



Northern Ireland
Assembly

Research and Information Service Bill Paper

Sinéad McMurray

Organ Donation: The Introduction of Soft Opt-Out Legislation in Northern Ireland

NIAR 237-2021

Key Points

There are three types of organ donation - donation after circulatory death (DCD), donation after brain stem death (DBD) and living donation. One deceased donor can potentially save or improve the life of up to nine other people and many more may be helped through the donation of tissues.

Very few patients die in circumstances that allow organ donation to proceed. In the UK only 1% of the population will die in circumstances where organ donation is currently considered possible.

Northern Ireland, along with England, Scotland and Wales, are part of an equitable UK organ sharing scheme. The system, including the NHS Organ Donor Register, is operated by NHS Blood and Transplant, (NHSBT) on behalf of all regions of the UK.

Since the establishment of the NHSBT, the UK has made significant gains in increasing the number of organs available and the number of transplants. The number of deceased organ donors has almost doubled from 809 (2007/08) to 1,580 (2019/20) and the number of transplants from these donors has increased by 58% from 2,384 to 3,760.

These gains were achieved from a growing focus on ensuring that the NHS embraced organ donation as a usual part of end-of-life care and sustained efforts to increase consent or authorisation for deceased organ donation.

Despite these improvements, on average three people per day die in the UK due to a lack of available organs. In Northern Ireland, around 10-15 people die every year waiting on an organ transplant.

The international standard for world class performance is recognised to be an 80% consent rate (Spain, Poland and Republic of Ireland are all greater than 80%). This is the target consent rate to which all UK regions aspire. However, the current overall consent rate across the UK is 69%.

In 2019/20, Northern Ireland had the lowest consent rate of all four regions at 62%. This is despite approximately 80% of the population stating they agree with organ donation in principle. Wales currently has the highest consent rate in the UK at 69%.

The most commonly debated strategy to try and improve organ donation consent rates is the relative merits of an opt-out system for organ donation (termed “presumed or deemed consent”) versus the opt-in system (termed “explicit consent”) to increase organ donor rates.

Departing from the more traditional opt-in, express consent model of organ donation, whereby *not* donating is the default, deemed consent considers all those who die to be donors in the absence of a formally expressed wish to the contrary. It is a system that has been implemented across the world and more countries consider the move each year.

Spain is the world leader for the implementation of the opt-out system, where “deemed consent” legislation was passed in 1979. The rationale to support opt-out systems is that choosing organ donation consent as the default option bridges the gap between public support for organ donation and actual donation registration statistics.

However, the rise in donor rates in Spain was not observed until 10 years after legislation implementation when a national organisation for organ donation was founded to co-ordinate the donation and transplantation process. It is difficult to establish whether the improvement in consent rate is attributable to legislation change alone or whether it was associated with a number of other interventions introduced as part of opt out implementation.

The broader international evidence including the experience of Spain, and more recently Wales, suggests that legislative system changes that are accompanied by complementary interventions at different levels of society and the health system appear to have the most success.

Family refusal ranks as the biggest single identified obstacle to organ donation in the UK. An increase in donor consent/authorisation rates to 85% would deliver almost 500 additional donors annually, and as a result is widely regarded as the element of the donation pathway most in need of improvement. Introducing opt out legalisation is considered to prompt individuals to make a decision on organ donation in life and inform their families of this fact thus removing the onus on families to make this decision on behalf of their loved one.

Wales became the first region in the UK to implement opt out legislation when the *Human Transplantation (Wales) Act 2013* took effect in 2015. Since the introduction of the new legislation, Wales have gone on to have the highest organ donation consent rate in the UK reaching an all-time high of 77% in 2018/19.

Scotland and England have also recently introduced similar opt out legislation under the *Human Tissue (Authorisation) (Scotland) Act 2019* and the *Organ Donation (Deemed Consent) Act 2019* respectively.

The Acts are very similar and central to each is the notion of deemed consent. Within this legislative framework, consent by a deceased person will be ‘deemed’ if the individual is aged 18 and over (16 in Scotland), has lived in the specified region for 12 calendar months or more and is ordinarily resident there in a voluntary capacity, the person has had the capacity to understand the notion of deemed consent for a significant period before death and died in the specified region.

Excepted adults are those who had not been ordinarily resident in the region for the 12 months prior to their death or had lacked capacity to understand deemed consent for a significant period before their death.

Furthermore, those who have actively recorded a decision in writing before they died as to whether they do or do not consent to organ donation (e.g. through the ODR) are also exempt.

Deemed consent will also 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.

The Family remain a central part of the decision-making process. In the event that the family of the deceased have an objection to organ donation occurring, even where the deceased has expressed a wish to donate, donation will not go ahead.

All three regions have undertaken extensive media campaigns to inform the public of their options under the new legislation. For ministers in Wales and Scotland this is a legal duty.

On July 5th 2021 the NI Minister for Health Robin Swann MLA introduced ***the ‘Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2021***. The bill which contains one clause, will amend section three of the Human Tissue Act 2004 (current legislation governing organ donation in NI) to provide that the deemed consent of the person amounts to ‘appropriate consent’ for the purposes of certain organ transplantation activities except in cases where the person is considered to be excepted.

In Northern Ireland excepted persons include those who had not been ordinarily resident in the region for the 12 months prior to their death or had lacked capacity to understand deemed consent for a significant period before their death. Furthermore, those who have actively recorded a decision in writing before they died as to whether they do or do not consent to organ donation (e.g. through the ODR), Prisoners and those under 18 are also exempt.

The bill will also amend section 15 of the *Health (Miscellaneous Provisions) Act (Northern Ireland) 2016* to extend the DoH’s existing statutory duty to promote organ donation annually by including specific advice and information within the annual campaign about the law on statutory soft opt out and about how people can record their decisions if they wish. Further it will amend section 16 of *the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016* to extend the duty of the DoH to report their opinion as to whether that Act has been effective in promoting transplantation.

The consultation carried out prior to the bill being introduced to the Assembly also highlights areas where there will be no change to the legislation including transplantation of rare and novel tissues. There are no plans to change the commitment to honouring an individual’s decision regarding faith/ beliefs and the support and advice available to families.

As with England, Scotland and Wales, the family will remain central to the decision making and will always be consulted before donation. The Human Tissue Authority will develop a code of practice for NI which will set out how the new arrangements will work in practice, including discussions with the family.

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1 Introduction - organ donation

Organ transplantation surgery is thought to be one of the most effective forms of medical treatment for patients with organ failure affecting the heart, kidneys, lungs, pancreas, liver and small bowel. Recent years have also seen an increase in the number of transplants of tissue and bone aimed not at saving lives, but improving quality of life. Using tissue and bone donations, medics are able to repair and rebuild the bodies and lives of severely injured people and improve the health and quality of life for patients suffering from chronic illness.¹

One donor can potentially save or improve the life of up to nine other people and many more may be helped through the donation of tissues.²

On average three people per day die in the UK due to a lack of available organs. In Northern Ireland around 10-15 people die every year waiting on an organ transplant.³ Patients from black, Asian and minority ethnic backgrounds are more likely to need an organ transplant than the rest of the population as they are more susceptible to illnesses such as diabetes and hypertension, which may result in organ failure.⁴ There is a much smaller number of potentially matched donors for these groups.⁵

There are three different types of donation⁶:

- **DCD (donation after circulatory death)** (also known as 'non-heartbeating donation' or 'donation following cardiac death'). This refers to the retrieval of organs for the purpose of transplantation from patients whose death is confirmed using cardio-respiratory criteria⁷;
 - There is an important distinction between 'controlled DCD' where death follows the planned withdrawal of life-sustaining treatment, and 'uncontrolled DCD' where death is sudden and unexpected;
- **DBD (donation after brain stem death)** – refers to patients whose death has been confirmed using neurological criteria;
 - Donors after brain death provide, on average, one more organ for transplantation than donors after circulatory death; and
- **Living donation** - A living person can donate their kidney, part of their liver, and tissue donations of bone and amniotic membrane. Thirty nine percent of all organ

¹NHS Blood and Transplant (NHSBT), What can you donate?, <https://www.organdonation.nhs.uk/helping-you-to-decide/about-organ-donation/what-can-you-donate/>

² Department of Health, Public Consultation Document on the introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/consultations/health/doh-organ-donation-consultation.pdf>

³ As cited directly above

⁴ NHS Blood and Transplant (NHSBT), Why Black, Asian and minority ethnic donors are needed, <https://www.nhsbt.nhs.uk/how-you-can-help/get-involved/key-messages-and-information/why-black-asian-and-minority-ethnic-donors-are-needed/>

⁵ As cited directly above

⁶ Building on Progress: Where next for organ donation policy in the UK? British Medical Association, February 2012, page 12, http://bma.org.uk/-/media/Files/PDFs/Working%20for%20change/Shaping%20healthcare/organdonation_buildingonprogressfebruary2012.pdf

⁷ NHS Blood and Transplant (NHSBT), Donation after circulatory death, <https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/donation-after-circulatory-death/>

donors are living donors and living donor transplantation represents 21% of total transplant activity.⁸

Very few patients die in circumstances that allow organ donation to proceed. In the UK only 1% of the population will die in circumstances where organ donation is currently considered possible.⁹ For clinical and practical reasons, the patient must die from the 'right' diseases (that is, be free of transmissible agents such as cancer and significant infections), in the 'right' place (that is, in hospital and probably in an ICU), and in the 'right' way (that is, death must be, at least to some extent, expected and predictable). Most donors have suffered a catastrophic brain injury from intracerebral bleeding, trauma, or hypoxia, and have been treated in intensive care.¹⁰

2 Organ donation policy and strategy in the UK

Improvements in rates of organ donation require action in two areas: (i) developing the infrastructure within which donation takes place and (ii) increasing the number of donors.

