Northern Ireland Assembly

Research and Information Service
Bill Paper

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Human Transplantation Bill

NIAR 650-15

This Bill Paper provides a thematic discussion of the Human Transplantation Bill for Northern Ireland with clause scrutiny where relevant, providing comparison mainly to the Welsh Act and to the recently introduced Scottish Private Member's Bill where pertinent. It also provides an overview of statistics, policy/strategy and current relevant law in Northern Ireland and neighbouring jurisdictions. The financial impact of the Bill is dealt with in a separate RaISe paper NIAR 671-15.

Executive Summary

In NI, the Human Transplantation Bill was introduced as a Private Member's Bill by Mrs Jo-Anne Dobson MLA on 13 October 2015 and completed second stage on 16 November 2015. The Bill contain 22 clauses and one Schedule and seeks to implement a new soft 'opt-out' system for consent to organ donation by using a two stage consent process ('express' or 'deemed' consent).

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. NI already has the highest organ donation rate in the UK.

All four jurisdictions of the UK have signed up to the NHS Blood and Transplant's most recent strategy, *Taking Organ Donation Transplantation to 2020: A UK Strategy*[1] (2013), which builds on the work of the previous Organ Donation Taskforce, working within the current legislative framework (with Wales being the only country to implement an opt-out consent system to date in the UK).

The key legislative provisions of Mrs Dobson's Bill deal with the issue of **consent** to donation of organs - 'express consent' and 'deemed consent' applying to adults in different circumstances with 'express consent' applying to children.

Clause 3 of the Bill provides for 'express consent' for adults being provided by: the person themselves (living or deceased) (via, for example, the ODR); a person appointed by the person themselves ('appointed representative'); or if the 'appointed representative' person is unable to give a person who stood in a 'qualifying relationship' to the person immediately before death.

Clause 4 provides for deemed consent for adults and applies when express consent does not apply – when an adult has died and has not made his or her views on transplantation known, then the person is 'deemed' to have consented to transplantation. However, deemed consent is not 'effective' unless it is **affirmed** by a 'qualifying person' that the person **would not have objected** to the activity.

This requirement for affirmation has been described by the Bill sponsor as the main safeguard in the Bill.

The Bill has been compared to the Welsh Act, however, a key difference is that it places 'deemed consent' as the default consent position for adults unless express consent is required or a relative or friend of longstanding of the deceased objects on the basis of recent views of the deceased.

[1] Taking Organ Donation Transplantation to 2020: A UK Strategy, NHSBT, http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_summary.pdf

Whereas, the NI Bill places ‘express consent’ as the default position and ‘deemed consent’ only applies when the ‘cases’ for express consent do not apply and the affirmation described above can also be given.

The requirement for a positive affirmation from the ‘qualifying person’ that the person **would not have objected** seems to be a higher ‘hurdle’ in the NI Bill than what is required under the Welsh Act and could make it more difficult in NI for the ‘deemed consent’ to lead to donation.

The Bill abolishes the application in NI of Section 1 (subsection 1) of the Human Tissue Act 2004, thus seemingly preventing a ‘qualifying person’ giving consent to donation, under clause 4, if they cannot give the positive affirmation required.

This paper highlights the last ‘case’ in clause 3 (no decision of the person in place and no appointed person is ‘able’ to give consent so the person in the ‘qualifying relationship gives express consent) – the ‘qualifying person’ does not have to provide the positive affirmation that they do in clause 4 (deemed consent - adults), i.e. the deceased person has actually appointed a person to deal with the issue of consent and this appointed person is not ‘able’ to give consent so the task passes to a person in a ‘qualifying relationship’.

It appears from the Bill that this person can then give ‘express consent’ without any knowledge of the deceased’s wishes on the matter and this differs from the positive affirmation required in clause 4.

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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 heart, kidneys, lungs, pancreas and liver. Recent years have also seen a number of transplants of tissue aimed not at saving lives, but improving quality of life. 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. Patients from Asian and afro-Caribbean descent 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.[3] There is a much smaller number of potentially matched donors for these groups.[4]

There are three different types of donation[5]:

- **DCD (deceased donation – donation following circulatory death)** (also known as 'non-heartbeating donation' or 'donation after cardiac death'). This refers to the retrieval of organs for the purpose of transplantation from patients whose death is confirmed using cardio-respiratory criteria[6];
    - 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; and
- **DBD (deceased donation – donation following brain stem death)** – the "*UK standard for the neurological determination of death is based upon the principle that complete loss of brain-stem function is of itself sufficient to allow the diagnosis of death to be confirmed and the belief that such a state can be recognised clinically in most cases*"[7];

[2] Human Transplantation (Wales) Bill, Explanatory Memorandum, paragraph 6, http://www.assembly.wales/Laid%20Documents/PRI-LD9121-EM%20-%20Human%20Transplantation%20(Wales)%20Bill%20-%20Explanatory%20Memorandum-03122012-241088/pri-ld9121-em-e-English.pdf

[3] NHS Blood and Transplant (NHSBT), Organ donation and ethnicity, https://www.organdonation.nhs.uk/about-donation/organ-donation-and-ethnicity/

[4] Working together to save lives, The Organ Donation Taskforce Implementation Programme's Final Report, 2011, Department of Health, DHSSPS, Healthier Scotland, Welsh Government, page 7, http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_130341

[5] 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

[6] NHS Blood and Transplant, Donation after circulatory death, http://www.odt.nhs.uk/donation/deceased-donation/donation-after-circulatory-death/

[7] NHS Blood and Transplant, Donation after Brain-stem Death, http://www.odt.nhs.uk/donation/deceased-donation/donation-after-brain-stem-death/

- **Living donation** - Kidneys are the most common organ donated by a living person[8]. A living person can also donate part of their liver, and tissue donations of bone and amniotic membrane.[9]

Across the UK, **NHS Blood and Transplant (NHSBT)** is the organisation responsible for all aspects of the donation process. It also monitors post-transplant outcomes and manages and promotes awareness of the NHS Organ Donor Register.[10]

In Northern Ireland (NI) more than 654,500 people have signed the NHS Organ Donor Register, these registrations account for around 35% of the population. At present, around 200 people in Northern Ireland are on the transplant waiting list and each year around 15 people die waiting for an organ.[11]

2 Organ Donation Policy and Strategy – UK and Republic of Ireland

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 UK-wide

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] About a third of all kidney transplants carried out in the UK are from living donors, Living Donation, NHSBT, https://www.organdonation.nhs.uk/about-donation/living-donation/

[9] NHS Blood and Transplant (NHSBT), Living Donation, https://www.organdonation.nhs.uk/about-donation/living-donation/

[10] NHSBT, Who we are, http://www.nhsbt.nhs.uk/who-we-are/, webpage accessed 24/11/15

[11] Organ Donation NI, Where are we now, www.organdonationni.info/where-are-we-now, webpage accessed 02/12/15

[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/

These were fully implemented by the NHSBT and the devolved administrations. As part of its work, the ODT reviewed consent systems across the world (Table 1 summarises these systems).

