

FROM THE MINISTER OF HEALTH



Department of

Health

An Roinn Sláinte

Mánnystrie O Poustie

www.health-ni.gov.uk

Mr Colm Gildernew MLA
Chair, Committee for Health
Room 410
Parliament Buildings
Stormont
BT4 3XX

Castle Buildings
Stormont Estate
BELFAST, BT4 3SQ
Tel: 028 9052 2556
Email: private.office@health-ni.gov.uk

Your Ref:
Our Ref:
Date: 08 September 2021

Dear

Following the First Stage Reading of the Organ and Tissue (Deemed Consent) Bill on 5 July 2021, I understand that officials have now been invited to brief the Health Committee on Thursday 9 September 2021.

A briefing paper is attached which includes details of the officials due to attend. I hope the Committee will find the briefing useful.

Yours sincerely

Robin Swann MLA
Minister of Health

DEPARTMENT BRIEFING FOR THE HEALTH COMMITTEE ORGAN AND TISSUE (DEEMED CONSENT) BILL

Purpose

1. The draft Organ and Tissue (Deemed Consent) Bill aims to change the statutory framework for organ and tissue donation in Northern Ireland to a soft opt-out, or "deemed consent", consent system.
2. The purpose of this paper is to provide the Committee for Health with a briefing on the draft Bill in advance of the evidence session scheduled on Thursday 9 September 2021.
3. Departmental officials attending the evidence session will be:
 - Mr Ryan Wilson, *Director of Secondary Care*
 - Mr Ian Plunkett, *Head of Organ Donation Bill Team*

Background and Policy Objectives

4. The donation of organs and tissues after death helps to save and improve many lives in Northern Ireland each year. Just one donor could transform the lives of up to nine other people. Last year in Northern Ireland there were 51 deceased donors, resulting in 113 transplants throughout the UK. In total, 87 Northern Ireland residents received transplants.
5. Around 115 people in Northern Ireland are on the transplant waiting list, and every year around 10-15 people in Northern Ireland die waiting on an organ transplant. 49% of our population have now joined the NHS Organ Donor Register (ODR) – a steady increase from 30% since 2013. Many more than this – consistently around 90% – say that they support organ donation. In spite of this, around one in four families decide not to proceed with donation when faced with this decision, most often because they do not know what their loved one would have wanted, or what decisions they have made.
6. The main policy objective is to increase the current rate of consent in the small number of cases in which it is clinically possible for organ donation to proceed

after a person's death. Doing so will increase the overall number of donors, and ultimately the number of lifesaving organs available for transplantation.

7. Over half a million people die each year in the UK, but only around 5,000 of those die in circumstances that mean that their organs could be considered for transplantation.
8. Whilst a change in law will not increase the size of the UK donor pool, it has the potential to increase the consent rate in situations where a potential organ donor has been identified. This is generally a person for whom further intensive care has no prospect of bringing about recovery.

NB. In light of the ongoing pandemic, it should be noted that COVID-19 is a clinical contra-indication to potential organ donation, i.e. anyone with suspected COVID-19 cannot be considered as a potential donor after their death.

9. In Northern Ireland, and in other UK regions until recently, the consent rate has remained at around two-thirds of potential donors. The strategic aim is to achieve a sustained 'world class' consent rate of 80% or higher.
10. Changing the statutory framework will require new primary legislation to change the current system in Northern Ireland, in which people can choose to 'opt in' or 'opt out' on the ODR, to a new statutory opt-out system in which consent is deemed or presumed except in certain exempt circumstances, or if a person has made a decision to opt out during their lifetime. This is sometimes known as "deemed consent".

Consultation

11. In July 2020 the Health Minister announced his intention to consult the public on proposals for the introduction of a deemed consent system. This was last considered in 2015/16, when Jo-Anne Dobson's Private Member's Bill was ultimately withdrawn after detailed consideration by the Health Committee. Since then, statutory soft opt-out systems have been introduced in Wales, and more

recently in England and Scotland. The draft Bill would introduce a similar statutory framework for consent as now exists in other parts of the UK.