2.1 Infrastructure to manage organ donation – NHS Blood and Transplant

Northern Ireland, along with England, Scotland and Wales, 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 donors anywhere in the UK are transplanted into individuals with the greatest need and the best chance of success. The system, including the NHS Organ Donor Register, is operated by NHS Blood and Transplant, (NHSBT) on behalf of all regions of the UK.¹¹

In December 2006, the Organ Donation Taskforce (ODT) was charged with focusing on developing the infrastructure within which donation takes place. Its remit was to identify barriers to donation and transplantation and recommend ways to overcome them within the existing operational and legal framework across the UK.

The ODT reported in January 2008 with 14 recommendations which were "modelled on national and international best practice including the Spanish system, which has one of the highest rates of donation in Europe".¹²

*'Spain is taken to be the gold standard for deceased organ donation and may be close to the limit in terms of the rate of deceased organ donors that can be achieved.'*¹³

⁸ NHS Blood and Transplant (NHSBT), Living Donation, <https://www.odt.nhs.uk/living-donation/>

⁹ <https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

¹⁰ Rudge C. J. (2018). Organ donation: opting in or opting out?. The British journal of general practice : the journal of the Royal College of General Practitioners, 68(667), 62–63.

¹¹ Department of Health (2020) Public Consultation Document on the introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/consultations/health/doh-organ-donation-consultation.pdf>

¹² Organ Donation and Transplants, POSTNOTE 441, Houses of Parliament, September 2013, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-441#fullreport>

¹³ Levitt, M, (2015), Could the organ shortage ever be met?, *Life Sci Soc Policy*. 2015 Dec; 11: 6, <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC4513003/>

The recommendations which were set out in the concluding report '*Organ Donation Taskforce Report: 'Organs for Transplant'*' were fully implemented by the NHSBT and the devolved administrations. The ODT did not recommend a legislative change for the UK as it was envisaged that full implementation of its recommendations would lead to a 50% increase in donors.¹⁴

Following the publication of the taskforce report in 2008 and the subsequent NHSBT strategies '*Taking Organ Transplantation to 2020*' and the '*Living Donor Kidney Transplantation 2020 Strategy*', the UK has made significant gains in increasing the number of organs available and transplants.

2.2 Positive gains in the number of available organs and transplants

The number of deceased organ donors has almost doubled from 809 (2007/08) to 1,580 (2019/20) and the number of transplants from these donors has increased by 58% from 2,384 to 3,760.

Figure 1: Deceased donors and transplants in the UK, 1 April 2007 to 31 March 2020 and active transplant list at 31 March 2020



*2019/20: Many patients became suspended from the active transplant list as transplant centres reacted to the COVID-19 pandemic in March 2020. Therefore, 29 February 2020 has been used as a more representative date for the number of patients on the active transplant list at year end in 2019/20.

¹⁴ Organ Donation and Transplants, POSTNOTE 441, Houses of Parliament, September 2013, <http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-441#fullreport>

The increase in deceased donations over the last decade stemmed from a growing focus on ensuring that the NHS embraced organ donation as a usual part of end-of-life care including the introduction of:

- Increased numbers of specialist nurses in organ donation;
- Every hospital having access to a dedicated clinical lead supported by a donation committee;
- Dedicated organ retrieval teams serving the entire UK, available 24/7;
- Clinicians having access to ethical and legal advice to help them facilitate donation and;
- Regional collaboratives bringing together leaders in organ donation.¹⁵

Figure 1 demonstrates data up as far as 2019/20. The COVID-19 pandemic led to unprecedented challenges for UK transplantation and as such figures for 2020/2021 do not accurately reflect typical donation and transplantation activity.

Despite the challenges presented by the pandemic, the NHSBT reports that they were able to conclude the year with 75% of proceeding deceased donor activity (1,180) and 78% of deceased donor transplants (2,947) compared to the previous year. These numbers compared favourably to international activity and reflect the solid infrastructure that has been put in place since the ODT recommendations¹⁶

2.3 Sustained efforts to increase consent for organ donation

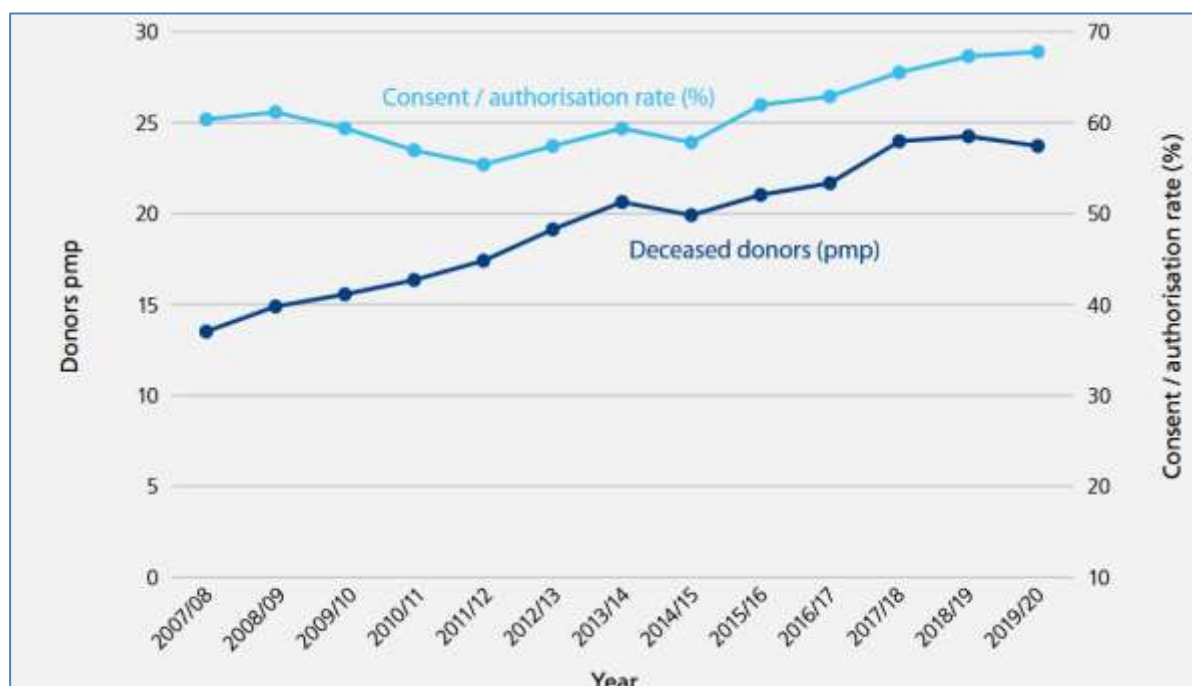
The sustained effort to increase consent or authorisation for deceased organ donation is also thought to have played a significant part in the gains made since 2008. The 'consent rate' is an internationally used measure to indicate the number of potential donors for whom consent to proceed with donation is confirmed. It is measured by the number of families who agree to support donation going ahead divided by the number of potential donor families approached for donation.¹⁷ Figure 2 outlines the changes in overall consent/authorisation rate and donors per million population (pmp) in the UK since 2007.

¹⁵ NHSBT (2020) Organ Donation and Transplantation 2030: Meeting the Need: A ten-year vision for organ donation and transplantation in the United Kingdom <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

¹⁶ Organ Donation and Transplantation Activity Report 2020/21 Available at: <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/24053/activity-report-2020-2021.pdf>

¹⁷ Department of Health (2020) Public Consultation Document on the introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/consultations/health/doh-organ-donation-consultation.pdf>

Figure 2: Overall consent/authorisation rate and donors per million population (pmp) in the UK, 1 April 2007 to 31 March 2020¹⁸



The international standard for world class performance is recognised to be an 80% consent rate (Spain, Poland and Republic of Ireland are all greater than 80%).¹⁹ This is the target consent rate to which all UK regions had aspired within the last UK-wide strategy (2013-2020). The overall consent rate across the UK (for the year 2019/20) was 68%. Positively, this represents a 1% rise on the previous year's figure and the fifth consecutive year of continuous improvement in the overall figure for the UK.²⁰ In 2020/21 it climbed a further 1% to 69%.

Table one below demonstrates that in 2019/20 NI had the lowest consent rate of all four nations at 62%. Wales reported the highest consent rate in the UK at 69%. Interestingly, Wales consent rate has fallen from an all-time time high of 77% in 2018/19 to 69% in 2019//20. However, 69% still marks a significant improvement in the consent rate for Wales since the country introduced soft opt-out legislation in 2015.