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. The hoped for increase did occur in the five years 2007-08 to 2012-1 but this did not translate into the predicted number of transplants, since the main increase came from DCD, who on average donate fewer organs than DBD. There was only a small increase in DBD donors.[14]

Table 1: Organ Donation – Consent Systems Across the World

Option	Details
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. Example: Austria.
2. A 'hard' opt out system which does not cover some groups (i.e. exempted 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 (i.e. exempted group) that is defined in law as being against an opt out system. Example: Singapore where Muslims chose to opt out as a group.
3. A 'soft' opt out system	**Option 3 a: 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. Example: Belgium.
	Option 3b: Relatives should be consulted Doctors can remove organs from every adult who dies ('deemed consent' - 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, for example, Spain In Wales the soft 'opt-out' also provides for a person with a close relationship to provide evidence that the person did not want to be an organ donor.[1]
4. A 'soft' opt in system (current system in England, Scotland and Northern Ireland)	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 not to proceed if faced with opposition from relatives.
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.
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.

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

All four jurisdictions of the UK have signed up to the NHSBT's most recent strategy, *Taking Organ Donation Transplantation to 2020: A UK Strategy*[15] (2013), which builds on the work of the ODT, within the current legislative framework (with Wales being the only country to implement an opt-out consent system to date). The 2020 Strategy is being led by the understanding that the UK needs "a transformation in donor and family consent to match the transformation already underway in NHS organ donation and transplantation services".[16]

The 2020 Strategy highlights the actions to date including[17]:

- Increased numbers of specialist nurses in organ donation;
- Every hospital has access to dedicated Clinical Lead and is supported by a Donation Committee;
- Dedicated organ retrieval teams serving the entire UK, available 24/7
- Clinicians now have access to ethical and legal advice to help them facilitate donation and are increasingly viewing organ donation as a normal part of end-of-life care; and
- Regional Collaboratives are bringing together leaders in organ donation.

The 2020 Strategy sets outcomes to reach by 2020 and aims to:

- Increase the consent rate from 57% to 80%;
- Increase the average UK rate of deceased donation to 26 donations per million population (pmp) (NI is already at this level); and
- Transplant 5% more of the organs offered by donors and families.

The 2020 Strategy notes that:

> *Although more people have agreed to donate organs over the past five years, this is because more people have been asked to do so. The proportion of families who refuse to allow their relatives organs to be used, sometimes even when they are informed that their relative wanted to be a donor has not changed in most parts of the UK.*[18]

The 2020 Strategy details plans to streamline the donation process and highlights the importance of a co-ordinated research programme on improving transplantation. It states, for example, that if variation between different regions were minimised and with

[15] Taking Organ Donation Transplantation to 2020: A UK Strategy, NHSBT, http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_summary.pdf
[16] Taking Organ Donation Transplantation to 2020: A UK Strategy, NHSBT, page 5, http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_summary.pdf
[17] As above, page 18
[18] Taking Organ Donation Transplantation to 2020: A UK Strategy, NHSBT, page 6 http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_summary.pdf

all hospitals performing at the higher end of the scale it is estimated that there would be a total 500 more donors a year across the UK.[19]

2.2 Northern Ireland

In NI, the Assembly passed a motion in 2012 with a commitment that the Minister for Health, Social Services and Public Safety would look at how organ donation could be increased. In February 2013 a Departmental press release illustrated the need to engage with the public and encourage debate around changing the current system of organ donation in NI to a soft opt-out system.[20]

The Public Health Agency highlighted that[21]:

> *Many European countries have adopted opt-out systems, of which Spain is considered the 'gold standard' as donation rates there are the highest in the EU. However, caution is advised in attributing rates of donation in Spain to a presumed consent system. It is worth noting that donation rates in Spain did not rise until 10 years after presumed consent legislation was introduced. Furthermore, higher donation rates coincided with improved infrastructure and organ donation being accepted as a cultural norm… Despite this cautionary note, countries with the highest organ donation rates have presumed consent systems of donation.*

In June 2013, the Public Health Agency (PHA) surveyed the NI public about their attitudes towards organ donation and undertook a process of stakeholder engagement to inform the direction of a public information campaign. The campaign objective was to raise awareness about organ donation and to encourage people to talk about their donation wishes with family and friends. The media campaign ran in 2014.[22]

Subsequently, Social Market Research conducted a representative survey of over 1000 people in NI to assess awareness of the campaign and its key messages; the public's intended behaviour towards organ donation compared to the earlier survey in 2013; and explored attitudes towards a potential change to a system of 'presumed consent' system.

[19] Organ Donation and Transplants, POSTNOTE 441, Houses of Parliament, September 2013, page 4, http://researchbriefings.parliament.uk/ResearchBriefing/Summary/POST-PN-441#fullreport

[20] Organ Donation: Public Attitudes and Stakeholder Engagement in NI 2013, Public Health Agency, Executive Summary, https://www.organdonationni.info/sites/organdonationni.info/files/publications/organ%20donation%20report.pdf

[21] As above

[22] Evaluation of a Public Information Campaign on Organ Donation, PHA, September 2015, http://www.publichealth.hscni.net/publications/evaluation-public-information-campaign-organ-donation

Some of the findings pertinent to the consideration of the Private Member's Bill, the Human Transplantation Bill (NI), sponsored by Mrs Jo-Anne Dobson, were as follows[23]:

- Changing to 'presumed consent' (or 'deemed consent' as the Bill refers to this type of consent) - 61% said they would be in favour of changing to such a system where it is presumed that a person has consented to donation unless they have registered their objection, or their family / close friend says no (56% in 2013):
  - with 10% against (18% in 2013);
  - 16% requiring more information (8% in 2013) and
  - 14% undecided (18% in 2013);
- Reaction to a new system if introduced - 28% said they are not currently on the organ donation register (ODR) but 'did not think' they would opt out if a new system were introduced (37% in 2013);
  - 12% said they are not currently on the ODR but would opt out (14% in 2013);
  - with 28% currently on the ODR and opting to remain on it (25% in 2013);
  - with 6% currently on the Register saying they would take their name of the Register if the system was changed (2% in 2013);
  - 27% were undecided as to how they would react if they system were changed (22% in 2013);
- 60% were in favour of an alternative system of 'mandatory choice' (54% in 2013) where everyone would be required by law to register their choice about organ donation.

Stakeholder engagement by the PHA in 2013 with charities, transplant recipients and those on the waiting lists; donor families; Health and Social Care staff and the BMA highlighted the positives and concerns raised of introducing a soft opt out system in NI[24]:

The positives included:

- Marking a cultural change and encouraging altruistic behaviour among the public;
- A potential increase in donors and available organs; and
- Raising the profile of organ donation.

Concerns among stakeholders included:

- Public perception of a conflict of interest for medical staff considering end of life care;
- People may not seek out a separate 'opt-out' register, and use of the ODR (which will still be in operation) may decline; and

[23] As above, Executive Summary

[24] Organ Donation: Public Attitudes and Stakeholder Engagement in NI 2013, Public Health Agency, Executive Summary, https://www.organdonationni.info/sites/organdonationni.info/files/publications/organ%20donation%20report.pdf

- The pool of potential donors could reduce from the current situation, where all families are asked to consider donation if medically appropriate (whether the person is one is on the ODR or not), to one where only the families of those who have not opted-out register are asked.

