without this information, surgeons are extremely unlikely to accept an organ for transplant.

#### Protecting an individual's wish to donate

Under the current consent system, donor family conversations are always focused on what the potential donor wanted, so the family are always encouraged by the SNOD to support their loved one's last known decision. Time will be spent exploring concerns a family may have, but the patient's decision is always central to that conversation.

Under the proposed deemed consent system, the focus of the donor family conversation will shift: unless there is a known expression or decision to become or not to become a donor, then the patient is considered as being willing to donate. The family will be encouraged by the SNOD to support this position. If the Bill is passed, the relevant code of practice will be revised accordingly, and staff working in Intensive Care Units (ICUs) will receive training under the revised code before the new system goes live.

In this way, the Bill preserves the protection of an individual's decision, as donation can proceed either where there is first-person consent, or where consent can be deemed, however it does not mandate that it *must* proceed (this would be known as 'hard opt-out'). In circumstances where a family strongly objects to donation proceeding – whether their loved one's consent has been affirmed or deemed – the absolute protection of an individual's decision could only be guaranteed if there were an appetite to challenge this from a legal position. My Department would not support legislation overriding a family's objection in these circumstances, as this would entail a significant risk of losing the support of medical and nursing professions, who have a duty of care to the bereaved family as well as to the patient. This highlights the importance of the revised code of practice and staff training in relation to donor family conversations, combined with a promotional campaign which will focus attention on directing citizens to both make and share an informed decision about donation.

### **Workforce and resources**

#### Increase in workforce, infrastructure and other resources

I understand that the Committee has asked Belfast Health and Social Care Trust for further input regarding potential resource requirements.

My Department has been working closely with NHS Blood and Transplant (NHSBT) throughout the entire legislative process to determine what additional resource may be required across Northern Ireland in order to implement the new opt-out legislation successfully, based on the recent experiences of health systems across other UK regions.

Whilst deemed consent will not increase the size of the potential donor pool, it is hoped that it will increase donation by about 10-15 deceased Northern Ireland donors per year, spread across all 10 ICUs. As this will involve patients who have already been admitted to ICU, there is no anticipated material increase in demand in terms of ICU beds and intensive care doctors.

However, in order to sustain donation at the anticipated level, it is envisaged that four additional SNODs will be required for the region. Further additional costs will be incurred due to factors such as increased demand on NHSBT specialist retrieval teams as consent/donation rates grow over time, updating the IT infrastructure (e.g. the ODR), clinical training, and public awareness/education.

These costs are included in a business case which is currently being considered for the implementation and maintenance of a deemed consent system.

#### Duty on Ministers to provide resources

I am aware that provision was made within the equivalent Welsh Act in 2013 for the Welsh Minister to make the resources required for implementation available to Local Health Boards. This was particularly important at that time, as Wales was the first UK region to introduce deemed consent legislation, and this measure ensured that the new law would be met with sufficient funding.

However, it is worth noting that other UK nations and crown dependencies have since introduced, or are in the process of introducing, their own deemed consent systems. Furthermore, my Department has an existing strategic commitment to implementing NHSBT's new *Organ Donation and Transplantation 2030: Meeting the Need* strategy, which I and fellow UK Health Ministers agreed to support when this was published on 1 June 2021. Under the strategy, all UK regions aim to maximise donation consent rates and organ utilisation, and to enhance the current infrastructure in line with available funds in order to meet the anticipated increase in transplantation.

In general, my Department would not support a duty which may constrain future administrations' ability to prioritise resource allocation and service provision in accordance with need, for example, during a pandemic. Furthermore, the existence of a new statutory duty to implement a system of deemed consent, in addition to the above strategic commitment, provide sufficient rationale for the necessary funds to be prioritised within Departmental budgets without the need for additional statutory ring-fencing of specific funds.

Accordingly, in line with normal practice for policy implementation, and subject to business case approval, funds will be prioritised and allocated as required.