Both Scotland and NI demonstrated significant gains in consent rates (73% and 79% respectively) in 2020/21 but the DoH have highlighted that due to Covid-19 and other factors this is not considered a sustained increase to the overall number of consented donors; and organs donated were significantly lower than previous years.²¹

¹⁸ NHSBT (2020) Organ Donation and Transplantation 2030: Meeting the Need: A ten-year vision for organ donation and transplantation in the United Kingdom <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

¹⁹ As cited directly above

²⁰ Organ Donation and Transplantation Activity Report 2020/21 Available at: <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/24053/activity-report-2020-2021.pdf>

²¹ Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

Table 1: Organ donation consent rates, years 2013-2021, England, Wales, Scotland and Northern Ireland²²

	England	Wales	Scotland	Northern Ireland
2013/2014	60%	54%	62%	57%
2014/2015	59%	49%	54%	60%
2015/2016	63%	59%	57%	59%
2016/2017	63%	64%	63%	64%
2017/2018	66%	70%	57%	66%
2018/2019	67%	77%	64%	63%
2019/2020	68%	69%	65%	62%
2020/2021	68%	69%	73%	79%

2.4 Inequalities and challenges remain

Despite the absolute number of people listed for a transplant falling (7,661 in 2007/8 to 6,138 in 2019/20) and a reduction in the waiting time for a transplant, still too many people wait too long or die before transplantation. There may also be further unmet need, in that not all patients who could benefit from a transplant are currently added to the transplant waiting list.

Inequalities also remain across areas of the UK and in the types of organ transplant. For example, the fall in the number of people waiting for a kidney, liver or pancreas masks an increase in the number of people waiting for a heart or lungs. People from a BAME background are also still disproportionately affected by shortfalls and longer waits for a suitable kidney for transplantation and there are lower rates of organ donation amongst these communities.²³

In 2021, the NHSBT published a new strategy '*Organ Donation and Transplantation 2030: Meeting the Need*'. The strategy notes that previous efforts have focusing mainly on organ donation initiatives and while there remains great potential for increases in donor numbers in both living and deceased organ donation, there are also opportunities for the UK to increase organ utilisation using new technologies and techniques.

²² Data taken from section 13 of NHSBT Organ and Tissue Donation and Transplantation Activity Reports 2013/2014 – 2020/2021 <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>

²³ NHS Blood and Transplant BAME Annual Report <https://www.odt.nhs.uk/statistics-and-reports/bame-annual-report/>

The new strategy will focus on addressing organ utilisation challenges and support the development of models of organ recovery – where organs can be assessed and treated with precision medicine prior to transplantation.

Furthermore, the strategy will focus on issues related to BAME communities with the strategy highlighting that the shift in ethnicity across the UK will require a greater focus on how to ensure equitable outcomes for all.²⁴

The substantial policy developments and subsequent improvements in both the numbers of donors and transplants in the UK has taken place at a time of significant legislative change with regard to organ donation across the four regions. Organ donation laws vary across the different regions in the United Kingdom, the details of which will be discussed in section four of this report.

3. International organ donation legislation – overview

There is a continued disparity between the supply and demand for organs across countries with an established infrastructure to facilitate transplantation. This has led to the development of different strategies to bridge this gap to ensure people do not die while waiting for organ transplantation.

The most commonly debated strategy is the relative merits of an opt-out system for organ donation (termed “presumed or deemed consent”) versus the opt-in system (termed “explicit consent”) to increase organ donor rates.

Departing from the more traditional opt-in, express consent model of organ donation, whereby *not* donating is the default, deemed consent considers all those who die to be donors in the absence of a formally expressed wish to the contrary.²⁵ It is a system that has been implemented across the world and more countries consider the move each year.

The rationale to support opt-out systems is that choosing organ donation consent as the default option bridges the gap between public support for organ donation and actual donation registration statistics.²⁶ In addition to bypassing the possible apathy or procrastination of people who have good intentions to donate, choosing opt-out as the default mechanism for organ donation also informs the public of the recommended course of action from policymakers. For example, experimental evidence suggests presuming organ donation is the default option for citizens may make them consider that to be the natural choice, whereas presuming the opposite makes the choice special rather than the norm.²⁷

On the other hand, public concerns raised about opt-out systems include not trusting doctors to work as hard to save the lives of registered organ donors, moral objection and worries of

²⁴ <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

²⁵ Parsons, JA (2021) Deemed consent for organ donation: a comparison of the English and Scottish approaches. *Journal of Law and the Biosciences*, Volume 8, Issue 1, January-June 2021

²⁶ As cited directly above

²⁷ (2019) Comparison of organ donation and transplantation rates between opt-out and opt-in systems *Kidney International* Volume 95, Issue 6, June Pages 1453-1460

the management of the objection registry for those who do decide to opt-out of donation.²⁸ Additional concerns that exist include compromising the freedom of choice to donate²⁹ and conflicts with religious beliefs.³⁰

Internationally, there are a wide range of different systems that are used for organ donation consent, the merits for which are a continued subject of debate. Table 2 provides more details on these systems.³¹

Table 2: Different types of organ donation consent systems

1: A 'hard' opt out system	Doctors can remove organs from every adult who dies - unless a person has registered to opt out. This applies even if relatives know that the deceased would object to donation but had failed to register during life. <i>E.G. Austria</i>
2: A 'hard' opt out system which does not cover some groups	Doctors can remove organs from every adult who dies - unless a person has registered to opt out OR the person belongs to a group that is defined in law as being against an opt out system. <i>E.G. Singapore where Muslims are exempt.</i>
3: A 'soft' opt out system	<p>Option 3a: No need to consult relatives. Doctors can remove organs from every adult who dies - unless a person has registered to opt out OR the person's relatives tell doctors not to take organs. It is up to the relatives to tell the doctors because the doctors may not ask them. <i>Example: Belgium</i></p> <p>Option 3b: Relatives should be consulted. Doctors can remove organs from every adult who dies - unless a person has registered to opt out. It is good practice for doctors to ask the relatives for their agreement at the time of death. <i>Example: Spain</i></p>
4: A 'soft' opt in system	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. It is normal practice to let relatives know if the person has opted in and doctors can decide not to proceed if faced with opposition from relatives <i>Example: Northern Ireland</i>
5: A 'hard' opt in system'	Doctors can remove organs from adults who have opted in. It is up to each person to decide if they want to opt in. Relatives are not able to oppose the person's wishes.

²⁸ Cohen, C (1992) "The Case for Presumed Consent". *Transplantation Proceedings*. **24** (5): 2168–2172.

²⁹ U.S. Department of Health and Human Services (2013) 2012 National Survey of Organ Donation Attitudes and Behaviors. *U.S. Department of Health and Human Services: Health Research and Services Administration*: 47. September 2013.

³⁰ Leins, C (February 12, 2016). "Should the Government Decide if You're an Organ Donor?". U.S. News and World Report.

³¹ Department of Health (2008) Organs for Transplants: A report from the Organ Donation Taskforce.

6: A choice to opt in or opt out

Option 6a: People can register their choice to opt in or opt out.

Option 6b: People must register their choice to opt in or opt out.

It is reasonable to expect an increase in the organ donation rate after the introduction of an opt out system, but the system does not translate into an increase in the organ donation rate universally, at least not in the initial stage.³² Spain is the world leader for the implementation of the opt-out system, where “deemed consent” legislation was passed in 1979. However, the rise in donor rate was not observed until 10 years later when a national organisation for organ donation with essential resources was founded to co-ordinate the donation and transplantation process.³³

The deceased organ donation rate in Spain is the highest in the world at 47 per million population (pmp). However, countries like Sweden (19 pmp) and Luxembourg (15 pmp) have low organ donation rates despite adoption of similar opt out systems.³⁴ It is argued that the establishment of a national transplant network across all Spanish hospitals, a vast transplant coordinator network, a drive to promote donation after circulatory death, as well as the use of expanded criteria allografts to increase organ utilisation have all been more important in improving donation rates in Spain rather than simply the opt out system it adopted.³⁵

The success of the Spanish model prompted the European Union to approve a directive to boost rates of organ availability by adapting the Spanish model of developing a coordination system at national level and at hospital level.³⁶ The World Health Organization also urged countries to do the same in order to work towards achieving national self-sufficiency, reduce mortality rates and combat organ trafficking.³⁷

Wales adopted an opt out system for organ donation in 2015 and has shown significant gains with regard to organ donation consent rates, currently the highest in the UK. However, it is difficult to establish whether the improvement in consent rate in Wales can be attributable to legislation change alone or whether it was associated with a number of other interventions introduced as part of opt out implementation. Wales implemented deemed consent 2 years after the legislation was passed in 2013.³⁸

The years in between allowed for an extensive media promotion campaign by the Welsh government informing the Welsh public that the law around organ donation was changing

³² Man Shrestha, B (2020) Organ donation: England will have “opt-out” system from May 2020 *BMJ* 368:m752

³³ Bramhall S. (2011). Presumed consent for organ donation: a case against. *Annals of The Royal College of Surgeons of England*, 93(4), 270–272

³⁴ Man Shrestha, B (2020) Organ donation: England will have “opt-out” system from May 2020 *BMJ* 368:m752

³⁵ Etheredge HR. (2021) Assessing Global Organ Donation Policies: Opt-In vs Opt-Out. *Risk Manag Healthc Policy*. 2021; 14:1985-1998

³⁶ R. Watson (2010) Pan-European organ transplant scheme promises to cut waiting times *BMJ*, 340 (2010)

³⁷ F.L. Delmonico, *et al.* A call for government accountability to achieve national self-sufficiency in organ donation and transplantation. *The Lancet*, 378 (2011), pp. 1414-1418

³⁸ Welsh Government (2015) Update to survey of public attitudes to organ donation: key figures from wave 10..

