

Human Tissue (Authorisation) (Scotland) Bill

Policy Memorandum

Introduction

1. As required under Rule 9.3.3 of the Parliament's Standing Orders, this Policy Memorandum is published to accompany the Human Tissue (Authorisation) (Scotland) Bill introduced in the Scottish Parliament on 8 June 2018.
2. The following other accompanying documents are published separately:
 - Explanatory Notes (SP Bill 32–EN);
 - a Financial Memorandum (SP Bill 32–FM);
 - statements on legislative competence by the Presiding Officer and the Scottish Government (SP 32–LC).
3. This Policy Memorandum has been prepared by the Scottish Government to set out the Government's policy behind the Bill. It does not form part of the Bill and has not been endorsed by the Parliament.

Policy Objectives of the Bill

4. Organ and tissue donation and transplantation is an incredible development in modern healthcare which continues to save and significantly improve lives. Conditions that severely limit lives, or which are ultimately fatal, can be cured or significantly improved by the transplantation of replacement organs and tissue from donors. Yet despite the very real benefits of transplantation there is still a shortage of organs, and over 500 people in Scotland are waiting for a transplant at any one

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 point.¹ It is important therefore that the Scottish Government, working with its partners, does all it can to maximise the number of donors, particularly as only around 1% of people die in circumstances where they can become a deceased organ donor.²

5. Organ and tissue donation and transplantation is dependent on the generosity, commitment and skill of a number of different people. Deceased donations occur immediately following tragic events and at a time of great sorrow. The willingness of donor families to think of other people and the gift of donation at such times makes their generosity all the more special. Donation is also reliant on the commitment, dedication and skill of those in the NHS who work collaboratively across many disciplines to facilitate donation and transplantation. This work is supported by a commitment from the Scottish Government, working in partnership with others to continue to promote donation.

6. Authorisation is an important factor which affects whether donation, and ultimately transplantation, can proceed. Scotland already has the highest proportion of people registered on the NHS Organ Donor Register (ODR) in the UK (46%³ compared to a UK average of 38%⁴), but surveys show that even more Scots support donation.⁵ This suggests, therefore, that many people who support donation simply do not get around to registering their wishes. Additionally, each year a significant proportion of families refuse authorisation for their loved one's organs to be donated. In 2017-18 in 44% of cases in Scotland where family members were approached about donation, authorisation was not given or (in a few cases)

¹ <https://nhsbtddb.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

² Taking Organ Transplantation to 2020 – A UK Strategy https://nhsbtddb.blob.core.windows.net/umbraco-assets-corp/4241/nhsbt_organ_donor_strategy_summary.pdf

notes that over half a million people die each year in the UK, but fewer than 5000 people each year die in circumstances or from conditions where they could become donors.

³ <https://nhsbtddb.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

⁴ https://nhsbtddb.blob.core.windows.net/umbraco-assets/1616/united_kingdom.pdf

⁵ For example, in a survey (unpublished results of 2016 Organ Donation Campaign) of 1032 people in Scotland in August 2016 carried out by TNS, 70% of people agreed that 'we should all register to be organ donors'.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 the family overrode the authorisation the person had previously given.⁶ It is important, therefore, to look at ways in which the Scottish Government can ensure individuals who would want to donate are able to do so. A move to a soft opt-out system is a way to do this.

7. The primary purpose of the Bill is to introduce a soft opt-out system of organ and tissue donation for the purposes of transplantation. The Human Tissue (Scotland) Act 2006 (“the 2006 Act”) currently provides the legal basis for authorisation of donation for transplantation and other purposes. The 2006 Act provides that organs and tissue can only be donated by someone if either the person has authorised donation before death or if their nearest relative authorises the donation on their behalf – this is known as an “opt-in” system. The Bill will provide a new, additional category of “deemed authorisation” which will apply to most adults who have not otherwise explicitly opted in or out of donation via the ODR, or who have not otherwise recorded an explicit decision about donation for transplantation. This would mean that where the person was not known to have any objections to donation, the assumption would be that the donation could proceed. As well as retaining the legal basis for individuals to explicitly opt in to donation, the Bill will also provide a legal basis for an explicit declaration of non-authorisation (or “opting out”).

