

# **ORGAN AND TISSUE DONATION (DEEMED CONSENT) BILL**

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## **EXPLANATORY AND FINANCIAL MEMORANDUM**

### **INTRODUCTION**

1. This Explanatory and Financial memorandum has been prepared by the Department of Health (“the Department”) in order to assist the reader of the Bill and to help inform debate on it. It does not form part of the Bill and has not been endorsed by the Assembly.
2. The Memorandum needs to be read in conjunction with the Bill. It is not, and neither is it meant to be, a comprehensive description of the Bill. Where a clause or part of a clause does not seem to require an explanation or comment, none is given.

### **BACKGROUND AND POLICY OBJECTIVES**

3. 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.
4. There is widespread public support in the United Kingdom for organ donation, with around 80% of people saying that they support organ donation ‘in principle’, and would be willing to donate their organs and tissue after they have died. Over the last 10 years, the number of organ donors has increased by 75% and transplants from deceased donors have increased by 56%. There are almost 25 million people on the NHS Organ Donation Register (ODR).
5. Despite this, there is a shortage of donors in Northern Ireland, with around 115 people waiting for a transplant. 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. Since the introduction of an opt-out system in Wales, consent rates from deceased donors in Wales have increased from 58% in 2015 to 70.7% in 2020. However, the international standard for world class performance is recognised to be an 80% consent rate. This is the target consent rate to which all UK regions have aspired within the current UK-wide strategy (2013-2020). However, the current overall consent rate across the UK (for the year 2019/20) is around 70%. The consent rate in Northern Ireland is 64%, and has not increased significantly for several years despite consistently high levels of support for organ donation and consistent growth in registrations on the ODR.
6. Under the current rules in Northern Ireland, a person is considered a possible organ donor following their death if they actively took steps to consent in their lifetime or in

the absence of a decision made in life, the family can consent on the patient's behalf.

7. 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.
8. Whilst a change in the law will not increase the number of cases in which it is clinically possible for organ donation to proceed after a person's death, 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.
9. The Bill would change the current system in Northern Ireland, from one where 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 often referred to as "deemed consent".

## **CONSULTATION**

10. The policy underlying many of the provisions in this Bill was the subject of consultation by the Department. The consultation was launched in December 2020 and sought views on a number of issues regarding the implementation of the new system of deemed consent. The Department received just under 2000 responses from individuals and organisations.
11. The Department's response to the consultation, will be published shortly. The Department set out its proposals for implementation. These include changes to the ODR to make it easier to record a decision and a 12-month transition period between the legislation being passed and the changes coming into effect, to allow time for an extensive awareness and education campaign before the implementation of the new system to ensure all members of the public are fully aware of the implications of the legislative change. That awareness and education campaign will continue as the new system is being implemented.

## **OVERVIEW**

12. The current law on consent for the use of bodies and most human organs and tissue relevant material is set out in the Human Tissue Act 2004 ("the 2004 Act"). The 2004 Act, among other things, makes provision with respect to activities involving human tissue, such as organ transplantation, and authorises the removal, storage and use of organs and tissues for the purpose of transplantation if there is "appropriate consent". The meaning of appropriate consent differs depending on whether the relevant material is obtained from an adult or child, but, under the 2004 Act as it currently stands, the overarching principle for activities which are to take place after an individual's death is that consent must be given expressly by a decision of the individual which is in force

- immediately before their death, or by a decision by a person appointed by them or in a “qualifying relationship” with them.
13. The Bill amends the 2004 Act to provide that consent to organ and tissue donation in NI will be deemed to have been given by a potential adult organ donor before their death unless they had expressly stated that they did not wish to be an organ donor or one of the exceptions applies.
  14. This is often referred to as an “opt-out” system of consent as a person will be deemed to have given consent to becoming an organ donor unless they have otherwise indicated. The Bill does not propose any changes to the rules on consent to organ donation in respect of children under 18 or people who have expressly made a decision on consent before their death (either by recording their decision to give or refuse consent or appointing someone to make that decision on their behalf).
  15. This Bill also does not propose any change to consent concerning transplants from living persons and the consent of the donor will continue to be required in those circumstances. Further, the Bill sets out that deemed consent will not apply where a person in a qualifying relationship to the deceased (partners, certain family members or a friend of long standing) provides information that would lead a reasonable person to conclude that the deceased potential organ donor would not have consented to be an organ donor. This has been referred to as a “soft opt-out” system as evidence of the known wishes of the deceased person has to be considered in deciding whether consent should be deemed to have been given.
  16. The Bill also provides exceptions applicable to the following groups of adults, in respect of whom the deemed consent provisions will not apply:
    - people who were short-term visitors or temporarily resident in Northern Ireland for less than 12 months immediately before dying. Examples could include overseas workers, students, overseas Armed Forces personnel; and
    - people who lacked the capability to fully understand the consequences of deemed consent for a significant period before dying.
  17. Deemed consent will not apply in respect of all organs and tissues. Organs and tissues that are to be included within deemed consent will be set out in regulations made by the Department.
  18. The Bill will also amend the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 to extend the Department’s existing statutory duty to report to the Assembly to include, at least once every five years, the opinion of the Department as to whether both the 2016 Act and the new Organ and Tissue Donation (Deemed Consent) Act, have been effective in promoting transplantation. The Bill also includes a duty on the Department to inform the public at least once a year specifically about deemed consent and how a person can during their lifetime record their own decisions about transplantation after their death of parts of their body, or appoint someone to make decisions after their death about transplantation of parts of their body.