<https://gov.wales/sites/default/files/statistics-and-research/2019-04/public-attitudes-organ-donation-wave-10-key-figures.pdf>

and they had to make a decision: either to opt-in, opt-out or have their consent deemed. The Welsh government committed £2 million, over 2 years to the campaign achieving 74% population awareness of the legislative change before implementation.³⁹

The NHS Blood and Transplant's team of specialist nurses in organ donation who cover Wales, felt that a period of adjustment (with an increase in training needs) was required for healthcare staff to become fully accustomed to the change in style and language of the family approach under the new legislation. It is though that familiarity with the legislation, training and growing confidence of the specialists who approached families regarding donation, as well as high public awareness contributed heavily to the observed increase in consent rates.⁴⁰

However, it is also questionable whether the same improvement could have been achieved without the impetus of legislation change. The broader international evidence including the experience of Wales, suggests that a move to an opt out system and the associated changes (e.g. increased media awareness raising, staff training) is likely to impact positively on many important factors that promote organ donation (public awareness, numbers on the ODR and deemed consent/authorisation rates). Thus, legislation is likely to be a catalyst for other beneficial changes in the wider system.⁴¹

Recent literature and systematic reviews suggest that there is no numerical consensus on which donation system (opt-in or opt-out) is superior, and overall, the body of evidence that examines whether opt out legislation in isolation causes increases in donation and transplant lacks robustness and is sparse.⁴²

Legislative system changes that are accompanied by complementary interventions at different levels of society and the health system appear to have the most success.

4. Organ donation in the UK: maximising opportunities

As previously mentioned, only a very small proportion of the deaths in the UK represent potential organ donors, normally occurring where the deceased has been on a ventilator in a hospital intensive care unit. Figure 3 illustrates the potential deceased organ donor population in the UK in 2019/20 and clearly highlights the small proportion of deaths in the UK that represent potential donors.⁴³

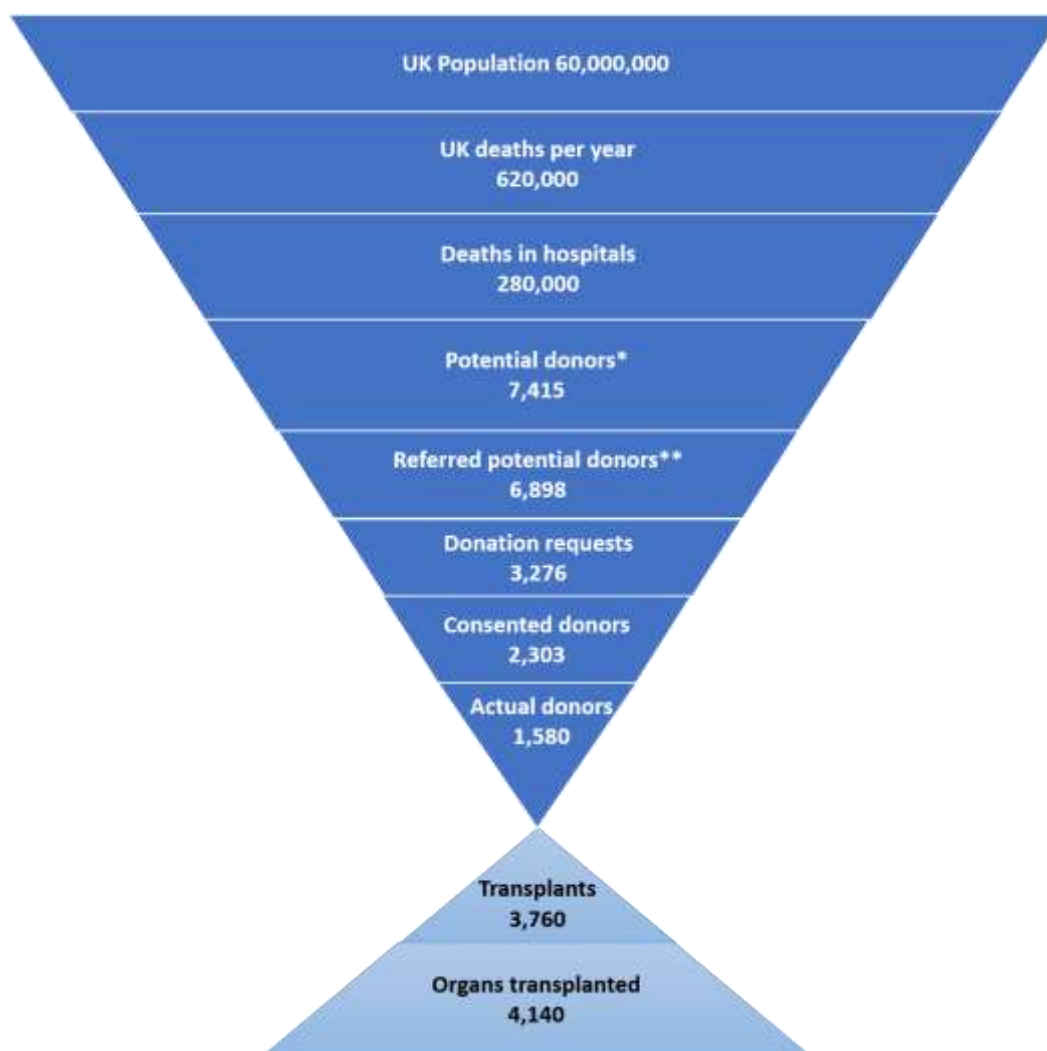
³⁹ Welsh Government (2015) Update to survey of public attitudes to organ donation: key figures from wave 10. <https://gov.wales/sites/default/files/statistics-and-research/2019-04/public-attitudes-organ-donation-wave-10-key-figures.pdf>

⁴⁰ Madden, S (2020) The effect on consent rates for deceased organ donation in Wales after the introduction of an opt-out System, Volume 75, Issue 9 September 2020 Pages 1146-1152

⁴¹ Niven, J and Chalmers, N (2018) Opt-out organ donation: A rapid evidence review Scottish Government, Health and Social Care <https://www.gov.scot/binaries/content/documents/govscot/publications/research-and-analysis/2018/07/opt-out-organ-donation-rapid-evidence-review/documents/00538437-pdf/00538437-pdf/govscot%3Adocument/00538437.pdf>

⁴² Etheredge HR (2021) Assessing Global Organ Donation Policies: Opt-In vs Opt-Out. *Risk Manag Healthc Policy*. 14:1985 1998 **and** Shrestha, BM (2020) Organ donation: England will have "opt-out" system from May *BMJ*;368:m752

⁴³ NHS Blood and Transplant Annual Activity Report 2019/20, data taken from Figure 2.3, <https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/19481/activity-report-2019-2020.pdf>

Figure 3: UK potential deceased organ donor population, 1 April 2019 –31 March 2020

* Potential donor -patients for whom death was confirmed following neurological tests or patients who had treatment withdrawn and death was anticipated within four hours

** Referred potential donor –Potential donor who was discussed with a Specialist Organ Donation Nurse

In the last decade, the UK has seen a sustained increase in deceased organ donors and deceased donor transplants. At the same time numbers on the transplant waiting list have been falling year on year. This fall reflects an increasing number of transplants performed over the last ten years and a reasonably steady number of patients joining the transplant list each year.⁴⁴ Furthermore, the gains being made in living donations has reduced the demand for more complex deceased transplant options for long-waiting patients.⁴⁵

Despite encouraging progress over the last decade, opportunities for donation continue to be missed. There are a number of complex factors impacting upon donation and utilisation of

⁴⁴ NHS Blood and Transplant Annual Activity Report 2016/17 https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

⁴⁵ NHS Blood and Transport (2021) Organ Donation and Transplantation 2030: Meeting the Need Available at: <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

organs for transplant. Donor characteristics continue to change: donors are older, more obese, more likely to have co-morbidities and less likely to have suffered a trauma-related death, all of which have adverse effects on transplant outcome. Furthermore, transplantation depends on clinicians recognising the potential for organ donation and this does not always happen, particularly when donation after circulatory death is a possibility.⁴⁶

The NHSBT also cite family decline rates as the biggest single identified obstacle to organ donation in the UK. An increase in donor consent/authorisation rates to 85% would deliver almost 500 additional donors annually, and as a result is widely regarded as the element of the donation pathway most in need of improvement.⁴⁷

4.1 Family refusal

There are three broad and complementary strategies to increasing consent/authorisation for organ donation – ensuring a planned and collaborative approach in the way donation is raised with a family, promotional behaviour change campaigns that seek to improve the public's support for donation and legislative reform that might 'reset' societal expectations.