The Bill sponsor, Mrs Dobson MLA, undertook her own consultation process with regard to the Bill. There were over 1,300 responses and a summary report was produced. It showed[25]:

> *an 82% support amongst respondents for changing the law and moving to a soft opt-out system. There was also 61% support for retaining the key role of the family and 86% for protecting the rights of those who lacked capacity in the legislation.*

2.3 Republic of Ireland

In the Republic of Ireland, Organ Donation and Transplant Ireland (ODTI) (formerly the National Organ Donation and Transplantation Office) was established in 2011. It acts under legislation SI 325 (2012) as the delegated body for the HSE, to establish quality standards and protocols for the entire solid organ donation/transplantation process.

The ODTI has collaborated with the relevant hospitals to implement and improve organ donation structures, commencing with Organ Donation Nurse Managers and Intensive Care Consultants with a special interest in organ donation. [26]

All organ donations are coordinated through the Irish Procurement Office in Beaumont Hospital in Dublin.[27] Individuals indicate their wishes regarding organ donation by carrying an organ donor card or signing the organ donation option on the back of their driving license.

Individuals are advised to tell the next-of-kin of their wish to be an organ donor, but relatives are not bound by these wishes and their consent is always required. In all cases, the medical team requests the next-of-kin to donate the organs of a deceased person. In practice, the consent of the next-of-kin is accepted as valid and a refusal by the next-of-kin is not contested.[28]

Patients in NI can join the Republic of Ireland's transplant register, but they cannot be on both registers at the same time. A protocol is in place for NI to utilise the Republic

[25] Human Transplantation Bill: Mrs Jo-Anne Dobson MLA, Official Report (Hansard), Committee for HSSPS, 4 November 2015
[26] ODTI Annual Report 2014, http://www.hse.ie/eng/about/Who/organdonation/Annual%20report%202014.pdf
[27] Beaumont Hospital, Dublin, Facts about Organ Donation in Ireland, www.beaumont.ie/index.jsp?p=454&n=457
[28] Organ and body donation, Public Service Information, Citizens Information Board, webpage accessed 30th November 2015, http://www.citizensinformation.ie/en/health/blood_and_organ_donation/organ_and_body_donation.html

of Ireland's organ retrieval teams if one is not available from the UK, this is used rarely, for example in extreme weather conditions.[29]

3 Organ Donation – UK Statistics for Deceased Donation

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. Based on 2014/15 figures[30]:

- Total UK deaths of 576,000 led to;
  - 1,923 consented donors of which:
    - 1,282 became actual donors.; and
      - this equated to 3,322 transplants of 3,736 organs.

Tables 2 to 5 show the UK statistics for each jurisdiction regarding deceased donations following brain stem death (DBD) and donation following circulatory death (DCD) (numbers of donations and pmp - donations per million population) for the past five years.

The mean pmp donations for the past five years (NI – 23.7; Wales – 22.7; England – 18.4; and Scotland – 18.5) clearly show that NI is leading the way in the UK as regards total deceased donations.

Table 2: Northern Ireland

	DBD		DCD		Total Deceased Donations	
Year	Number	PMP	Number	PMP	Number	PMP
April 2010-March 2011	38	21.2	2	1.1	40	22.3
April 2011-March 2012	36	20.0	3	1.7	39	21.7
April 2012-March 2013	29	16.0	11	6.1	40	22.1
April 2013-March 2014	33	18.1	15	8.2	48	26.4
April 2014-March 2015	34	18.6	14	7.7	48	26.2

[29] NI Assembly, Plenary Debate, 21st February 2012, http://www.niassembly.gov.uk/Assembly-Business/Official-Report/Reports-11-12/21-February-2012/#a8

[30] NHS Blood and Transplant Annual Activity Report 2014/15, Figure 2.3, http://nhsbtmediaservices.blob.core.windows.net/organ-donation-assets/pdfs/activity_report_2014_15.pdf

Source: NHS Blood and Transplant (NHSBT) - Organ Donation and Transplantation Activity Reports 2010/2011, 2011/12, 2012/13, 2013/14 and 2014/15[31]

Table 3: Wales

	DBD		DCD		Total Deceased Donations	
Year	Number	PMP	Number	PMP	Number	PMP
April 2010-March 2011	53	17.7	30	10.0	83	27.7
April 2011-March 2012	37	12.3	38	12.6	75	24.9
April 2012-March 2013	38	12.4	18	5.9	56	18.3
April 2013-March 2014	37	12.1	23	7.5	60	19.5
April 2014-March 2015	38	12.3	33	10.7	71	23.1

Source: NHS Blood and Transplant (NHSBT) - Organ Donation and Transplantation Activity Reports 2010/2011, 2011/12, 2012/13, 2013/14 and 2014/15[32]

Table 4: England

	DBD		DCD		Total Deceased Donations	
Year	Number	PMP	Number	PMP	Number	PMP
April 2010-March 2011	494	9.5	324	6.3	818	15.8
April 2011-March 2012	521	10.0	366	7.0	887	17.0
April 2012-March 2013	580	10.9	440	8.3	1020	19.2
April 2013-March 2014	644	12.0	453	8.5	1097	20.5
April 2014-March 2015	629	11.7	431	8.0	1060	19.7

Source: NHS Blood and Transplant (NHSBT) - Organ Donation and Transplantation Activity Reports 2010/2011, 2011/12, 2012/13, 2013/14 and 2014/15[33]

[31] NHSBT- Organ Donation and Transplantation Activity Reports 2010/2011, 2011/12, 2012/13, 2013/14 and 2014/15, http://www.odt.nhs.uk/uk-transplant-registry/annual-activity-report/

[32] As above

[33] As above

Table 5: Scotland

	DBD		DCD		Total Deceased Donations	
Year	Number	PMP	Number	PMP	Number	PMP
April 2010-March 2011	49	9.4	17	3.3	66	12.7
April 2011-March 2012	53	10.2	28	5.4	81	15.5
April 2012-March 2013	55	10.5	38	7.2	93	17.7
April 2013-March 2014	62	11.7	46	8.7	108	28.3
April 2014-March 2015	65	12.2	32	6.0	97	18.2

Source: NHS Blood and Transplant (NHSBT) - Organ Donation and Transplantation Activity Reports 2010/2011, 2011/12, 2012/13, 2013/14 and 2014/15[34]

According to NHSBT statistics, the total UK number of deceased donors in 2014/15 was 1,282 (772 DBD and 510 DCD). This represented the first decrease (3%) in 11 years. The number of deceased donors in the UK remained stable over a number of years but following the implementation of the ODT recommendations in 2008, the numbers rose. This increase continued for six years until 2014/15. The number of patients on the active transplant list at 31 March 2015 is 83 fewer than on the same date last year. This reflects an increasing number of transplants performed over the last 10 years and a reasonably steady number of patients joining the transplant list each year, There have been 1,050 to 1,150 living donors each year in the last six years in the UK. Compared with last year's high, there was a 5% fall to 1,092 living donors in 2014/15.[35]

4 Current UK Legislation/Organ Donation Register – Overview

The legislative framework for donation in England, Scotland and NI is currently that of a opt-in system of consent, where an individual expresses their choice to donate organs or tissue by, for example, joining the ODR or carrying an organ donor card and *legally* relatives are unable to oppose the wishes of the individual. In clinical practice, however, donation is unlikely to go ahead in the face of strong opposition or severe distress of relatives.