#### Cost of administration of an opt-out system

The current system operates on the basis of an Income Generation Agreement between NHSBT and my Department, at a cost of approximately £2.4m per annum. NHSBT is a Special Health Authority with responsibility for the administration of the overall UK system for organ donation and transplantation, including organ retrieval, allocation, storage, transportation and donor consent. The system is based upon the recommendations from an independent taskforce in 2008 which led to significant investment across each region of the UK, including in specialist nursing and retrieval teams as well as the ODR. This has led to a 95% increase in deceased donors and

a 58% increase in deceased donor transplants in the UK since 2008.

This arrangement would continue following any decision by the Assembly to move to an opt-out system in Northern Ireland, with appropriate adjustments being made to funding levels in line with increased transplantation demand/activity and subject to business case approval. NHSBT has completed a detailed analysis of what would be required to give effect to any changes to the legislative framework in Northern Ireland, based on the experiences across other UK regions. This includes one-off administration costs of approximately £450k during the first two years of implementation (2022/23-2023-24) for the recruitment of staff to handle public enquiries, training of clinical and NHSBT staff, changes to the ODR. Thereafter, additional recurrent costs of approximately £660k per annum are anticipated to sustain the additional SNOD staff, transplant activity and education/awareness programmes.

The Committee has enquired whether the same objective, i.e. a sustained increase in the consent rate to at least 80% per annum, could alternatively be achieved by investing these costs in improvements in the existing system. In donor number terms, this equates to approximately 10-15 additional consented donors per year. The current infrastructure and level of funding is not considered a major barrier to achieving this; rather it is the case that deemed consent can be a catalyst to increasing the consent rate through sustained behaviour and cultural change. In this sense, the introduction of deemed consent is one of a range of complementary measures, alongside continued public education, staff training and initiatives to improve organ utilisation, which can help to achieve the strategic aim.

## **Exceptions**

### Inclusion of children over 16

37% of respondents to my Department's consultation did not agree that those under the age of 18 should be exempt from deemed consent provisions under the Bill. The most common reason given was that children have the capacity to give consent from the age of 16. My Department does not dispute that 16-18 year olds would have the competence to give their consent and to understand the processes around deceased organ donation. The question of whether deemed consent provisions should apply to this age group, in the absence of an affirmative decision given in life, requires further consideration.

The current policy proposal as drafted in the Bill means that, unlike adults, for children below 18, there will not be a presumption in favour of organ donation if they have not opted out. This reflects the fact that 18 is widely recognised as the age at which one becomes an adult, and gains full citizenship rights. Under the proposed framework, those under the age of 18 can still join the organ donor register, and can still become organ donors after death, however as consent would not be deemed in these difficult circumstances, this would remain a decision for the young person's family, in consultation with the SNOD team.

Northern Ireland, along with other UK regions, is part of an equitable UK organ sharing scheme. This means that NI citizens benefit from being part of the UK 'pool', in which organs from deceased donors anywhere in the UK are transplanted into individuals with the greatest need and the best chance of success. As noted above, the system by NHSBT on behalf of all regions of the UK.

Deemed consent legislation in Wales, England and Jersey classify from 18 years as the age in which deemed consent applies. Scotland has a different legal framework which recognises 16 year olds as adults, and therefore deemed authorisation would apply from this age.

However, it is important to note that Wales', England's and Northern Ireland's deemed consent legislation each amend the Human Tissue Act 2004. Consistency across the countries working under the Human Tissue Act is essential. NHSBT advises that having a different age for deemed consent in Northern Ireland would add an additional layer of complexity for specialist nurses and clinicians involved in organ donation, as in some cases staff will be travelling between jurisdictions.

The Office of Legislative Counsel has also advised that to lower the age to 16 would require further amendment to the Human Tissue Act 2004, and would also raise potentially difficult issues around the respective roles of persons with parental responsibility for the young person, and other persons in a qualifying relationship.

#### Extension of Deemed Consent to include those who are from other UK jurisdictions

My Department has considered whether the deemed consent provisions in the Bill should be widened to include those who are resident in other UK jurisdictions. This has been suggested due to Northern Ireland being the fourth UK nation to introduce deemed consent, and would, in theory, expand the application of deemed consent beyond eligible Northern Ireland residents to include eligible residents of other UK regions who pass away whilst visiting Northern Ireland.