8. Deemed authorisation will not apply to people in excepted categories; children under the age of 16, adults who do not have the capacity to understand the nature and consequences of deemed authorisation, or adults resident in Scotland for less than 12 months. These groups would require explicit authorisation – either self-authorisation during their lifetime or, upon their death, authorisation by a nearest relative (for adults) or a person with parental rights and responsibilities (PRRs) (for children).

9. The Bill also contains some new substantive policies, associated with organ and tissue donation, which will ensure that the existing statutory framework in the 2006 Act continues to operate effectively and that opportunities for successful donation are optimised. These include more flexibility in the timing of the authorisation process and clarity about authorisation for pre-death procedures undertaken in some cases as part of the donation pathway.

10. Organ and tissue donation and transplantation is a complex and multi-faceted process, often operating to time pressures. No single measure will radically increase donation rates. Instead, action needs to be

⁶ Data provided by NHSBT

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 taken on every single part of the donation pathway in order to drive continuous improvement. The Scottish Government has already committed to a package of measures to increase donation and transplantation. These are set out in *A Donation and Transplantation Plan for Scotland 2013-2020* (the Plan).⁷ The introduction of a soft opt-out system of donation will add to these existing efforts.

11. At the same time, it is important to guard against any harm to the progress made so far, as international experience shows that if legislative change is not implemented carefully donation rates can be negatively impacted. The Government's policy in supporting organ and tissue donation and transplantation, and in developing the Bill, continues to have these important potential consequences in mind.

Contribution to the Government's Purpose and National Outcomes

12. The introduction of a soft opt-out system of organ and tissue donation aims to support a Healthier Scotland and in particular the Purpose target of increasing healthy life expectancy in Scotland. It will also in part, and over the longer term, help support the Purpose target of maintaining Scotland's position on labour market participation as the top performing country in the UK. Increasing the number of transplants undertaken is expected to allow individuals to return to work who are otherwise unable to do so because of serious illness.

Background

Policy context and progress so far

13. In 2013, the Scottish Government published the Plan which set out the ways in which it hopes to improve donation and transplantation in Scotland. The Plan builds on the progress made by implementing the recommendations of the UK Organ Donation Taskforce since 2008. The implementation of the Plan is monitored by the Scottish Donation and Transplant Group (SDTG). The SDTG brings together representatives of the donation and transplant communities in Scotland, as well as patient representatives who are transplant recipients, and provides expert advice and makes recommendations to the Scottish Government on matters relating to organ and tissue donation and transplantation.

⁷ <http://www.gov.scot/Resource/0042/00427357.pdf>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

14. The Plan identifies five priorities the Scottish Government wishes to deliver: increasing the number of people who have made their wishes about donation known; increasing the availability of organs; making every donation count; ensuring NHS Scotland supports donation and transplantation; and ensuring the public in Scotland is informed and engaged about donation and transplantation. Significant progress has been made since the publication of the plan, including:

- high profile publicity campaigns to encourage people to join the ODR being run;
- an internationally-recognised schools educational resource pack to increase awareness amongst pupils about organ and tissue donation;
- work with Kidney Research UK which trains volunteers from South Asian communities to become peer educators to increase awareness of kidney disease and organ donation;
- a dedicated regional manager for Scotland to manage the Specialist Nurses for Organ Donation (SNOD) and to take forward key initiatives to help increase donation.

15. Since the start of focussed work to increase donation numbers in Scotland, which started with the UK Organ Donation Taskforce in 2008, there has been:

- an 89% increase in deceased donor numbers in Scotland (up from 54⁸ to 102⁹)
- a 78% increase in the number of lifesaving transplant operations from deceased donors undertaken for patients living in Scotland (from 211¹⁰ to 375¹¹)
- a 22% decrease in the number of people resident in Scotland on the active transplant waiting list (689¹² to 534¹³).