[34] NHS Blood and Transplant Annual Activity Report 2014/15, Figures 2.1 and 2.2, http://nhsbtmediaservices.blob.core.windows.net/organ-donation-assets/pdfs/activity_report_2014_15.pdf

[35] As above

The Human Tissue Act 2004 (HTA 2004) came into force on 1st September 2006 and applies to England, Wales and NI. It established an updated legislative framework for regulating body donation and the removal, storage, and use of human organs and tissues (replacing the the Human Tissue Act 1961, the Anatomy Act 1984, and the Human Organ Transplants Act 1989).

The HTA 2004 makes 'consent' the fundamental principle underpinning the lawful removal, use and storage of human tissue. It sets out detailed requirements for obtaining consent in different situations, including obtaining consent from adults who lack the capacity to consent, children, and from the deceased or their relatives/representatives. It makes the removal, storage and use of human tissue without consent, and the taking and testing of DNA without consent, illegal.[36]

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.

The provisions of **The Human Tissue (Scotland) Act 2006** (HTA 2006), which is applicable in Scotland, closely mirror the 2004 Act.[37] However, it specifically uses the term 'authorisation' as opposed to 'consent' to provide the legal authority for the removal and use of organs for the purposes of transplantation.[38]

In Wales the relevant legislation governing organ donation is now the **Human Transplantation (Wales) Act 2013,** which changed its legislative framework to a soft opt-out system on 1st December 2015. This system means that unless an individual makes a clear decision that they either wanted to be a donor (opt-in) or did not want to be an organ donor (opt-out) they will be treated as though they have no objection to donation after their death and their consent will be 'deemed' unless a person with a close relationship can provide evidence that the person did not want to be an organ donor (soft opt-out)[39].

Within this legislative framework in Wales, consent by a deceased person will be 'deemed' if all the below apply to the individual[40]:

- 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;

[36] 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, webpage accessed 24/11/15

[37] 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, webpage accessed 24/11/15

[38] Legislative Framework, Organ Donation and Transplantation, NHSBT, http://www.odt.nhs.uk/donation/deceased-donation/consent-authorisation/legislative-framework.asp, webpage accessed 24/11/15

[39] As above

[40] As above

- Has had the capacity to understand the notion of deemed consent for a significant period before death (12 months); and
- Died in Wales.

Key with regard to donation across the UK is how consent (authorisation in Scotland) for organ retrieval after death (deceased organ donation) may be given:[41]

> *The Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 and the Human Transplantation (Wales) Act 2013 give primacy to the decision of the individual however they have been stated and recorded. This can be done in various ways – verbally, by having a Donor Card, in writing, via the various means of accessing the NHS Organ Donor Register (ODR) or in Wales by not opting-out of donation. All are regarded as equally valid forms of consent / authorisation for organ retrieval after death.*

If the wishes of the individual are not known, or cannot be determined, then decision making passes to:

- A nominated representative and then to a person in a 'qualifying relationship' (England and NI)[42];
- To the adults 'nearest relative' (Scotland)[43]; and
- In Wales, 'deemed consent' now applies[44] under the Human Transplantation (Wales) Act 2013 Act - their consent will be deemed to have been given unless a person with a close relationship can provide evidence that the person did not want to be an organ donor.[45]

The NHSBT notes that all three Acts recognise the validity of the wishes of competent minors;

> *Where the wishes of the individual are not known or the minor was not competent to deal with the issue, consent / authorisation passes to those with parental rights and responsibilities, or in their absence to an individual in a qualifying / nearest relationship.*[46]

[41] Legislative Framework, Organ Donation and Transplantation, NHSBT, http://www.odt.nhs.uk/donation/deceased-donation/consent-authorisation/legislative-framework.asp, webpage accessed 24/11/15
[42] Human Tissue Act 2004, Section 3, http://www.legislation.gov.uk/ukpga/2004/30/section/3
[43] Human Tissue (Scotland) Act 2006, Section 7, http://www.legislation.gov.uk/asp/2006/4/section/7
[44] Human Transplantation (Wales) Act 2013, http://www.legislation.gov.uk/anaw/2013/5/contents/enacted
[45] Legislative Framework, Organ Donation and Transplantation, NHSBT, http://www.odt.nhs.uk/donation/deceased-donation/consent-authorisation/legislative-framework.asp, webpage accessed 24/11/15
[46] Legislative Framework, Organ Donation and Transplantation, NHSBT, http://www.odt.nhs.uk/donation/deceased-donation/consent-authorisation/legislative-framework.asp, webpage accessed 24/11/15

The Human Tissue (Scotland) Act 2006 provides for children aged 12 and over to give consent for donation in Scotland[47] and the HTA 2004 provides for children to provide consent for donation in the rest of the UK.[48]

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 considered legally competent can join the ODR and "entry in the Register provides legal consent for the donation of your organs".[49]

On 9th July 2015, NHSBT (in collaboration with the devolved governments) launched the new NHS ODR. It holds all the existing registrations from the previous ODR for England, NI, Scotland and Wales and now enables any resident in the UK to record[50]:

- 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.

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.[51]

5 Human Transplantation Bill (NI)

In Northern Ireland, the Human Transplantation Bill was introduced as a Private Member's Bill by Mrs Jo-Anne Dobson, MLA on 13 October 2015 and completed second stage on 16 November 2015. The Bill contains 22 clauses and one Schedule and seeks to implement a new soft 'opt-out' system using a two stage consent process (express or deemed consent).

The Bill covers both live and deceased donation for adults and children and is designed to fit into the legislative framework of the Human Tissue Act 2004 with amendments to that Act covered in the Schedule.

There are two potential UK comparators, Wales and Scotland – Wales has already legislated in this area with the Transplantation (Wales) Act 2013 and this Act has already been outlined in Section 4 of this paper.

[47] Human Tissue Scotland Act 2006, Section 8, http://www.legislation.gov.uk/asp/2006/4/contents
[48] Human Tissue Act 2004, Section 2, http://www.legislation.gov.uk/ukpga/2004/30/section/1
[49] Organ Donation and Transplantation, NHS Blood and Transplant, www.nhsbt.nhs.uk/what-we-do/organ-donation-transplantation/, webpage accessed 24/11/15
[50] New Organ Donation Register, NHSBT, Launch letter, 9th July 2015, Sally Johnson, Director of Organ Donation and Transplantation, http://www.nhsbt.nhs.uk/news-and-media/news-articles/news_2015_07_09.asp
[51] New Organ Donation Register, NHSBT, Launch letter, 9th July 2015, Sally Johnson, Director of Organ Donation and Transplantation, http://www.nhsbt.nhs.uk/news-and-media/news-articles/news_2015_07_09.asp

In Scotland, a Private Member's Bill entitled the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill was introduced in the Scottish Parliament on 1 June 2015. It also proposes a soft 'opt-out' system of consent and largely consists of amendments to the Human Tissue (Scotland) Act 2006. It adopts the terminology of the 2006 Act, in particular by referring to 'authorisation' rather than 'consent' for 'organ donation'.[52]

This section presents a thematic discussion of the NI Bill and clause scrutiny where relevant, providing comparison mainly to the Welsh Act and to the recently introduced Scottish Private Member's Bill where pertinent.