Family refusal very often reflects the understandable difficulties that families face when losing a loved one and there are two main ways this can be addressed. First of all, family refusal is less likely when the possibility of donation is raised by trained requestors -specialist nurses for organ donation (SNOD). There is conclusive evidence to show that the training and skilled support of donation professionals improve rates of family authorisation for organ donation.⁴⁸ However, there are still occasions when this does not happen and when donation is raised by clinical staff who have had little training in what is a very delicate task.⁴⁹

Table 3 below shows the primary reasons families in the UK gave for refusing consent for donation in 2019/20.⁵⁰

⁴⁶ NHS Blood and Transplant Annual Activity Report 2016/17 https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

⁴⁷ Increasing consent and authorisation rates, OTD Website, Available at: <https://www.odt.nhs.uk/deceased-donation/best-practice-guidance/consent-and-authorisation/>

⁴⁸ B. Domínguez-Gil, et al.(2010) Decrease in refusals to donate in Spain despite no substantial change in the population's attitude towards donation Organs, tissues & cells, 13 (2010), pp. 17-24 *and* W. Hulme, et al. (2016) Factors influencing the family consent rate for organ donation in the UK Anaesthesia, 71 (2016), pp. 1053-1063

⁴⁹ NHS Blood and Transplant Annual Activity Report 2016/17 https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

⁵⁰ NHS Blood and Transplant Annual Activity Report 2016/17 <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/19481/activity-report-2019-2020.pdf>

Table 3: Reasons why family did not support organ donation, 1 April 2019 to 29 February 2020*

Primary reason for family not supporting donation	%
Patient had previously expressed a wish not to donate	25.4%
Family were not sure whether the patient would have agreed to donation	14.1%
Family felt the length of time for the donation process was too long	13%
Family did not want surgery to the body	9.9%
Family felt patient had suffered enough	9.1%
Family felt it was against their religious/cultural beliefs	5.2%
Family were divided over the decision	3.9%
Family felt that the body should be buried whole (unrelated to religious/cultural reasons)	3.5%

**The above table list includes the most frequently cited reasons, less frequently cited reasons can be found in Organ Donation and Transplantation Activity Report 2019/20*

There is considerable variation between transplant units and clinicians in their approach to risk when offered a donor organ for one of their patients. It can take many transactions to place organs with recipients, slowing down the process and resulting in extra stress for everyone involved. Sometimes donor families withdraw consent because they can no longer cope with the time involved.⁵¹ This is evident in table 3 with 13% of respondents suggesting this as the main reason they refuse to donate their loved one's organs.

Secondly, families are much more likely to support donation when the individual's decision is known beforehand. Families often hesitate to authorise organ procurement because they do not feel entitled to interfere with such an individual decision, especially when the deceased's wish is unknown (14.1% of families in 2019/20).⁵² This demonstrates the importance of education and awareness campaigns that encourage individuals and families to decide on organ donation and discuss it in life. This is particularly important for families from black and Asian communities, where there is little tradition of organ donation but many people waiting for a transplant.⁵³

Legislation is seen as a potential enabler of further progress towards increasing the consent rate. As previously discussed, the example of Wales suggests that legislative change plays a role in increasing donation rates when introduced in tandem with other initiatives including education and awareness campaigns.⁵⁴

⁵¹NHS Blood and Transplant Organ Donation and Transplantation Activity Report 2016/17: Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

⁵²Bea, S (2021) Opt-out policy and the organ shortage problem: Critical insights and practical considerations, Transplantation Reviews Volume 35, Issue 1

⁵³ NHS Blood and Transplant Organ Donation and Transplantation Activity Report 2016/17: Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/4657/activity_report_2016_17.pdf

⁵⁴ NHS Blood and Transplant Organ Donation and Transplantation Activity Report 2018/19: Available at: <https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/16537/organ-donation-and-transplantation-activity-report-2018-2019.pdf>

4.2 Innovative technologies and collaborative working in hospitals

In order to effectively increase donation rates regardless of opt-out legislation, it is important to continue to foster a hospital culture of donation and to further integrate organ donation as a regular process in end-of-life care in hospitals.⁵⁵ The aim is to activate all potential opportunities for deceased donation, both after brain-death and circulatory-death diagnosis when possible⁵⁶

The appointment and expertise of specialist nurses and clinical leads in organ donation remains of paramount importance, but it needs to be coupled with the collaboration of other healthcare practitioners in intensive care units and emergency departments. Donation specialists largely depend on other practitioners' notification, thus enlisting their collaboration and providing adequate training is an integral part of current strategies of best practice in the UK.⁵⁷

Besides specialised staff, technological equipment is also essential to support donation processes and ensure the procurement of viable organs for transplants. For example, effective donor management requires the use of *in situ* regional perfusion technology to ensure optimal organ functionality and minimise organ damage.⁵⁸ Effective donor management also requires the availability and use of *ex situ* perfusion machines that keep retrieved organs functional allowing enhanced preservation and longer timeframes before transplant.⁵⁹ These technological innovations are fundamental in increasing the quantity and also the quality of donated organs for transplants, especially in the settings with a donation after circulatory death programme.⁶⁰

As discussed previously, the most recent strategy by the NHSBT '*Organ Donation and Transplantation 2030: Meeting the Need*' has shifted priority from increasing the number of available donors to focusing on developing opportunities for the UK to increase organ utilisation using new technologies and techniques and further developing models of organ recovery.⁶¹

5. Current UK legislation/organ donation register – overview

Throughout the UK, the main way for a person to make their wishes known during life is to join the Organ Donation Register (ODR). Everyone irrespective of age or health and who is

⁵⁵ Bea, S (2021) Opt-out policy and the organ shortage problem: Critical insights and practical considerations, *Transplantation Reviews* Volume 35, Issue 1

⁵⁶ Citerio, G et al. (2016) Organ donation in adults: a critical care perspective *Intensive Care Med*, 42 (2016), pp. 305-315

⁵⁷ Bea, S (2021) Opt-out policy and the organ shortage problem: Critical insights and practical considerations *Transplantation Reviews* Volume 35, Issue 1,

⁵⁸ Organ donor research: towards a more effective system *The Lancet Editorial*, 390 (2017), p. 1928

⁵⁹ D. Nasralla, et al (2018) A randomized trial of normothermic preservation in liver transplantation *Nature*, 557 (2018), pp. 50-56

⁶⁰ Bea, S (2021) Opt-out policy and the organ shortage problem: Critical insights and practical considerations *Transplantation Reviews* Volume 35, Issue 1, January 2021

⁶¹ NHS Blood and Transplant (2021) *Organ Donation and Transplantation 2030: Meeting the Need* Available at: <https://nhsbt.dbe.blob.core.windows.net/umbraco-assets-corp/23463/meeting-the-need-2030.pdf>

considered legally competent can join the ODR and “entry in the register provides legal consent for the donation of your organs”.⁶²

On 9th July 2015, NHSBT (in collaboration with the devolved governments) launched the new NHS ODR. It continues to hold all the existing registrations from the previous ODR for England, NI, Scotland and Wales and allows any resident in the UK to record:

- A decision to be a donor;
- A decision not to be a donor;
- A decision to appoint/nominate a representative to make a decision about organ donation after the person's death.⁶³

This is different to the previous ODR which only had the option to record a decision to be an organ donor. The new options were made to support the implementation of the Human Transplantation (Wales) Act 2013.⁶⁴

As at 31 March 2021, 40% of the UK's population has signed up on the NHS Organ Donor Register (England, Wales, Scotland and NI were 38%, 42%, 51% and 49%, respectively).⁶⁵

The recent changes in legislation in Scotland and England has seen an increase in the number of opt in registrations on the NHS ODR from 26.0 to 26.7 million at the end of March 2021. There were also 2 million people who chose to opt out of donating their organs after death. However, this is much lower than the initial estimates for opt out registrations when the law changed –the forecast was 8% of people opting out, when in fact it's just over 3%.⁶⁶

Prior to the introduction of new legislation in England and Wales, the legislative framework governing both regions with regard to organ donation was that of an opt-in system of consent, described in the **Human Tissue Act 2004** (HTA 2004).⁶⁷ Northern Ireland is currently governed by the HTA 2004.

The HTA 2004 established the Human Tissue Authority to regulate relevant activities across the UK through a system of licensing and the production and provision of directions and guidance.⁶⁸

⁶² *Organ Donation and Transplantation*, NHS Blood and Transplant Website, www.nhsbt.nhs.uk/what-we-do/organ-donation-transplantation/,

⁶³ NHS Blood and Transplant launches new Organ Donor Register, Organ donation website: Available at: <https://www.organdonation.nhs.uk/get-involved/news/nhsbt-launches-new-organ-donor-register/>

⁶⁴ As cited directly above

⁶⁵ NHS Blood and Transplant (2021) Organ Donation and Transplantation Activity Report 2020/21. Available from: <https://www.odt.nhs.uk/statistics-and-reports/annual-activity-report/>.

⁶⁶ As cited directly above

⁶⁷ The Human Tissue Act 2004 ODT Clinical Website. Available at: <https://www.odt.nhs.uk/odt-structures-and-standards/regulation/the-human-tissue-act-2004/>

⁶⁸ The Human Tissue Act 2004 ODT Clinical Website. Available at: <https://www.odt.nhs.uk/odt-structures-and-standards/regulation/the-human-tissue-act-2004/>

In Scotland, prior to the introduction of new legislation in March 2021, organ donation was governed under the provisions of **The Human Tissue (Scotland) Act 2006** (HTA 2006), which closely mirrored the 2004 Act.⁶⁹

5.1 Wales

Wales became the first nation in the UK to implement opt out legislation when the Human Transplantation (Wales) Act 2013 (HTWA 2013) came into force in December 2015 to much praise. It was declared a ‘progressive policy’ for a ‘progressive nation’ by Mark Drakeford, the Cabinet Secretary for Health and Social Services at the time.⁷⁰ Under the HTWA 2013, any deceased adult who is not ‘excepted’⁷¹ is deemed to consent to organ donation unless they had a decision relating to donation in force immediately before their death or had appointed a person or persons to handle the issue of consent on their behalf.⁷² The act also allows for a relative or friend of long standing of the deceased to object to donation proceeding based on views held by the deceased,⁷³ provided a reasonable person would conclude that the relative or friend knows that the deceased’s most recent view would have been against consenting to donation.⁷⁴

Under the HTWA 2013 the family is still very much involved in the decision-making process. Thus, Wales can be said to have adopted a soft opt out system. The family are involved in discussions both to provide information about the person’s residency and medical history, as well as to say whether they knew that the deceased person had an objection to organ donation.⁷⁵ If the deceased person did have such an objection, organ donation would not go ahead. However, the legislation states that the objection must be based on the known views of the deceased, rather than the views of the family.