⁸ Data provided by NHSBT

⁹ <https://nhsbtbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

¹⁰ Data provided by NHSBT

¹¹ <https://nhsbtbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

¹² Data provided by NHSBT

¹³ <https://nhsbtbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

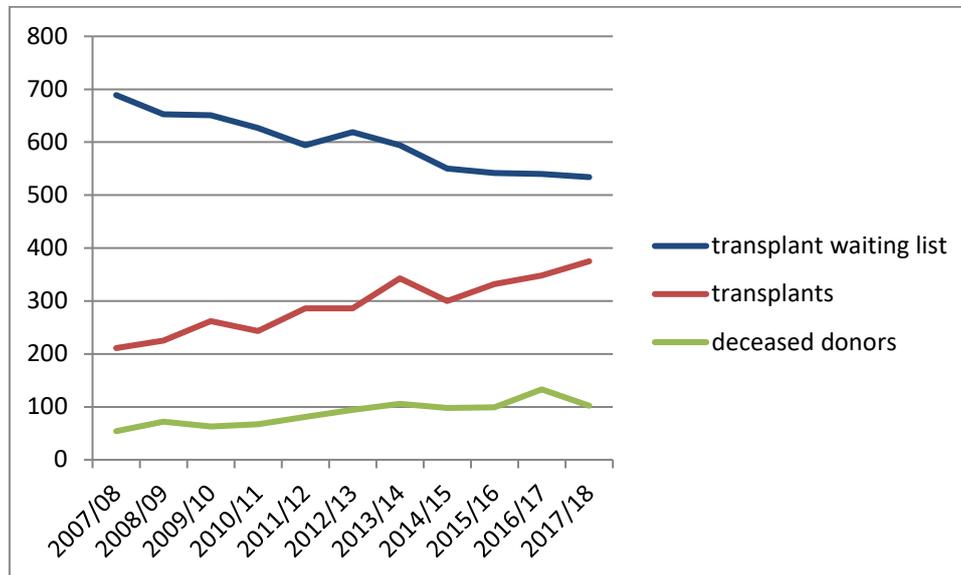
This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

16. While figure 1 shows that numbers of deceased organ donors have been gradually increasing over recent years, donation rates do fluctuate, particularly given the relatively small numbers involved. Given the complexity of the donation process and pathway, there are a number of different unrelated factors which can affect organ or tissue donor numbers, including: the number of individuals dying in circumstances suitable for donation; co-morbidities of potential donors; and the timing of death – either in advance of a donation discussion taking place, or after the permitted timeframe for donation to proceed. Despite significant improvements to the process and pathway in recent years, 2017-18 has seen a decrease in the numbers of deceased organ donors¹⁴ compared with the exceptionally high number of donors in 2016-17. This reflects that many of the factors which impact on donor numbers are not within the control of NHS staff. It is important therefore that the Scottish Government continues to do it can to increase donation and transplantation.

¹⁴ *ibid*

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Figure 1: changes in number of deceased organ donors in Scotland, transplants and those on the waiting list over time¹⁵



UK context

17. Organ donation and transplantation is delivered on a collaborative basis across the UK. NHS Blood and Transplant (NHSBT) has developed a UK-wide strategy on organ donation and transplantation, *Taking Organ Transplantation to 2020*, with the four UK Health Departments. The strategy was developed in response to the report of the UK Organ Donation Task Force and sets out the key areas where further activity is required across the UK as a whole. The Scottish Plan is in line with and complements the UK strategy, but it focuses specifically on the devolved health infrastructure in Scotland and those activities which may be unique to, or be differently delivered in Scotland.

18. Organ donation and the allocation of organs to transplant recipients is managed across the UK by NHSBT, a Special Health Authority established under the NHS Act 1977.¹⁶ NHSBT employs the SNODs who are specially trained to approach families about donation in a sensitive way. NHSBT is responsible for managing the UK's national transplant waiting list and for matching and allocating organs on a UK-wide basis. This means that some organs from donors in Scotland may go to people in other parts of the UK, and people in Scotland may receive an organ from elsewhere in the UK. NHSBT also manages the NHS Organ Donation Register ("ODR") on

¹⁵ Data provided by NHSBT

¹⁶ National Health Service Act 1977 (c.49)

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 behalf of the four UK countries. The ODR is a database into which information is recorded regarding the wishes of individuals in relation to deceased organ and tissue donation. Individuals can join directly by contacting NHSBT, or via partner organisations such as the Organ Donation Scotland website, the DVLA, Boots (the chemist) or via a GP registration form.

19. Separately, most tissue donation in Scotland is managed by the Scottish National Blood Transfusion Service (SNBTS), although NHSBT manages donation of eyes across the UK. SNBTS has its own Tissue Donor Co-ordinators (TDCs), specialist nurses who work closely with NHSBT SNODs to coordinate donations in cases where both organs and tissue may be donated.