5.1 Authorisation of Transplantation Activities and Relevant Material

Clause 2(1) is a key provision stating that the transplantation activities are only legal if the appropriate **consent** is in place – be that 'express consent' (Clauses 3,5,6, and 7) or 'deemed consent' (Clauses 4 and 8).

Clause 2(2) describes what is meant by four human transplantation activities in the Bill – storing the body, removing relevant material from the body (of which it consists or contains, e.g. a heart or a kidney), storing relevant material which has come from the body, and using relevant material – all for the purposes of transplantation.

Clause 2(3) provides for lawful transplantation activity, without consent, if the material was imported from outside NI and it was removed from a human body outside NI.

Clause 17 defines 'relevant material' - "*material, other than gametes, which consists of or includes human cells, but does not include embryos from outside the human body or hair and nail from a living person*".[53]

5.2 Consent (Express and Deemed)

5.2.1 Express Consent – Adults

Clause 3 of the Bill deals with the default position for adults - 'express consent' and the 'cases' in which it applies. 'Express consent' is required if:

- The person is alive (living donation – person's express consent); or
- The person has died and:

[52] Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill, Explanatory Notes, http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89893.aspx

[53] Embryo and gametes have the same meaning as in sections 1(1), 4 and 6 the Human Fertilisation and Embryology Act 1990 in the other provisions of that Act (apart from section 4A)

- their decision to consent or not to consent to donation was in force immediately before death - person's express consent;
    - no decision of the person in place but the person had appointed a person ('appointed representative') to deal with consent - appointed representative gives express consent;
    - no decision of the person in place and no appointed person is 'able' (defined in clause 9(12)) to give consent - person in 'qualifying relationship' gives express consent.

Clause 3 does not apply if the person is an 'excepted adult' or the transplantation covers excluded 'relevant material'.

In the last 'case' (no decision of the person in place and no appointed person is 'able' to give consent so the person in the 'qualifying relationship gives express consent) – the 'qualifying person' does not have to provide the positive affirmation in clause 4 ('deemed consent' for adults).

In the case in clause 3, the deceased person has actually appointed a person to deal with the issue of consent and this appointed person is not 'able' to give consent so the task passes to a person in a 'qualifying relationship'. It appears from the Bill that this person can then give 'express consent' without any knowledge of the deceased's wishes on the matter and this differs from the positive affirmation required of a person in a 'qualifying relationship' in clause 4.

Clause 3 of the Bill is the first place where the concepts of appointed representatives/persons and 'qualifying relationships' (covered in clauses 9 and 10 of the Bill) are mentioned. In the Welsh Act the reader is given more assistance by being referred to the sections where these matters are dealt with.

5.2.2 Deemed Consent – Deceased Adults

Clause 4 represents a key change in the law for NI regarding consent to organ donation. It does not apply to 'excepted adults' (clause 5) or to 'excluded material' (clause 7). It provides for 'deemed consent' - if an adult in NI has died and none of the cases of clause 3 (express consent for adults) apply, meaning the person has not made their views on transplantation known nor appointed a person (appointed representative) to deal with the issue, then the person is 'deemed' to have consented to transplantation.

However, that is not the end of the matter as clause 4(2) provides for 'deemed consent' to only be 'effective' when reasonable efforts have been made in the circumstances to contact 'qualifying' persons (clause 4(2)(a)); and it is positively 'affirmed' by a "qualifying person" (as defined in clause 10) that the person **would not have objected** to the activity. The person making the affirmation must have 'reasonable grounds' for believing the person would not have objected (clause 4(2)(c)).

Paragraph 7(d) of the Schedule of the Bill requires the Code of Practice from the Human Tissue Authority to include guidance in connection with deemed consent, affirmations, objections to affirmations and the procedure for dealing with a potential state of conflict where there is an affirmation and an objection to that affirmation exist.

A key difference between the Welsh Act and the NI Bill is that the former places 'deemed consent' to transplantation activity (Section 4(2))[54] as the default consent position for adults unless:

- The 'case' is one in which express consent is required by the Act (Section 4(3));
- Or Section 4(4) applies (when a relative or friend of longstanding of the deceased objects on the basis of the most recent views held by the deceased and a 'reasonable person' would conclude that the relative or friend knew that the person **would have objected** to consent being given).[55]

The NI Bill places 'express consent' as the default position (clause 3) and 'deemed consent' (clause 4) only applies when the 'cases' listed for express consent do not apply (clause 4(3)(b)). In addition, deemed consent will not be effective unless there is 'affirmation' by a 'qualifying person' that they have 'reasonable grounds' the person **would not have objected** to the activity (clause 4(2)).

Potentially the NI Bill requirement for a positive affirmation from the 'qualifying person' that the person **would not have objected** is a higher 'hurdle' than under the Welsh Act and makes it more difficult than under the Welsh Act for the 'deemed consent' to lead to donation.

In a similar situation, the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (Section 6B(1)(vi)) provides for the transplantation activity to be legal once the 'authorised investigating person' has asked the adult's nearest relative, if any, "*whether the relative has actual knowledge that the adult was unwilling for the part to be removed and used for transplantation and has concluded, in the light of any answer given that the relative has no such knowledge*". This would also seem to be more likely to lead to donation than the affirmation required in the NI Bill.[56]

In addition, Mr James Douglas (Consultant Nephrologist), in presenting to the HSSPS Committee on 2nd December 2015, highlighted that the NI Bill as currently drafted in clause 4 prevents a 'qualifying person' giving consent to donation if they are not aware whether or not the person would not have objected and therefore cannot give the positive affirmation.[57]

[54] Human Transplantation (Wales) Act 2013, http://www.legislation.gov.uk/anaw/2013/5/contents/enacted

[55] Human Transplantation Bill: Mrs Jo-Anne Dobson MLSA, Official Report (Hansard), Committee for HSSPS, 4 November 2015, page 8, http://aims.niassembly.gov.uk/officialreport/minutesofevidence.aspx?&cid=10

[56] Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (Section 6B(1)(vi)), http://www.scottish.parliament.uk/S4_Bills/(1)Transplantation%20(Authorisation%20of%20Removal%20of%20Organs%20etc.)%20(Scotland)%20Bill/b72s4-introd.pdf

[57] Presentation by Mr James Douglas, Consultant Nephrologist, NIA TV broadcast, HSSPS Committee, Senate, NI Assembly, 2nd December 2015

This could prevent a 'qualifying person' giving consent to donation that could occur presently under the HTA 2004. However the Bill does not provide for that as it amends the HTA 2004, including abolishing the application in NI of Section 1 (subsection 1) of the HTA with regard to "appropriate consent to organ donation".[58]

5.2.3 Deemed Consent – Living Adults Lacking Capacity to Consent

Clause 8 provides for transplantations from a living adult who lacks the capacity to consent to the activity and where there is no express consent or not to consent decision in force. The person's consent to the activity will be 'deemed' "*if the activity is done in circumstances of a kind specified by regulations made by the Department*" (clause 8(2)).