In practice however, objection to donation by those in qualifying relationships, even where the decision of the deceased was to donate, donation would not proceed.⁷⁶ Furthermore, where those deemed to be in a qualifying relationship with the deceased can’t be contacted, the donation also will not go ahead.⁷⁷

⁶⁹ Human Tissue Act 2004 (Background and Summary), College of Medicine, Biological Sciences and Psychology, University of Leicester, <http://www2.le.ac.uk/colleges/medbiopsych/research/researchgovernance/human-tissue-act/human-tissue-act-2004-background-and-summary>

⁷⁰ Organ donation opt-out system given go-ahead in Wales, BBC News Website <https://www.bbc.co.uk/news/uk-wales-politics-23143236>

⁷¹ S.5 (3) Human Transplantation (Wales) Act 2013

⁷² S.4 (2) (a) and 4 (3) Human Transplantation (Wales) Act 2013.

⁷³ S.4 (4) (a) Human Transplantation (Wales) Act 2013.

⁷⁴ S.4 (4) (b) Human Transplantation (Wales) Act 2013.

⁷⁵ Jones, M (2015) New organ donation system comes into force in Wales, National Assembly for Wales Research Service. Available at: <https://research.senedd.wales/research-articles/new-organ-donation-system-comes-into-force-in-wales/>

⁷⁶ Parsons, JA Deemed consent for organ donation: a comparison of the English and Scottish approaches, Journal of Law and the Biosciences, Volume 8, Issue 1, January-June 2021

⁷⁷ Jones, M (2015) New organ donation system comes into force in Wales, National Assembly for Wales Research Service. Available at: <https://research.senedd.wales/research-articles/new-organ-donation-system-comes-into-force-in-wales/>

Within this legislative framework in Wales, consent by a deceased person will be ‘deemed’ if all the below apply to the individual:

- Is aged 18 and over;
- Has lived in Wales for 12 calendar months or more and is ordinarily resident in Wales in a voluntary capacity;
- Has had the capacity to understand the notion of deemed consent for a significant period before death (12 months); and
- Died in Wales.⁷⁸

Excepted adults are those who had not been ordinarily resident in Wales for the 12 months prior to their death or had lacked capacity to understand deemed consent for a significant period before their death.⁷⁹

The HTWA 2013 also places a legal duty on Welsh Ministers to promote transplantation by supporting a campaign at least once every 12 months to inform the public of how deemed consent operates in the absence of express consent.⁸⁰ Further, for the first five years after the Act’s coming into force, Welsh Ministers were required to report what has been done to fulfil this duty to the National Assembly for Wales annually.⁸¹

In November 2017, the Welsh Government published an evaluation of the HTWA 2013. The evaluation report looked at several aspects of the implementation of the act. It found that early figures on organ donation rates had not increased since the introduction of the deemed consent system, but public awareness and support for the new system was high, and family consent rates had increased.

It was suggested in the report that a longer period of time would be needed to draw firmer conclusions around the impact of the change in the law as well as highlighting the importance of continuing to monitor public attitudes alongside the routine data on organ donation in Wales (and more generally across other parts of the UK for comparison).

A study in the Journal of Medical Ethics, published in February 2018, assessed the Welsh legislation “in light of concerns that it would decrease procurement rates for living and deceased donation, as well as sparking an increase in family refusals”. It found that none of these concerns had come to pass, “with Wales experiencing more registered donors, fewer family refusals and more living donations”.⁸²

⁷⁸ As above

⁷⁹ S.5 (3) Human Transplantation (Wales) Act 2013

⁸⁰ S.2 (2) Human Transplantation (Wales) Act 2013

⁸¹ S.2 (3) Human Transplantation (Wales) Act 2013

⁸² Albertsen A (2018) Deemed consent: assessing the new opt-out approach to organ procurement in Wales, Journal of Medical Ethics 2018; 44:314-318.

5.2 England

In May 2020, England introduced the Organ Donation (Deemed Consent) Act 2019 (DCA 2019). Also known as *Max and Keira's Law* - In recognition of two children considered to have inspired the change after Max was saved by the donated heart of Keira - the Act brought into force a system of deemed consent for adults in England.⁸³

The rationale behind the move to deemed consent in England was, at least in part, evidence of public support. According to the explanatory notes to the DCA 2019, around 80 per cent of the English public support organ donation 'in principle', so the intention of the Act was to bring the reality in line with public opinion.⁸⁴

The Bill provides that, in the absence of a deceased adult having made express provision in relation to consent before their death or having appointed someone to decide on consent for them, the default position in most cases will be that consent will be deemed to have been given.⁸⁵

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. The DCA 2019 places responsibility on the Human Tissue Authority to provide guidance as to what constitutes sufficient evidence to conclude that the deceased would not have consented.⁸⁶

The HTA Code of Practice, as updated on May 20, 2020, notes that the role of those in qualifying relationships is important, and that sensitive communication and engagement with them is essential.⁸⁷ Where deemed consent applies, the guidance states that the Specialist Nurse should explain the situation to those in qualifying relationships, thereby giving them an opportunity to demonstrate that the deceased would not have wanted to be a donor.⁸⁸ Of note, if it is not possible to speak with those in qualifying relationships to the deceased, the HTA Code of Practice states that donation should *not* proceed.⁸⁹ This is on the basis that it risks undermining public confidence which might outweigh the benefits of donation.⁹⁰

⁸³ Timeline for Max and Keira's Law How England moved to an opt out system for organ donation, *Organ Donation Website*, available at: <https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/timeline-for-max-and-keiras-law/>

⁸⁴ Organ Donation (Deemed Consent) Bill as introduced in the House of Commons on 19 July 2017(Bill 12) explanatory Notes <https://publications.parliament.uk/pa/bills/cbill/2017-2019/0012/en/18012en.pdf>

⁸⁵ As cited directly above

⁸⁶ S.27 (8) (8ZB) Human Tissue Act 2004, as amended by s.2 (4) Organ Donation (Deemed Consent) Act 2019.

⁸⁷ Human Tissue Authority, *supra* note 23, at para 80.

⁸⁸ Human Tissue Authority, *supra* note 23, at para 87

⁸⁹ Human Tissue Authority, *supra* note 23, at para 91.

⁹⁰ Parsons, JA (2020) Deemed consent for organ donation: a comparison of the English and Scottish approaches, *Journal of Law and the Biosciences*, Volume 8, Issue 1

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 are short-term visitors or temporarily resident in England for less than 12 months, such as overseas workers, students and overseas Armed Forces personnel; and
- people who lack the capability to fully understand the consequences of deemed consent for a significant period before dying.⁹¹

Unlike in Wales, the DCA 2019 details no duty on Ministers to raise public awareness of organ donation, however the NHSBT launched a long-running campaign to increase awareness around the upcoming changes to the laws.⁹²

Concerns have been raised that the public awareness campaign to accompany the introduction of deemed consent has thus far been overshadowed by coverage of the COVID-19 pandemic and will likely continue to be indefinitely. Commentators have highlighted that this could result in a significant proportion of the population being unaware of the new system and the fact that they are now potential organ donors. In the absence of sufficient public awareness, the autonomy of such individuals may be undermined, as being unaware of the new system prevents them from exercising their right to opt out.⁹³

5.3 Scotland

In Scotland, a similar model of deemed consent to that of England and Wales came into force in March 2021. The Human Tissue (Authorisation) (Scotland) Act 2019 allows the donation of a deceased adult's organs for transplantation to proceed where no objection has been raised.

In Scotland, deemed consent will not apply to a person who (a) had in force an opt-out declaration at the relevant time,⁹⁴ (b) was not ordinarily resident in Scotland for at least 12 months before the relevant time,⁹⁵ or (c) is incapable of understanding the nature and consequences of deemed consent.⁹⁶

Again, as in England, another individual will be able to demonstrate objection on behalf of the deceased. The guidance accompanying the new act '**Guidance on authorisation requirements for deceased organ and tissue donation and pre-death procedures**' states that:

⁹¹ Organ Donation (Deemed Consent) Bill as introduced in the House of Commons on 19 July 2017 (Bill 12) explanatory Notes <https://publications.parliament.uk/pa/bills/cbill/2017-2019/0012/en/18012en.pdf>

⁹² Timeline for Max and Keira's Law How England moved to an opt out system for organ donation, *Organ Donation Website*, available at: <https://www.organdonation.nhs.uk/uk-laws/organ-donation-law-in-england/timeline-for-max-and-keiras-law/>

⁹³ Parsons JA and Moorlock G. (2020) A global pandemic is not a good time to introduce 'opt-out' for organ donation. *Medical Law International*; 20(2):155-166.

⁹⁴ S.6D (1) (b) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

⁹⁵ S.6D (2) (a) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

⁹⁶ S.6D (2) (b) Human Tissue (Scotland) Act 2006, as amended by s.7 (2) Human Tissue (Authorisation) (Scotland) Act 2019.