Family role in organ and tissue donation

20. If someone is dying or dies in circumstances where they could become a donor, which is usually in an intensive care unit or occasionally an emergency medicine department, a SNOD will check to see if the patient has authorised donation on the ODR. After clinicians managing the care of the patient have agreed that nothing more can be done to save the patient, and the family has come to terms with this, a sensitive discussion with the patient's family will start to take place with regard to the possibility of donation.

21. Under current legislation, if a person has not authorised donation on the ODR or via other means (such as carrying a donor card), a member of the family is able to make a decision on whether to authorise donation. The family member can only authorise donation if they have no actual knowledge that it would have been against the person's wishes. There are often many family members present at the bedside and although authorisation is only required from one individual (the nearest relative or, in the case of children, a person with PRRs), there is usually discussion between family members which informs the decision. SNODs support the family during this difficult time and answer any questions the family may have. SNODs are skilled communicators who routinely discuss donation with families in crisis, families in conflict and families with complex dynamics, and are trained to work with families to reach a consensus view on donation. The sensitive and supportive approach from the SNOD, which is a real strength of the current approach, will continue.

22. If donation is to proceed, the clinical team caring for the patient will work with the SNOD, who will ensure all the necessary clinical checks are

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 made. This will include checking that there are suitable recipients for each organ that can be donated. Throughout this process, the comfort and needs of the donor patient remain paramount and the main focus of the clinical staff in the critical care unit will be on caring for their patient.

23. Families will continue to have an important role in the donation process in a soft opt-out system. The intention is to give effect to the wishes of the potential donor, and the family will play a vital part in communicating the person's views, whether this is for or against donation. The family's role specifically in terms of authorisation for transplantation will change because many potential donations which, under the current system, would have required authorisation from a family member because the potential donor did not authorise donation themselves could be deemed to be authorised under the soft opt-out system. However, provided donation was not against the person's wishes, families will still perform an authorisation role for donation for other purposes such as for research, education and training and audit and quality assurance, and will also be able to authorise for those people in excepted categories. Families will also be able to authorise for less commonly donated types of organs/tissue, which will not be covered by deemed authorisation. The family will also still perform a key role in providing the crucial travel, medical and personal history information about their loved one, to ensure the safety of transplantation.

Move to an opt-out system

24. In June 2015 the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill was introduced to the Scottish Parliament as a Member's Bill. This Bill aimed to introduce an opt-out system in Scotland. During consideration of the Bill the majority view of the Scottish Parliament's Health and Sport Committee was that the Bill should not progress beyond stage 1 due to serious concerns over the practical implications of the Bill. However, the Committee recognised that there could be merit in developing a workable soft opt-out system and called on the Scottish Government, which indicated it supported the aims of the Bill, to consult on further methods to increase donation and transplants in Scotland, including a soft opt-out system. The Committee suggested that this should be undertaken as an early priority in the subsequent Parliament, and that the Scottish Government should learn from the experience of Wales and consider legislating as appropriate.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

25. The Scottish Government carried out a public consultation¹⁷ over 14 weeks from 7 December 2016 to 14 March 2017. The consultation sought views on increasing numbers of successful donations in Scotland. The consultation looked at two ways to potentially increase numbers of deceased organ and tissue donors; by seeking to increase numbers of referrals, for example by encouraging clinicians to refer to a SNOD or TDC patients who have died or are expected to die in circumstances which would potentially enable them to be an organ or tissue donor, and by seeking to increase the number of times when donation is authorised. In particular, the consultation sought views on the introduction of an opt-out system of donation on the proviso that such a system could be developed in a way which would do no harm to trust in the NHS or to the safety of transplantation. The consultation also sought views on whether deemed, as well as explicit, authorisation should allow certain actions to be taken before death to help facilitate donation, such as blood tests, X-rays, urine tests or planning the timing of withdrawing the patient's life-sustaining treatment.