An example of these circumstances may be where it may be in the best interests of a person incapable of giving consent, to donate material to a living relative.[59]

This Clause raises the issue of capacity for the second time in the Bill (first raised in clause 5). It is not clear in the Bill if the intention for this clause is an informal discussion with close family to assess capacity (see discussion of clause 5 – section 5.2.5) or if a more formal assessment of capacity would be required to act under clause 8.

If a more formal capacity test is required, this may mean that the impact of any current formal tests of capacity and the potential impact of the Mental Capacity Bill for NI (presently in Committee Stage) may need to be taken into consideration as regards the definition of lack of capacity.

5.2.4 Express Consent – Children

Clause 6 of the Bill deals with'express consent' and the 'cases' in which it is required for children (those aged less than 18 years). Table 3 of the Bill applies and 'express consent' is required if the:

- Child is alive and the case below does not apply – the child's express consent
- Child is alive and no decision of the child to consent or not to consent is in force and either the child is not competent to consent/not consent or is competent but fails to consent/not consent - consent of person with parental responsibility;
- Child has died and:
    - their decision to consent or not was in force immediately before death - the child's express consent;
        - but the child had appointed a person to deal with consent - appointed representative gives express consent;

[58] Human Tissue Act 2004, Section 1, http://www.legislation.gov.uk/ukpga/2004/30/section/1

[59] Human Transplantation Bill, Explanatory and Financial Memorandum, Clause 3, Human Transplantation Bill, NIA Bill 64/11-16, Explanatory and Financial Memorandum, Clause 8, http://www.niassembly.gov.uk/assembly-business/legislation/primary-legislation-current-bills/human-transplantation-bill/

- no decision is in place but the child had appointed a person to deal with consent but no appointed representative is 'able' to give consent - person with parental responsibility immediately before death gives express consent or if no such person exists, a person who stood in a 'qualifying relationship gives express consent;
- none of the above 'cases' apply - a person with parental responsibility immediately before death gives express consent or if no such person exists, a person who stood 'qualifying relationship 'gives express consent.

Clause 3 in the NI Bill does not apply if the transplantation covers excluded 'relevant material' (see 4.1 of this paper).

A decision or appointment made by the child is only valid "*if the child was competent to deal with the issue of consent when it was made*" (clause 6(4)). The meaning of competence is described in clause 18(3). The intent is "*this means that the child can only consent to donating an organ if the child understands what this really means*".[60]

The relevant section in the explanatory memorandum for the Welsh Act describes how it "*would be normal practice for a person with parental responsibility to be consulted to establish whether the child was 'Gillick' competent*[61] *to make the decision*" – meaning the child should have the maturity to understand the nature and consequences of the decision.[62] Given the description given in the explanatory memorandum for the NI Bill, it would seem that the legislative intent is the same as Wales and that 'Gillick' competence applies.

5.2.5 Express Consent – Excepted Adults

Clause 5 provides for 'express consent' being required for two 'subsets' of deceased adults:

- An adult who immediately before death had not been **'ordinarily resident'** in NI for a period of at least 12 months (clause 5 (3)(a));
  - This introduces the importance of establishing residency for the purposes of the Bill. The term 'ordinarily resident' is also used in the Welsh Act and is not defined in either the NI Bill or the Welsh Act. In Wales it is to be assessed on a case by case basis, "*the concept means a person's abode in a particular*

[60] Human Transplantation Bill, Explanatory and Financial Memorandum, Clause 3, Human Transplantation Bill, NIA Bill 64/11-16, Explanatory and Financial Memorandum, Clause 6, http://www.niassembly.gov.uk/assembly-business/legislation/primary-legislation-current-bills/human-transplantation-bill/

[61] Care Quality Commission, http://www.cqc.org.uk/content/nigels-surgery-8-gillick-competency-and-fraser-guidelines - The 'Gillick Test' helps clinicians to identify children aged under 16 who have the legal capacity to consent to medical examination and treatment. They must be able to demonstrate sufficient maturity and intelligence to understand the nature and implications of the proposed treatment. In 1983, a judgment in the High Court laid down criteria for establishing whether a child had the capacity to provide valid consent to treatment in specified circumstances, irrespective of their age. Two years later, these criteria were approved in the House of Lords and became widely acknowledged as the Gillick test,

[62] Human Transplantation (Wales) Bill, Explanatory Memorandum, paragraph 34, http://www.assembly.wales/Laid%20Documents/PRI-LD9121-EM%20-%20Human%20Transplantation%20(Wales)%20Bill%20-%20Explanatory%20Memorandum-03122012-241088/pri-ld9121-em-e-English.pdf

place or country which has been adopted voluntarily and for settled purpose [e.g. education or employment] *and part of the regular order of life for the time being*"[63]; and

- The Scottish Bill, Section 6B(3) provides for a rebuttable presumption that an adult (16 years and over) had a reasonable opportunity to record an objection if he or she had been 'habitually resident' in Scotland for any continuous period of six months, therefore 'deemed consent' could apply after six months of residence as opposed to 12 months in the Welsh Act[64] and NI Bill.

- An adult who for a "significant period before dying lacked **capacity** to understand the notion that consent to transplantation activities can be deemed to be given" (clause 5(3)(b)):
  - This is the first mention of capacity in the Bill. The definition of capacity as required by the Bill is not further defined. However, the legislative intent may be the same as the Welsh Act - no formal capacity assessment but a judgement reached by discussion with those closest to the deceased:

capacity can fluctuate and therefore the arrangements need to be flexible rather than overly prescriptive in the legislation. A discussion with the person's family in which these issues are sensitively addressed will therefore be the most practical method of determining whether someone lacked capacity for the requisite period.[65]

With regard to excepted adults, 'express consent' is required in the cases as already described in clause 3 for an adult where express consent is required, except for the addition of a 'catch-all' case - excepted adult has died but none of above apply - person in 'qualifying relationship' gives express consent. This may mean that the same issues as described in section 5.2.1 for clause 3 for express consent by 'qualifying persons' also apply here).

5.2.6 Express Consent – Excluded Material

Clause 7 of the Bill provides for express consent to be required for both adults and children in the unusual case of the removal of 'excluded relevant material'. The Bill does not define such material but provides for it to be specified by the DHSSPS in regulations (clause 7(2)). Clause 7(3) does provide examples of such material as being 'composite' and 'novel' material' (for example, faces and limbs).

For adults, 'express consent' is required in the 'cases' as already described in clause 3, except for the addition of a 'catch-all' 'case' - the adult has died but none of the other

[63] Human Transplantation (Wales) Bill, Explanatory Memorandum, paragraph 24, http://www.assembly.wales/Laid%20Documents/PRI-LD9121-EM%20-%20Human%20Transplantation%20(Wales)%20Bill%20-%20Explanatory%20Memorandum-03122012-241088/pri-ld9121-em-e-English.pdf paragraph 24

[65] As above, paragraph 38

'cases' apply – a person in 'qualifying relationship' gives express consent. his may mean that the same issues as described above for clause 3 for express consent by 'qualifying persons' also apply here).

For children, 'express consent' is required in the 'cases' as already described for clause 6. A decision or appointment made by the child is only valid "*if the child was competent to deal with the issue of consent when it was made*" (clause 7(6)).