My Department would not support such a provision due to a number of practical considerations. Firstly, the potential net benefit is miniscule, as only 1% of all deaths occur in situations where donation is possible, therefore such a provision would only apply to a tiny subset of these cases. Secondly, my Department's public consultation strongly supported the exemption of visitors to Northern Ireland from deemed consent provisions. Thirdly, this would be operationally complex because specialist nurses would have to ascertain whether deemed consent would apply to a potential donor in their country of residence. The legislation has to consider what is reasonably practicable regarding the role that clinicians play at the bedside. And finally, this would require policy agreement from other UK Health Ministers and possibly the UK Government.

### **Other Issues**

#### Impact of Brexit on Organ Donation

The Committee has heard evidence from NHSBT, which manages the organ donation and allocation system for the UK. NHSBT has confirmed that it has not experienced any difficulty in transporting organs both around the UK and with EU countries when required.

As a result of EU Exit, Departmental officials are working with colleagues across the UK to develop a Common Framework for organs, tissues and cells. The Common Framework will set UK quality and safety standards, with the aim facilitating ease of procurement, testing, storage, sharing, transportation, and traceability of this material. It is envisaged that individual Ministers will retain the right to make decisions for their own jurisdiction, allowing for divergence by one or more administrations as required,



in order to respond to needs, such as location-dependent health concerns.

#### Living donor programme

The evidence from Wales since the introduction of deemed consent in 2015 is that the Living Donor programme has been maintained at the same activity level as before the law change. One of the key foundations for the *Meeting the Need* UK strategy is the strength of the public support for organ donation and this includes living donation, hence it sets out the actions to support and maximise the potential for living donation. Northern Ireland's renal transplant service leads the way in terms of living donation, and this will continue to be promoted as part of my Department's comprehensive public awareness and education programme.

#### Public Awareness and promotional campaigns

The Committee has heard evidence from the Public Health Agency about the planning which is underway for a comprehensive education and awareness programme in relation to deemed consent. The Bill proposes an additional statutory duty in relation to annual promoting and reporting specifically about deemed consent. This will build upon my Department's existing statutory duty to promote organ donation and transplantation. The objective is to ensure that the legislative changes are fully understood across all sections of the population, and that as many people as possible are aware of the law change, and how to register decisions if they wish.

In the longer term, the majority of this work would become part of the rolling programme for promotion of organ donation, much of which is achieved at minimal cost due to the current co-ordinated and collaborative working approach. Subject to the enactment of the Bill, an enhanced programme of intensive communications will run throughout the 12-month implementation period to ensure adequate time for awareness before go-live, and for a further 12 months of thereafter.

Activity will be tailored to specific audiences as well as the general population, and ensure these audiences are engaged with in the most appropriate manner for them. Engagement has commenced with lead organisations to arrange focus groups for members or leaders to establish their communications requirements. This includes BAME networks, faith networks, and older networks. Working with the community and voluntary sector will further strengthen outreach across all parts of society. Engaging with children and young people is an important approach, therefore the completion and launch of our schools' resources is important.

Campaign planning will examine the use of a range of media channels to maximise exposure. A media strategy is being developed to analyse and plan the most effective channels and timings. Research will be planned at regular intervals, including a baseline survey prior to any awareness activities. This will monitor levels of awareness and understanding of the law change, and any insights will be used to amend awareness activities if required.

#### List of permitted organs

The Committee has enquired whether the list of permitted (or excluded) organs, to which deemed consent provisions would apply, should be provided in primary or in secondary legislation or on the face of the Bill. The advice my Department has received from NHSBT, drawing on the experience of other jurisdictions, is that permitted organs should be included in secondary legislation. This will allow for the law to be responsive

to the advances medical practice without the delays that would otherwise be involved with making amendments to primary legislation.

I trust that this information will assist the Committee in its consideration of the Bill.  
Officials will be happy to provide further details as required.

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Yours sincerely

A handwritten signature in blue ink, appearing to read 'Robin Swann', is positioned above the printed name.

**Robin Swann MLA**  
**Minister of Health**