26. More generally, attitudes towards opt-out have shifted over time across the UK. Before 2000 a majority of people in the UK did not support an opt-out system of organ donation, but since then support has increased to an average of 60%.¹⁸ Prior to Wales moving to an opt-out system, the Welsh Government conducted a review of three public opinion surveys. The public opinion survey of a representative sample of adults living in Wales in 2012 found that 49% of respondents were in favour of changing to an opt-out system, while 22% were against.¹⁹ This has increased over time: one year after the new law came into force, 71%²⁰ of the Welsh public were in favour of the soft opt-out system. The most recent Scottish survey ran in 2016 and found that 58% agreed that "everyone should be presumed to be willing to be a donor unless they register a wish otherwise", whereas 28%

¹⁷https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf

¹⁸ Rithalia A, McDaid C, Suekarran S, Norman G, Myers L, Sowden A, "A systematic review of presumed consent systems for deceased organ donation," Health Technol Assess, vol. 13, no. iii, pp. 1-95, 2009.
<https://www.ncbi.nlm.nih.gov/pubmed/19422754>

¹⁹ <https://gov.wales/statistics-and-research/public-attitudes-organ-donation/?lang=en>

²⁰ <http://gov.wales/docs/caecd/research/2017/171130-evaluation-human-transplantation-wales-act-impact-en.pdf>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 disagreed.²¹ Further, when the Welsh Government consulted on moving to an opt-out system in 2012 there was 52% support for such a move, with 39% against.²² This compares to the public consultation in Scotland in 2017 where 82% of respondents were in favour of an opt-out system, with 18% against.²³

27. Following the support²⁴ shown for moving to an opt-out system, and for the specific proposals as outlined in the consultation, the Scottish Government announced its intention to introduce legislation in June 2017 and a commitment was included in *A Nation With Ambition: The Government's Programme for Scotland 2017-18*.

28. To ensure that the soft opt-out system works best, a sub group of the SDTG has been established to:

- Help Scottish Government develop proposals for the introduction of an opt-out system of organ and tissue donation, with reference to the *A Donation and Transplantation Plan for Scotland 2013-2020*.
- Ensure professionals are kept informed of progress with the legislation.
- Identify key messages for public and professionals to support the introduction of an opt-out system.
- Consider proposals for implementation.

International evidence for opt-out systems of donation

29. The evidence presented is based on a rapid evidence review undertaken by Scottish Government.

30. International evidence suggests that opt-out legislation can be effective as part of a package of measures to increase organ donation, however, there is insufficient robust evidence to conclude that opt-out

²¹ Unpublished: TNS Organ Donation 2016 Campaign Evaluation (September 2016) – Q1/5: How much do you agree or disagree that: Everyone should be presumed to be willing to be an organ donor unless they register a wish otherwise

²² <http://www.wales.nhs.uk/news/22113>

²³ <https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/results/organ-and-tissue-donation-and-transplantation-analysis-of-responses.pdf>

²⁴ *ibid*

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Evidence from Wales

31. The Human Transplantation (Wales) Act 2013 brought a soft opt-out system into force in Wales in December 2015. There is now recent evidence of the impact of the opt-out system in Wales,²⁷ published in November 2017, which is of particular relevance given the similarities in the context. The evaluation found that there has largely been limited impact on deceased donation, although it suggests that a longer time is needed to draw firmer conclusions about the impact of the change in the law in Wales.

32. The evaluation found that there was high awareness of and support for the soft opt-out system among the general public and NHS staff. Awareness has generally increased over time, although there has been a slight drop in public awareness recently as awareness-raising had eased off. This suggests that campaigning needs to be maintained continuously. The evaluation of the Welsh system also examines understanding about the role of the family in the opt-out system. It concluded that there was a need to improve understanding among the public and NHS staff of the role of the family in decision making as there was some misunderstanding about the overall role, what happens if the family is distressed, family ability to “override” and the family providing evidence of a known objection held by the deceased.

33. The evaluation found that there was an increase in consent rates for donation, but that routine data did not show any consistent change in deceased organ donation in Wales. Given the increase in levels of consent, the evaluation suggests that either a lower number of eligible donors (i.e.

²⁵

<https://gov.wales/docs/caecd/research/121203optoutorgandonationen.pdf>

²⁶ *ibid*

²⁷ <https://gov.wales/docs/caecd/research/2017/171130-evaluation-human-transplantation-wales-act-impact-en.pdf>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

those who die in circumstances where donation could proceed and who do not have known medical conditions which mean donation is known not to be feasible) or fewer families being approached about donation have been factors in there not being an increase in the number of donors. There has also been an increase in the proportion of people on the ODR. Whilst this is encouraging, the evaluation also concluded that a longer period of time is needed to draw firmer conclusions about the law and other associated changes.