12. The Department ran a consultation which over 10 weeks from 11 December 2020 to 19 February 2021. Eight virtual engagement events were held, including a consultation meeting hosted by the British Heart Foundation NI on 28 January 2021 which was attended by members of the Health Committee. A total of 1917 written responses were received, showing broad support for the proposed legislative changes from a range of individuals, healthcare professionals, charity organisations, local government and professional bodies.
13. Of the 1917 responses received, a total of 108 responses were received from individuals identifying as Health and Social Care professionals, the vast majority of whom were supportive of the proposals.
14. A total of 15 responses were also received from health professional groups or organisations, none of which expressed opposition to the proposals. These included the Royal College of Physicians, the Royal College of Surgeons, the Royal College of GPs NI, the Royal College of Nursing, the British Medical Association NI, the General Medical Council, and the Human Tissue Authority. A wide range of charities and patient representative organisations also supported the proposals, including the British Heart Foundation, the Children's Heartbeat Trust, Kidney Care UK, and the NI Kidney Patients' Association. It is anticipated that many of these organisations will respond to the Committee's open call for evidence and will be granted the opportunity to put forward views as part of the formal Committee Stage, subject to Assembly agreement at the Second Stage.
15. The public consultation showed strong support for the need for an information campaign around any change in the law to provide for a deemed consent system. Provision is made within the draft Bill which would make this an ongoing statutory responsibility of the Department of Health, with a view to ensuring that both present and future generations would continue to be fully informed about the legislative framework, and would therefore be able to make fully informed

decisions about whether or not they wish to become organ donors. The aim of this provision is to mitigate any concerns about a potential lack of awareness or informed choice among the NI population regarding deemed consent, both now and in the future.

The Current Statutory Framework

16. Currently Northern Ireland has an 'opt-in' framework for consent for organ donation to proceed after a person's death. This means that donation will only ever proceed if a person had given their express consent for organ donation, usually by signing on to the ODR, and/or the person's family supports the donation proceeding. In the absence of a decision being recorded on the ODR, or the family are unaware of their loved one's donation intentions, they are asked to make a decision on their behalf.
17. The effect of the proposed change to the current law will be to shift the focus of the "donation conversation", which is conducted with families at end of life by expert NHS specialist nurses, to establish the known decisions of their loved one. Every other part of the end of life care pathway would remain unchanged and conducted in line with current clinical and professional standards.
18. The legislation underpinning organ donation and transplantation in England, Wales and Northern Ireland is the Human Tissue Act 2004, which covers all aspects of consent around both living and deceased organ donation. Subject to the enactment and Royal Assent to the draft Bill, legislation will be required to be laid at Westminster under negative resolution procedures to amend the relevant sections of the Human Tissue Act 2004 which are applicable to consent in Northern Ireland (i.e. consequential amendments).
19. The Human Tissue Act also established the Human Tissue Authority (HTA) as the UK regulator responsible for overseeing the legal consent requirements by providing advice and guidance to professionals via their Codes of Practice. It is likely that a new Code of Practice will need be written by the HTA for the changes in Northern Ireland (as was the case in Wales and England). It is envisaged that

this would proceed during the implementation phase alongside an extensive public engagement and education campaign about the law change.

Other UK Regions

20. Wales became the first region of the UK to implement a system of deemed consent from December 2015. The consent rate has increased from 58% in 2015 to 70.7% in 2020, although the impact was not immediate and took several years to begin to take effect, following an extensive media promotion and information campaign by the Welsh government.
21. In England, a new opt-out system came into effect from 20 May 2020, however it is too soon to analyse any impact on consent rates. Scotland's opt-out system came into effect from 26 March 2021.
22. Consent rates for the year 1 April 2019 - 31 March 2020 in each region of the UK are summarised in the table below:

Nation	Consent Rate (%)
England	68.3
Northern Ireland	64
Scotland	64.8
Wales	70.7

23. Consent rates for the year 1 April 2020 - 31 March 2021 in each region of the UK are summarised in the following table. It should be noted that these figures are not directly comparable to previous years, due primarily to the impact of COVID-19. Across the UK there was a 25% fall in the total number of deceased organ donors in 2020-2021, and a 28% decrease in organs donated.