## **COMMENTARY ON CLAUSES**

### **Clause 1: “Appropriate consent” to adult transplantation activities: Northern Ireland**

This clause amends section 3 of the 2004 Act to provide that the deemed consent of the person concerned amounts to appropriate consent for the purposes of certain transplantation activities unless the person concerned is an excepted adult. This is achieved in particular by the amendment to subsection (6)(ba). By shifting the default position in relation to consent away from an opt-in system to an opt-out one, it is hoped that consent for transplantation in the cases which are clinically suitable will rise towards the target percentage of 80 per cent.

There will be, of course, people who have actively recorded a decision in writing before they died as to whether they do or do not consent to organ donation, or who opted to appoint someone to make that decision on their behalf. In these cases, as in the case of children and living donors, there is no change to what constitutes “appropriate consent”. The Bill also provides that consent cannot be deemed to have been given where a person who stood in a qualifying relationship to the deceased provides information that would lead to a conclusion that the deceased would not have consented to organ donation.

Consent will not be deemed to have been given in cases where the transplantation is of novel material. This is to ensure that the new system of consent is in line with the common understanding of organ and tissue donation. Material that is permitted to be transplanted (permitted material) will be specified in regulations made by the Department following consultation. Regulations made by the Department under the provisions inserted by this Bill must be laid in draft before and approved by a resolution of the Assembly.

People who lacked capacity to understand deemed consent for a significant period before their death and those who were not ordinarily resident in Northern Ireland for at least 12 months before dying are excluded from the deemed consent system.

The clause amends section 15 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016 to include a duty on the Department to inform the public at least once a year specifically about deemed consent and how a person can during their lifetime record their own decisions about transplantation after their death of parts of their body, or appoint someone to make decisions after their death about transplantation of parts of their body. The clause also amends section 16(3)(a) of that Act to extend the duty of the Department to report the opinion of the Department as to whether that Act has been effective in promoting transplantation to include reporting also on whether this Bill has been effective in promoting transplantation.

## **FINANCIAL EFFECTS OF THE BILL**

19. Implementation of statutory opt-out costs are estimated in the region of £400-500k per year for up to nine years, mainly on public education and awareness, change management, IT infrastructure changes, processing additional registrations, evaluation and clinical training.

## **HUMAN RIGHTS ISSUES**

20. The provisions of the Bill are compatible with the European Convention on Human Rights.

## **EQUALITY IMPACT ASSESSMENT**

21. An Equality Impact Assessment was not deemed necessary following equality screening as the proposed policy and resulting legislation is not considered to have a detrimental impact on equality of opportunity or the promotion of good relations between section 75 groups.

## **SUMMARY OF THE REGULATORY IMPACT ASSESSMENT**

22. A Regulatory Impact Assessment was screened out as all sections of the community would be expected to benefit from the change in policy/legislation.

## **DATA PROTECTION IMPACT ASSESSMENT/DATA PROTECTION BY DESIGN**

23. A Data Protection Impact Assessment screening was completed. A full Assessment was not required.

## **RURAL NEEDS IMPACT ASSESSMENT**

24. As the Bill will have no differential impact on rural inhabitants, a full Rural Needs Impact Assessment is not appropriate.

## **LEGISLATIVE COMPETENCE**

25. At Introduction the Minister of Health had made the following statement under section 9 of the Northern Ireland Act 1998:

*“In my view the Organ Donation (Deemed Consent) Bill would be within the legislative competence of the Northern Ireland Assembly.”*