34. There is higher level of public awareness of and engagement with donation in Scotland than elsewhere in the UK, including in Wales, demonstrated most notably by the higher proportion of people on the ODR. This is likely as a result of annual, high-profile awareness raising activity being undertaken in Scotland, in accordance with the requirements of the 2006 Act.

35. The experience in Wales has informed the development of a soft opt-out system provided for in the Bill and will continue to be valuable as plans for implementation and public information are developed.

UK Government position

36. The UK Government published a 12 week consultation²⁸ on 12 December 2017 which sought views on the introduction of an opt-out system for England. The UK Government has subsequently indicated that it will support a Private Member's Bill to introduce opt out which is currently progressing through the UK Parliament. Opportunities for coordination regarding introduction of the systems will be considered where possible. Given the UK wide collaborative basis of donation and transplantation, work with relevant UK bodies will continue to ensure deemed authorisation is implemented in Scotland in a way which supports the aim of all of the UK countries to continue to work together to increase organ donation.

Evaluation

37. Evaluation and monitoring of the new system will be important to support the improvement of processes and gauge changes in public attitudes to donation. Statistics on organ donation and transplantation are currently collected and published by NHSBT on a routine basis and used to identify trends in authorisation rates, donor numbers and transplants, which will be crucial in tracking impact. Public attitudes and awareness are

²⁸<https://www.gov.uk/government/consultations/introducing-opt-out-consent-for-organ-and-tissue-donation-in-england>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 particularly important in an opt-out system and new data collections will be established in representative surveys to monitor these. Additionally, this will support the ongoing development of public information. The existing routine data and newly collected survey data will form an essential part of the intended impact evaluation. In addition, qualitative information, for example reasons for non-proceeding donations or feedback from families involved in the process is used to inform training and improvement to the organ and tissue donation and transplantation pathway. This information will continue to be collected under the opt-out system.

38. Furthermore NHS Health Scotland has supported the development of key draft objectives to assist an intended process evaluation, to be used to identify improvements to implementation processes and an impact evaluation, which will evaluate the effectiveness of the opt-out system. Due to the small numbers involved in deceased donation, a substantial period of time is required to make a robust assessment of effectiveness. The Welsh evaluation was conducted two years after implementation, but concluded that a longer time was required to establish effectiveness. Whilst there will be regular robust monitoring, a final impact evaluation report is intended for approximately 10 years after the system is introduced to gauge the change in attitudes to organ and tissue donation.

39. The key objectives of these evaluations are likely to be:

- Monitor cultural change regarding organ donation in relation to public attitudes and behaviour;
- Monitor awareness as a result of the legislative change;
- Monitor numbers of deceased donations and transplants, including where possible an estimate of those resulting from the legislative changes (although recognising in many cases it may be impossible to know whether a donation would have proceeded in the absence of an opt-out system);
- Evaluate the process of implementing opt out in order to review whether the processes and training in place are appropriate.

Progress and development

40. The Scottish Donation and Transplant Group, which provides advice to Scottish Ministers on all issues relating to organ and tissue donation and transplantation, will monitor progress and the impact of the opt-out system.

Overview of the Bill

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Summary - Soft opt-out system

41. Scotland currently has what can broadly be described as an “opt-in” system of deceased organ and tissue donation. This is provided for in the statutory regime set out in the 2006 Act, which regulates the removal and use of body parts for various purposes including transplantation, and allows adults and children 12 years of age or over, and in some circumstances nearest relatives (of adults) or a person with PRRs (with regards to children), to authorise donation.

42. The Bill will amend the 2006 Act, to supplement existing authorisation provisions with the introduction of a soft “opt-out” system for deceased organ and tissue donation. Specifically, the Bill will provide:

- for “deemed authorisation” of organ and tissue donation for adults for the purposes of transplantation of most types of organ and tissue;
- that an adult can record a declaration objecting to becoming an organ or tissue donor after death, i.e. “opt out”;
- safeguards for excepted categories of adults who will not be subject to deemed authorisation (adults who lack capacity and adults resident in Scotland for less than 12 months);
- safeguards in relation to less commonly donated types of organ and tissue (“excepted types”), which will not be subject to deemed authorisation;
- that, where a potential donor is deemed to have authorised donation of organ and tissue for transplantation, the removal of excepted types of organ and tissue, or the removal of commonly donated types of organ and tissue for purposes other than transplantation can only be carried out with authorisation by a nearest relative;
- a duty on a health worker to inquire as to whether there is an opt-in or opt-out decision in place; the potential donor’s most recent views about donation and pre-death procedures and, in the case of an adult, whether the potential donor is in an excepted category of adult;
- for information about the latest known view of an adult to supersede a previously recorded donation decision, or deemed authorisation.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