Nation	Consent Rate (%)
England	68
Northern Ireland	79
Scotland	73
Wales	69

24. Full details and contextualisation of these statistics can be found in NHS Blood and Transplant's annual activity report for 2020/21, at: <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/24053/activity-report-2020-2021.pdf>

Final Policy Content

25. The Explanatory and Financial Memorandum describes in detail the effect of Clause 3 of the draft Bill, which would make amendments to section 3 of the Human Tissue Act 2004, and to sections 15 and 16(3) of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016. This would give effect to the following policy proposals:

- It will be considered that everyone living in Northern Ireland agrees to donate their organs when they die, unless they have confirmed otherwise by opting out on the ODR, or otherwise making their decision known, or they are from one of the excluded groups (see below for further details);
- Individuals will still have the choice about whether or not they want to become a donor;
- Families will continue to play an important role in the consent process in all cases, however whilst the nature of the end of life discussion with families would change, the family will always be asked about the last known organ donation decision of their loved one, to ensure it is still accurate;
- Decisions based on faith and belief will continue to be respected;
- Deemed consent should not be applied in the case of donation of organs for research purposes, for which there is a separate process covered by the Human Tissue Act;
- Deemed consent should not be applied in the case of novel and rare types of transplants (e.g. face, limb, genitals), i.e. it will apply only in respect of human organs which are normally considered for transplantation: heart, lungs, liver, kidneys, pancreas and small bowel; as well as tissue including heart valves, corneas and bone; and
- The Department's existing statutory duty to promote and report on organ transplantation will be extended to include specific advice and information

within the annual campaign and report about the law on statutory soft opt-out and about how people can record their decisions if they wish.

26. The following groups will be exempt from deemed consent for organ donation:

- Children and young people under the age of 18;
- Adults who lack capacity to understand the new system, for example, an adult with advanced dementia or severe learning difficulties;
- People whose identity is unknown;
- People who are not ordinarily resident in Northern Ireland – this would include, for example:
 - tourists;
 - cross-border workers who reside in the Republic of Ireland;
 - people who are temporarily resident in Northern Ireland, such as: students; overseas Armed Forces personnel temporarily based in Northern Ireland; people on work placements from overseas or the Republic of Ireland; some prisoners who may be placed in any prison in Northern Ireland from other regions of the UK.

Promoting Organ Donation in Northern Ireland

27. It is acknowledged that legislative change alone will not achieve a sustained increase in organ donation consent rates. It can be a potential enabler of further progress towards this goal, if combined with increased public awareness and knowledge. Countries with mature opt-out systems and high rates of consent tend to also have high levels of public support and understanding around the benefits of organ donation and transplantation. The introduction of deemed consent for Northern Ireland must therefore be combined with the existing programme public communications and professional education which aims to embed long term cultural and behavioural change.

28. The Department of Health will therefore continue to implement the commitments set out in its 2018 policy statement, in line with the statutory duty to promote transplantation which was conferred on in by Part 4 of the Health (Miscellaneous Provisions) Act (NI) 2016. The overall objective of the policy is to promote a positive, cultural, long term change in attitudes and behaviours in relation to

organ donation. The Department works closely with the Health and Social Care (HSC) system, the public sector (including local government and the education system), and wider society, to promote organ donation through a coordinated and sustained communication programme. These commitments are not diminished by the proposed move to a statutory opt-out system, rather the proposed amendments to the Health (Miscellaneous Provisions) Act (NI) 2016 will further enhance the existing promotion and communications programme.