5.3 Promotion of Transplantation and Reporting

Clause 1 of the Bill puts three duties on the Department of Health Social Services and Public Safety[66] (DHSSPS): two broad duties (i) to promote transplantation and (ii) to provide information/increase awareness about transplantation. It also includes a specific duty detailed in clause 1(1)(c) and 1(2) to inform the public, at least once per year, about 'deemed consent' and the role of family and friends ('qualifying persons') in 'affirming' that deemed consent.

The Welsh Act includes an additional duty on the Welsh Ministers to ensure that "the resources available to Local Health Boards include the specialist skills and competencies required for the purposes of the Act".[67]

Clause 14 of the Bill establishes the post-legislative scrutiny required to be undertaken by the DHSSPS:

- Annually the DHSSPS must report to the NI Assembly on transplantation activities. The report must cover the steps taken by the DHSSPS to fulfil the duties in clause 1 and the "*number and nature of transplantation activities carried out in accordance with this Act*" (clause 14 (2)); and
- At least once every five years the report must include the opinion of the DHSSPS as to whether the Act is being effective in promoting transplantation and any recommendations for amending the law in that regard (Clause 14(3)).

The NI Bill provides for more thorough and long lasting post-legislative scrutiny than the Welsh Act, which states in clause 1(3) that the Welsh Ministers must report annually to the National Assembly for Wales for only the first five years on the steps taken to fulfil the similar duties under its clause 2(1).

[66] Clause 1 (1) states the Department for HSSPS, the correct term is the Department of HSSPS
[67] Human Transplantation (Wales) Act 2013, Clause 2(1)(d), http://www.legislation.gov.uk/anaw/2013/5/contents/enacted

5.4 Alternative Decision Makers

5.4.1 Appointed Representatives

Clause 9(1) of the Bill provides for a person to appoint one or more representatives ('Appointed Representatives') to represent them for purposes of clause 2 (Authorisation of transplantation activities). The Bill provides for the decision of the Appointed Representative(s) (when required) in clauses 3,5,6 and 7 to constitute 'express consent'.

Appointments made under the Human Tissue Act 2004 or the Welsh Act are to be treated as the appointment being made under clause 9 of the NI Bill (clause 9(11)).

If it is not "*reasonably practicable to communicate with a person appointed*" (9(12)) within the timeframe for consent to be acted on as regards the transplant activity, the person is to be treated as to **not being able** to give consent under clauses 3,5,6, and 7.

The Bill does not specify what will be considered 'reasonably practicable' so it may be necessary to consider adding this to be covered in the HTA Code of Practice that is specified in paragraph 7 of the Schedule.

Clause 9 sets out how the appointments are made and revoked, appointments may be:

- 'General' or 'limited' to consent to one or more transplantation activities (9(2));
- Made orally or in writing (9(3)):
    - Oral appointments are only valid if made in presence of two witnesses (9(4));
    - Written appointments are only valid if (9(5):
        - If signed by the person (or at the direction of the person in their presence) making it in presence of at least one witness who attests the signature;
        - It is contained in the will of the person making it;
- 9(6) explains that if a person appoints two or more persons in relation to the same transplantation activity, then they are regarded as appointed to act 'jointly and severally' (individually) unless the appointment provides that they are to act 'jointly', (i.e. one of the named appointments could give express consent unless the person has specifically stated that the two or more persons are to act jointly);
- An appointment may be revoked at any time (9(7)) and 9(3) to 9(6) apply to the revoking as they do to the making of the appointment;
- An appointed person can renounce their appointment at any time 9(9); and
- A person may not act under an appointment if they are a child or are "*of a description prescribed by regulations made by the Department*" (9(10).

In the Scottish Bill, section 5 enables an adult to appoint (in writing) up to three adult proxies (in priority order) to make decisions about the adult's body after his or her death regarding transplantation. The 'authorising investigative person' must determine if there is 'authorisation' (consent) and one of the steps is to contact the proxy or proxies in priority order. In addition, the Bill provides (section 1) for a register to be in place for an adult resident in Scotland to record free of charge the appointment of a proxy or proxies.[68] Such a register for 'appointed persons' is not referred to in either the Welsh Act or the NI Bill.

5.4.2 Qualifying Relationships

In Clauses 3,4,5,6 and 7 someone in a 'qualifying relationship' may be required to give consent to a transplantation activity. Clause 10 provides a list of 'qualifying relationships' and "for the purposes of the Act, a person is another person's partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship" (10(4)):

- Spouse, civil partner or partner;
- Parent or child;
- Brother or sister;
- Grandparent or grandchild;
- Child of a brother or sister;
- Stepfather or stepmother;
- Half brother or half sister; and
- Friend of long standing.

This list may be amended by the DHSSPS by order (10(3)).

Consideration was given in Wales to ranking the order of 'qualifying relationships' for the purposes of 'deemed consent' and providing information as to whether the deceased would have objected, However, "*it is considered that any person in this list should be able to provide information. The only time relationships are ranked is when express consent is to be given on behalf of a child or an excepted adult*".[69]

Unlike the Welsh Act, the NI Bill provides for the HTA Code of Practice (referred to in the Schedule) "*may make further provision on qualifying relationships, in particular on the ranking of qualifying relations*" (10(4)), for example, for the purposes of setting out further details on how to handle conflict where people in a qualifying relationship want

[68] Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill, Explanatory Notes, paragraph s15 - 25 http://www.scottish.parliament.uk/parliamentarybusiness/Bills/89893.aspx

[69] Human Transplantation (Wales) Bill, Explanatory Memorandum, paragraph 44, http://www.assembly.wales/Laid%20Documents/PRI-LD9121-EM%20-%20Human%20Transplantation%20(Wales)%20Bill%20-%20Explanatory%20Memorandum-03122012-241088/pri-ld9121-em-e-English.pdf

different things.[70] The Bill does not define a 'friend of long-standing' so the Code of Practice may also need to cover that issue.

The DHSSPS may well need to prepare its own code of practice if the Bill becomes law in order to fully cover all the issues and situations HSC staff may have to deal with.

The Human Tissue Act 2004 (which currently applies to NI) does rank these relationships in Section 27:

> *(4)The qualifying relationships for the purpose of sections 2(7)(b)(ii) and 3(6)(c) should be ranked in the following order—*
>
> *(a)spouse**[F1**, civil partner**]** or partner;*
>
> *(b)parent or child;*
>
> *(c)brother or sister;*
>
> *(d)grandparent or grandchild;*
>
> *(e)child of a person falling within paragraph (c);*
>
> *(f)stepfather or stepmother;*
>
> *(g)half-brother or half-sister;*
>
> *(h)friend of longstanding.*
>
> *(5)Relationships in the same paragraph of subsection (4) should be accorded equal ranking.*

5.5 Offences and Prosecutions

There are two main offences under Clause 11:

- A person commits an offence if they undertake a transplantation activity without the appropriate consent (be it express or deemed) being in place (11(1)); and
- A person commits an offence if they knowingly falsely represent to the person doing the activity that there is consent or that consent is not required (because it is not a transplantation activity) (11(3)).