43. To ensure that authorisation for donation continues to operate effectively, changes not directly connected to, but which read across to the proposed opt-out system, will also be made including:

- a function for Scottish Ministers to establish and maintain a register of donation decisions or assign an organisation to do so.
- specification of to whom a valid oral authorisation, opt-out declaration, or authorisation by nearest relative or person with PRRs can be given i.e. the ODR or a relevant health worker.
- flexibility around the timing of authorisations which may be given by the nearest relative or person with PRRs.
- the introduction of a statutory framework for authorisation for pre-death procedures in order to increase the chances of successful transplantation.

44. Changes are also made to the 2006 Act in relation to authorisation by a child, or on behalf of a child by a person with PRRs, to:

- include that a child aged 12 or over but under 16 can record a decision not to become an organ or tissue donor after their death i.e. “opt out”;
- provide for change of mind by a child who had previously recorded a donation decision;
- allow local authorities to authorise donation for children for whom it holds PRRs, in consultation with relevant parties;
- align the method of recording a donation decision for children with that for adults;
- require those persons with PRRs who can authorise donation on behalf of a child under 12 years to consider if the child may have been unwilling to donate and, if so, donation may not be authorised;
- provide for another person with a relationship with the child to be able to authorise donation in cases where there is nobody with PRRs for a child or the persons with PRRs are incapacitated.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Content of the Bill

Part 2 – Duties on Scottish Ministers

Information and awareness about authorisation of transplantation etc.

45. Section 1 of the 2006 Act places a statutory requirement on Scottish Ministers to promote, support and develop programmes of transplantation and promote information and awareness about donation. This information requirement is currently met in a number of ways, including through high profile public information media campaigns held each year. These campaigns have been instrumental in increasing registrations on the NHS ODR. The campaigns are supplemented throughout the year by targeted information, for example ongoing social media activity, an internationally-recognised schools educational pack, work undertaken by Kidney Research UK peer educators to raise awareness of organ donation among South Asian communities, and information being provided at public events.

46. In addition to the current duty, the Bill will also require Scottish Ministers to ensure that the public is aware of the implications of the introduction of deemed authorisation and the circumstances in which it applies. This will be an important part of the safeguards which will underpin the soft opt-out system. It will necessitate the development of new public information and changes to current messages around organ and tissue donation to ensure that the public understand the implications of the system. The consultation on increasing organ and tissue donation envisaged a high profile public information campaign for at least 12 months before commencement of the system, to raise awareness, and on a regular basis after implementation of the legislation to maintain awareness.

47. In developing public information, research will be undertaken to gauge people's understanding of the opt-out system and to ensure accessibility for different groups e.g. people with disabilities, in order to develop materials which meet different needs. In addition to the regular public information activity and awareness raising, a direct mailing is proposed to all households in the lead up to implementation. A small number of focus groups held with young people, people with learning difficulties and young people with experience of being looked after by a local authority as part of the consultation process identified clear and accessible information as a priority so that members of the public could make an informed decision.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

48. The Bill will also require Scottish Ministers to promote information and awareness about pre-death procedures associated with transplantation and how they are authorised.

Establishment and maintenance of register

49. The Bill will make provision for Scottish Ministers to establish and maintain a register of information relating to the views of persons who wish to be an organ and/or tissue donor after death (“the Register”) and those who do not wish to be an organ and/or tissue donor after their death. Scottish Ministers will also have a power to delegate the collation and maintenance of the Register to another body (“the Register organisation”). In practice these provisions will provide a statutory foundation for the current arrangements for the maintenance of the ODR which are the responsibility of NHSBT, which maintains the register on behalf of the countries of the UK. The intention is that NHSBT would continue to provide these services as the register organisation.