*The presence of authorisation permits organ and tissue donation to take place, but does not mandate that it must. Sometimes a clinician will reach the judgement that although the legal basis to proceed with donation is in place, the broader considerations involved mean that it should not go ahead.*⁹⁷

Thus, the family still remain very much central to the donation process.

Upon introducing deemed consent, Scottish Ministers are legally responsible for implementing means of public awareness; not only of the nature of deemed consent in terms of authorisation of transplantation, but also of pre-death procedures.⁹⁸ Similarly to Wales, Scottish Ministers must ensure continued promotion, not less than once each calendar year.⁹⁹ Whilst promotion is required annually, there is a lesser level of scrutiny in that there is no requirement to report activities to the Scottish Parliament. Nonetheless, this is more than is required by the DCA 2019 in England.

6. Northern Ireland: *The Organ and Tissue Donation (Deemed Consent) Bill 2021*

Currently in Northern Ireland there is an 'opt in' framework for consent for organ donation. 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 NHS Organ Donor Register and / or the family supports the donation proceeding. In the absence of an organ donor registration or if the family are unaware if the patient wanted to be a donor, the family are asked to decide on behalf of the patient.¹⁰⁰

In 2015 the Human Transplantation Bill was introduced as a Private Member's Bill by Mrs Jo-Anne Dobson and completed second stage on 16 November 2015. The Bill contained 22 clauses and one Schedule and sought to implement a new soft 'opt-out' system using a two-stage consent process (express or deemed consent).

Ultimately the Bill failed to progress with several areas of concern raised including by Consultant nephrologists and transplant surgeons at the Belfast HSC Trust. While being supportive of means to increase organ donation, they expressed caution about a legislative change that may have a detrimental effect on the willingness of the public to donate.¹⁰¹ It was suggested at the time that the bill should not proceed until it was possible to evaluate

⁹⁷ Scottish Government (2021) Organ and tissue donation - authorisation requirements: guidance. Available at: <https://www.gov.scot/publications/guidance-deceased-organ-tissue-donation-scotland-authorisation-requirements-donation-pre-death-procedures-1st-edition-published-march-2021-1st-ed/pages/1/>

⁹⁸ SS.1 (1) (d) and 1 (1) (e) Human Tissue (Scotland) Act 2006, as amended by s.2 (1) Human Tissue (Authorisation) (Scotland) Act 2019

⁹⁹ S.1(2) Human Tissue (Scotland) Act 2006, as amended by s.2 (3) Human Tissue (Authorisation) (Scotland) Act 2019.

¹⁰⁰ <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

¹⁰¹ Human Transplantation Bill, Second Stage Debate, Official Report Hansard, 16th November 2015, Volume 109, No 5, page 65

the impact of Public Health Agency Awareness Campaign on Organ donation which took place in 2014 as well as the changes to legislation in other devolved regions.¹⁰²

On July 5th 2021 the NI Minister for Health Robin Swann MLA introduced ***the ‘Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2021*** to amend the Human Tissue Act 2004 concerning consent to activities done for the purpose of transplantation and make consequential amendments about the provision of information about such consent.¹⁰³

The decision to proceed with the draft bill was driven by the strong public, professional and voluntary sector support for proposals put forward in the public consultation which ran for a period of 10 weeks from 11 December 2020 to 19 February 2021. The consultation received almost 2,000 responses.

6.1 Deemed consent

Under the new legislation, instead of requesting that everyone who supports organ donation should ‘opt in’ and record their decision on the ODR, it is considered that everyone— with the exception of certain exempt groups – would be willing to donate their organs unless they have formally opted out on the ODR, or expressed an objection to a close friend or relative during their lifetime that they do not want to be a donor after their death.

Section 3 of the 2004 Human Tissue Act will be amended 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.

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 are certain cases where there will be no change in the legislation as to what constitutes ‘appropriate consent’:

- I. Those who have actively recorded a decision in writing before they died as to whether they do or do not consent to organ donation;
- II. Those who opted to appoint someone to make that decision on their behalf;
- III. Children (under 18 years of age); and
- IV. living donors.

¹⁰² Public Health Agency (2014) Organ Donation Campaign Evaluation. Available at: <https://www.publichealth.hscni.net/sites/default/files/SMR%20PHA%20ORGAN%20DONATION%20REPORT%20%2002%2015.pdf>

¹⁰³ <http://www.niassembly.gov.uk/assembly-business/legislation/2017-2022-mandate/primary-legislation---bills-2017---2022-mandate/organ-and-tissue-donation-deemed-consent-bill/>

The Bill also provides that consent cannot be deemed to have been given where a person 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.¹⁰⁴

Questions have been raised as to the definition of what constitutes a "qualifying relationship" in the context of family consent.¹⁰⁵

Currently, clinical staff use the relevant hierarchy of relationships to determine which family member or friend will make the decision regarding donation. The hierarchy of relationships are set out in the Human Tissue Act 2004 (See Table 4) and provide a legal framework for staff who must approach families for consent or authorisation. This decision-maker can then decide whether or not to proceed with donation.¹⁰⁶

Where there is disagreement about donation, the family member who ranks highest in the applicable hierarchy has the legal authority to make the decision. Clinicians are urged to try and help families achieve a consensus, with a view to supporting the highest-ranking family to make a decision.¹⁰⁷ The hierarchy of relationships also applies in cases where the patient was not a registered organ donor, and no other evidence regarding their wishes exists.¹⁰⁸

Table 4: Human Tissue Act 2004 Clause 7(4) – Hierarchal order of ‘qualifying relationships’¹⁰⁹

1	Spouse or partner
2	Parent or child
3	Brother or sister
4	Grandparent or grandchild
5	Child of a person falling within 3 (brother or sister)
6	Stepfather or stepmother
7	Half-brother or half-sister
8	Friend of long-standing.

¹⁰⁴ Organ And Tissue Donation (Deemed Consent) Bill Explanatory And Financial Memorandum (Bill 30/17-22) <http://www.niassembly.gov.uk/globalassets/documents/committees/2017-2022/health/primary-legislation/organ-donation-bill/organ-and-tissue-donation-deemed-consent-bill-explanatory-and-financial-memorandum.pdf>

¹⁰⁵ Organ and Tissue Donation (Deemed Consent) Bill: Second Stage Executive Committee Business – in the Northern Ireland Assembly at 12:00 pm on 20th September 2021 <https://www.theyworkforyou.com/ni/?id=2021-09-20.2.1>

¹⁰⁶ UK Donation Ethics Committee (2016) Involving the family in deceased organ donation: A discussion paper. Available at: https://www.aomrc.org.uk/wp-content/uploads/2016/07/Involving_family_deceased_organ_donation_0416-2.pdf

¹⁰⁷ As cited directly above

¹⁰⁸ Cited in footnote 109

¹⁰⁹ Human Tissue Act 2004 Part 1 Clause 7(4) https://www.legislation.gov.uk/ukpga/2004/30/pdfs/ukpga_20040030_en.pdf

Questions have also been raised as to whether Organ donation would go ahead if family members cannot be contacted.¹¹⁰ The NHSBT has stated that if clinical staff cannot contact someone who knew the deceased well, even where there is a registered decision to donate on the NHS Organ Donor Register, donation will not proceed. The NHS has a duty to consider the safety of any organs for transplant and speaking to the family, or someone else appropriate, about medical and lifestyle history is important for this reason.¹¹¹

Building on how the system works in England and Wales for whom the Human Tissue Authority have developed codes of practice detailing how the new legislation will work in practice, a code of practice will be developed for NI and will set out how the new arrangements will work in practice, including the discussions between the specialist nurses and the family.¹¹²

A large number of respondents to the public consultation on the proposed bill thought that it was important that families or next of kin had an important consultative role to play at the point of organ retrieval. The majority of respondents (62%) agreed that in situations where there is no known organ donation decision, the family should always be consulted.¹¹³

Further, 40% of respondents felt that even where there is a known decision to donate recorded on the NHS Organ Donor Register, the family should always be asked about the last known organ donation decision of their loved one, to ensure it's still accurate.¹¹⁴

However, a significant number of respondents said that an express decision on organ donation should always be respected and that members of the deceased family should not be able to override the deceased's known decision. Families should only have to decide on organ donation where an individual's decision is not known.¹¹⁵

There was also concern around how this discussion would be handled in what is a very traumatic time for family and friends further highlighting the importance of people sharing their decision around organ donation. Some respondents felt that the introduction of an opt-out system would take the responsibility of making the decision away from the grieving relatives.¹¹⁶

¹¹⁰ Organ and Tissue Donation (Deemed Consent) Bill: Second Stage Executive Committee Business – in the Northern Ireland Assembly at 12:00 pm on 20th September 2021. <https://www.theyworkforyou.com/ni/?id=2021-09-20.2.1>

¹¹¹ Understanding consent for organ donation Organ Donation Website. Available at: <https://www.organdonation.nhs.uk/helpingyou-to-decide/about-organ-donation/consent/>

¹¹² Human Tissue Authority (2014) Code of Practice on the Human Transplantation (Wales) Act 2013 Available at https://bts.org.uk/wp-content/uploads/2018/01/HTA_CoP_on_Human_Transplantation_Wales_Act_2013_-_Final_-_May_2014.pdf and Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland

¹¹³ Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

¹¹⁴ As cited directly above

¹¹⁵ As cited in 115

¹¹⁶ As cited in 115

The DoH has stated that families will continue to play an important role in the consent process in all cases and the family will always be asked about the last known organ donation decision of their loved one, to ensure it is still accurate.¹¹⁷

6.2 Excepted adults

The DoH states that certain exceptions should be made to the general rule that everyone will be considered willing to donate their organs after their death unless they have recorded a decision to not donate. This belief is in line with the majority of respondents to the public consultation on the proposed bill.¹¹⁸

People who lack mental capacity, children under 18, people not ordinarily resident in NI, including visitors, those temporarily resident in NI and prisoners, are less likely to be aware of the system, understand the changes and make an informed decision. As such, these groups will be excluded from the new arrangements.¹¹⁹

With regard to establishing appropriate consent for those under the age of 18, 53% of those who responded to the question in the public consultation supported excluding children below 18. There were exceptions to this, with some suggesting that the cut-off point should be at different ages, ranging from 16, to over 18. The DoH considers that the new arrangements may be too complex for children below 18 to understand and decide what action they need to take and as such children below 18 will not be part of the new arrangements.