The clause provides a defence if the person 'reasonably believes' that consent was in place or that the activity is not a transplantation activity (11(2)).

The Welsh Act refers to a person not committing an offence if the Sections 3(3) and 13(1) apply. These are the sections relating to imported material and to preservation

[70] Human Transplantation Bill, Explanatory and Financial Memorandum, Clause 10, http://www.niassembly.gov.uk/assembly-business/legislation/primary-legislation-current-bills/human-transplantation-bill/

for transplantation. The equivalent in the NI Bill are 2(3) and 15(1) but are not currently referred to in clause 11.

11(4) provides for potential fines and imprisonment for these offences (equivalent to the Welsh Act 10(4):

> *(4)A person guilty of an offence under this section is liable—*
>
> *(a) on summary conviction to a fine not exceeding the statutory maximum,*
>
> *(b) on conviction on indictment to imprisonment for a term not exceeding 3 years, or to a fine, or both.*

Clause 12 provides that it is possible for organisations and groups to be guilty of offences under the Bill and clause 13 allows for proceedings under clause 11 only to be brought by the Director of Public Prosecutions for Northern Ireland. This is also the case in the Welsh Act.

5.6 Preservation for Transplantation

Clause 15 of the NI Bill (equivalent to clause 13 of the Welsh Act) makes it legal for the management of an institution to take minimum steps necessary to keep the body of a deceased person (lying in the hospital, nursing home or other institution) in such a way as to preserve organs for transplantation.

This authority to do this ceases "*once it has been established that express consent making removal of the part for transplantation lawful has not been, and will not be, given and that consent is not deemed to be given*" (clause 15(3)).

5.7 Orders and Regulations

Clause 19 sets out the procedure for making subordinate legislation:

> *19.—(1)No order or regulation under this Act may be made unless a draft of the order or regulation has been laid before, and approved by resolution of, the Assembly.*
>
> *(2) Orders and regulations made under this Act may contain such incidental, consequential, supplementary, transitional and savings provisions as appear to the Department necessary or expedient.*

Table 6 Summary of Subordinate Legislation in the Bill

Clause	Power conferred on	Form	Procedure
7(2) regarding 'excluded relevant material'	Department	Regulations	Affirmative
8(2) regarding activities involving material from living adults who lack capacity to consent	Department	Regulations	Affirmative
9(10)(b) regarding 'Appointed Representatives'- persons who may not act under an appointment	Department	Regulations	Affirmative
10(3) regarding amending the list of 'Qualifying Relationships'*	Department	Order	Affirmative

* The Schedule of the Bill provides for consequential amendments to the Human Tissue Act 2004, including the requirement for the Department to carry out a public consultation before amending the list of 'Qualifying persons' - with regard to Section 27 (HTA 2004) – the amendment provides for the addition of Section 27 (9A and 9B):

Schedule 7(f):

> *(f) after subsection (9) insert—*
>
> *"(9A) The relevant Northern Ireland department may by order amend subsection (4) in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015.*
>
> *(9B) Before making an order under subsection (9A) the relevant Northern Ireland department must carry out such public consultation as the department considers appropriate.".*

5.8 Consequential Amendments to the Human Tissue Act 2004

Clause 20 gives effect to the Schedule of the Bill. The Schedule makes consequential amendments to the Human Tissue Act 2004. Several of the most pertinent have already been described in the paper. The amendments include:

- The Bill abolishing the application in NI of Section 1(1) of the Human Tissue Act 2004, this prevents a 'qualifying person' giving consent to donation if they cannot give the positive affirmation as they are not aware whether or not the person **would not have objected**.[71] This could prevent a 'qualifying person' giving consent to donation that could occur presently under the HTA 2004.
- 7(d) of the Schedule of the Bill requires the Code of Practice from the Human Tissue Authority to include guidance in connection with deemed consent, affirmations, objections to affirmations and the procedure for dealing with a potential state of conflict where there an affirmation and an objection to that affirmation exist; and
- 7(f) of the Schedule provides for the addition of Section 27 (9A and 9B) to the Human Tissue Act 2004, which includes the requirement for the Department to carry out public consultation before amending the list of 'Qualifying persons':
    - (f) after subsection (9) insert—

    "(9A) The relevant Northern Ireland department may by order amend subsection (4) in so far as it applies to section 3, 5, 6 or 7 of the Human Transplantation Act (Northern Ireland) 2015.

    (9B) Before making an order under subsection (9A) the relevant Northern Ireland department must carry out such public consultation as the department considers appropriate."

6 Concluding Comments

The Human Transplantation Bill was introduced on 13 October 2015 and the NI Assembly has agreed the principles of the Bill as it completed second stage on 16 November 2015. The Bill seeks to implement a new soft 'opt-out' system for consent to organ donation by using a two stage consent process ('express' or 'deemed' consent).

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

[71] Presentation by Mr James Douglas, Consultant Nephrologist, NIA TV broadcast, HSSPS Committee, Senate, NI Assembly, 2nd December 2015

'presumed consent' do have higher rates of deceased donations but not higher rates of living donations:

> *The expectation is that a change to presumed consent will increase the number of donors. While the raw figures do not show a significant difference between countries with different consent models, a study that controlled for 'other determinants of organ donation', including religious belief and number of deaths in traffic accidents, found cadaveric donation rates to be 25 to 30 % higher in presumed consent countries while rates of living donation tend to be lower.*[72]

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. NI already has the highest organ donation rate in the UK.

However, caution has been advised from various quarters in attributing rates of donation in Spain to only its 'presumed consent' system as higher donation rates in that country coincided with improved infrastructure and organ donation being accepted as a cultural norm,

> *Evidence that infrastructure is crucial comes from Spain where the rise in donation rates came years after the 1979 presumed consent legislation. In 1989, ten years after the legislation, there were still only 14.3 donors per million population donors but this had increased to 35.1 by 2005.*[73]

The second stage debate[74] raised a number of issues, including highlighting that an opt-out system is not the 'silver bullet' to increase organ donations and will not achieve everything on its own.[75]

Other issues raised included the balance of power between 'appointed representatives' and family members and how such conflicts or conflicts between those in 'qualifying relationships' would be handled by Health and Social Care staff at the bedside.

The Bill does not rank the qualifying relationships but the Schedule of the Bill provides for the Code of Practice from the Human Tissue Authority to deal with such issues.

Consultant nephrologists and transplant surgeons at the Belfast HSC Trust, while being supportive of means to increase organ donation, have expressed caution about a legislative change that may have a detrimental effect on the willingness of the public to donate.[76]

[72] 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/

[73] 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/

[74] Human Transplantation Bill, Second Stage Debate, Official Report Hansard, 16th November 2015, Volume 109, No 5

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

[76] As above, page 72

The DHSSPS current policy direction is to fully implement the NHSBT Strategy on organ donation[77]:

> *The strategy does not propose that 'opt-out' legislation should be introduced as a UK-wide policy. The strategy aims to increase awareness and increase the number of donors and donated organs through society and individuals, NHS hospitals and staff, NHSBT and commissioners working together to achieve the desired outcomes.*

[77] Human Transplantation Bill, Second Stage Debate, Official Report Hansard, 16th November 2015, Volume 109, No 5, page 70