The classification of children as those under the age of 18 mirrors the opt out systems in Wales and England. Scotland on the other hand deems anyone over the age of 16 as an adult for the purposes of organ donation.¹²⁰

Currently, any person can record a wish to donate their organs without their mental capacity being assessed. This will not change, but those who lack the capacity to understand the effect of the new arrangements will not have their consent 'deemed' on their death, if they have not recorded an express decision.

6.3 Promoting awareness and assessing effectiveness

There is overall encouraging international and UK evidence to suggest that awareness of the legislation is likely to be a significant factor in ensuring an effective opt out system.

¹¹⁷ Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

¹¹⁸ As cited in footnote 119

¹¹⁹ Organ and Tissue Donation (Deemed Consent) Bill 30/17-22 <http://www.niassembly.gov.uk/globalassets/documents/legislation/bills/executive-bills/session-2017-2022/organ-and-tissue-donation-deemed-consent-bill/organ--tissue-donation-deemed-consent---as-introduced---full-print-version-.pdf> and Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland

¹²⁰ Scottish Government website, Record your organ and tissue donation decision, 2021, Available at: <https://www.gov.scot/news/organ-and-tissue-donation-law-change/>

Therefore, robust regular monitoring of public awareness will be important to support a potential opt out system.¹²¹ Feedback from the consultation on the proposed Bill highlighted that respondents felt it was vital to ensure a widespread advertisement and education programme is in place to ensure sufficient awareness among the public before the new system is implemented.¹²²

The DoH in NI already has a statutory duty to promote organ donation under *Part 4 of the Health (Miscellaneous Provisions) Act (Northern Ireland) 2016*, and in 2018 published a policy statement, outlining its key commitments to deliver this. The overall objective of the policy is, and remains, to promote a positive, cultural, long term change in attitudes and behaviours in relation to organ donation.¹²³

The bill will amend section 15 of the *Health (Miscellaneous Provisions) Act (Northern Ireland) 2016* to extend the DoH's existing statutory duty to include specific advice and information within the annual campaign about the law on statutory soft opt out and about how people can record their decisions if they wish.¹²⁴

The bill also amends section 16 of the *Health (Miscellaneous Provisions) Act (Northern Ireland) 2016* to extend the duty of the DoH to report the opinion of the DoH as to whether that Act has been effective in promoting transplantation.

6.4 Novel/rare and research transplant material

The general consensus from respondents to the public consultation on the bill was that Novel and Rare transplants should be kept separate from the other more common types of transplant that are currently taking place.

In the proposed bill, consent will not be deemed to have been given in cases where the transplantation is of novel material (e.g. Uterine or limb transplants). This is to ensure that the new system of consent is in line with the common understanding of organ and tissue donation.¹²⁵

Learning from the experience of other jurisdictions in this regard, rather than prescribing lists of exempt organs, NI Regulations will explicitly state the organs to which deemed consent will apply (i.e. heart, lungs, liver, kidneys, pancreas and small bowel, as well as tissue

¹²¹ Scottish Government (2018) Opt out organ donation: a rapid evidence review. Health and Social Care. Available at: <https://www.gov.scot/publications/opt-out-organ-donation-rapid-evidence-review/pages/1/>

¹²² Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland Available at: <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

¹²³ Department Of Health Policy Guidance Statement, Promoting Human Organ Donation and Transplantation In Northern Ireland (2018) <https://www.health-ni.gov.uk/sites/default/files/consultations/health/organ-donation-policy-statement.pdf>

¹²⁴ Organ And Tissue Donation (Deemed Consent) Bill Explanatory And Financial Memorandum Available at: <http://www.niassembly.gov.uk/globalassets/documents/committees/2017-2022/health/primary-legislation/organ-donation-bill/organ-and-tissue-donation-deemed-consent-bill-explanatory-and-financial-memorandum.pdf>

¹²⁵ Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

including heart valves, corneas and bone).¹²⁶ Regulations made by the DoH under the provisions inserted by this Bill must be laid in draft before and approved by a resolution of the Assembly.¹²⁷

Furthermore, deemed consent will 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 2004. Similar to donation of novel and rare tissues, the general consensus was that donations for research should require either express consent or remain as an opt-in option before being undertaken.

Some respondents suggested that:

- Extending the opt-out system to include donation for research may lead some people to opt out who would be happy to donate for transplantation alone; and
- most people will be aware of organ donation, have given some thought to their own wishes, and many people will have discussed their wishes with their family; again, the same is not true of participation in research.¹²⁸

6.5 Additional considerations

During the consultation the issue of what measures have been put in place to ensure the resources are available (additional trained medical staff) to meet the increase in available organs if this legislation is implemented was raised.

It has been noted by medical staff in England that increased donation is very likely to put strain on the existing health system, including the manpower (SNOD, intensivists, organ retrieval team, recipient surgical team, ward and theatre staffs), operating theatre resources and hospital beds, which can adversely impact on the delivery of services by other surgical specialties. Expansion of manpower, operating theatre facilities and beds is an essential requirement and should be put in place for achieving successful outcomes of opt-out system.¹²⁹

The DoH has also stated that there are no plans to change the current commitment to honouring an individual's decision regarding faith/ beliefs and the support and advice available to families.

¹²⁶ Cited directly above

¹²⁷ Organ And Tissue Donation (Deemed Consent) Bill Explanatory And Financial Memorandum (Bill 30/17-22) <http://www.niassembly.gov.uk/globalassets/documents/committees/2017-2022/health/primary-legislation/organ-donation-bill/organ-and-tissue-donation-deemed-consent-bill-explanatory-and-financial-memorandum.pdf>

¹²⁸ Department of Health (2021) Summary of responses to the public consultation: Introduction of a statutory opt-out system for organ donation for Northern Ireland <https://www.health-ni.gov.uk/sites/default/files/publications/health/doh-response-and-analysis-to-the-organ-donation-soft-opt-out-consultation.pdf>

¹²⁹ Shrestha, BM (2020) Opt-out system of organ donation in England – Potential outcomes and its implementation *BMJ* 2020;368:m752

7. Concluding comments

On July 5th 2021 ***the ‘Organ and Tissue Donation (Deemed Consent) Act (Northern Ireland) 2021*** was introduced the NI Assembly and passed second stage on the 20th September 2021.

The Bill seeks to implement a new soft ‘opt-out’ system for consent to organ donation and to extend the legal responsibilities of the DoH with regard to publicly promoting the new system and reporting on the success of the legislation following implementation.

There is not an entirely clear conclusion as to the level of impact the system of consent has on donation and transplantation levels in a country as many factors come into play, including the infrastructure required. However, it has been reported that countries with ‘presumed consent’ do have higher rates of deceased donations but not higher rates of living donations.¹³⁰

Many European countries have adopted opt-out systems of organ donation. In terms of organ donation rates and the transplant infrastructure in place, Spain is considered the ‘gold standard’ as donation rates there are the highest in the EU. However, commentators have cautioned against attributing rates of donation in Spain to only its ‘deemed consent’ system. Higher donation rates in that country coincided with improved infrastructure and organ donation being accepted as a cultural norm.¹³¹

While overall feedback from respondents to the public consultation on the introduction of opt out legislation in NI suggests strong support for the proposed change in legislation, some issues have been raised publicly including what constitutes a ‘qualifying relationship’ and what the outcome would be where family members object to donation taking place.

The bill does not define or rank qualifying relationships but the DoH have stated that a Code of Practice will be developed by the Human Tissue Authority to guide the practical implementation of the bill including how discussions with the family will be handled. Ultimately, the DoH has stated that the family will remain central to the decision-making process. This is the same approach that has been taken in the rest of the UK.

Caution has previously been advised that the introduction of opt-out legislation on its own is not a silver bullet¹³² and countries where legislative system changes that are accompanied by complementary interventions at different levels of society and the health system appear to have the most success.

¹³⁰ Levitt, M, (2015), Could the organ shortage ever be met?, *Life Sci Soc Policy*. 2015 Dec; 11: 6,

¹³¹ Etheredge HR. (2021) Assessing Global Organ Donation Policies: Opt-In vs Opt-Out. *Risk Manag Healthc Policy*. 2021; 14:1985-1998

¹³² Human Transplantation Bill, Second Stage Debate, Official Report Hansard, 16th November 2015, Volume 109, No 5, page 65