50. If someone is dying or dies in circumstances where donation is possible, the SNOD will check the ODR in the first instance to ascertain whether the person has recorded a decision on it. As part of the consideration process the SNOD is required to share this information with other health staff involved in the donation process and the family of the potential donor. It is important that the family are aware of the potential donor’s decision on the ODR so that they understand the decision and, if there is not a decision in place, that the potential donor may be deemed to have authorised donation for transplantation. The 2006 Act also requires health staff involved in the transplantation process to be satisfied that the correct authorisations are in place to allow donation to take place within the law. The Bill therefore provides that the register organisation can disclose such information to the relevant health bodies listed on the Bill and also identifies to whom the information can be disclosed, including family members.

51. The Bill provides that decisions (either to opt in or opt out) on the ODR are regarding transplantation, rather than for the other purposes listed in section 3 of the 2006 Act. This is also reflected in the authorisation and opt-out declaration provisions whereby those respective decisions made on the ODR are to be for transplantation only, whereas authorisation for donation for the other purposes may also be recorded in writing elsewhere. This reflects current practice whereby when a potential donor has opted in on the ODR, authorisation for the other purposes is sought from the nearest relative or person with PRRs. The Bill also enables Scottish

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Ministers by regulations to make changes to the information which the Register may hold so as to enable the requirements to adapt to changes in practice.

Part 3 - Authorisation of Removal and Use of Part of Body of a Deceased Person

Chapter 1 - Timing of authorisation

52. The 2006 Act currently allows authorisation for donation to be given, in certain circumstances, by a person's nearest relative or a person with PRRs in relation to a child, after the death of the potential donor. The Bill will provide flexibility around the timing of authorisation so that that it may be given before death where a person is expected to die imminently. However it is important that there are safeguards in the Bill to ensure donation can only be authorised ahead of death in certain circumstances. Therefore the Bill will permit such authorisation only where the potential donor is incapable of making a donation decision and, where the potential donor is receiving life-sustaining treatment, a decision has been taken to withdraw life-sustaining treatment and the potential donor is expected to die shortly after withdrawal of life-sustaining treatment. Flexibility around the timing of authorisation is, firstly, to support the successful transplantation of organs from donors who suffer cardiac death, known as donors after circulatory death or DCD donors (from whom organs must be removed as quickly as possible after death, to avoid deterioration); and secondly, to support the introduction of a statutory framework for authorisation for pre-death procedures (covered below) which will partly rely on authorisation for donation having been given before any such procedure is carried out.

53. Pre-death authorisation for donation will apply to transplantation, but will also extend to the other potential uses of organ and tissue permitted under section 3(1) of the 2006 Act, including, research training and audit or quality control.²⁹ This will mean that the process is not overly convoluted and families are not repeatedly asked at a very difficult time for authorisation for different purposes.

Chapter 2 - Authorisation by or on behalf of an adult

54. It is important that people will continue to be able to make the decision on organ and tissue donation which suits them, whether this is opting in, opting out, or in the case of some adults, doing neither in the knowledge that this means they will be deemed to have authorised

²⁹ "Quality assurance" is added to section 3(1) by the Bill

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 donation for transplantation after death. Evidence from other countries also shows that more successful soft opt-out systems are associated with the ability to opt in.³⁰ The soft opt-out system therefore provides three options for adults:

- The current ability for an adult to make an **express authorisation** for organ and tissue donation will continue (to “opt in”).
- An adult will be able to make an **opt-out declaration** for organ and tissue donation.
- An adult who does not make an express authorisation for transplantation or an opt-out declaration as respects transplantation, may be **deemed** to have authorised donation for transplantation of commonly donated types of organ and tissue.

55. In each of the scenarios the intention is to give effect to the donation decision of the potential donor. The responses to the consultation showed strong support for an opt-out system among individual respondents, but there was also a clear view among this group that the wishes of the individual should be paramount and families should not be able to override this decision.

56. The Bill therefore does not provide for an “override” by family members in the case of any of the decisions – opt in, opt out, or deemed authorisation. However, in the case where the potential donor has opted in or out there will be an ability for that person’s most recent known views to determine whether donation ultimately proceeds or not. Similarly, in deemed authorisation cases the Bill provides for family members or others to advise of any objection to donation which the potential donor held, rather than to advise of their own views. Families will therefore continue to play a crucial role in ensuring the potential donor’s views are respected.

57. Additionally, family involvement will continue to be crucial to the donation process in terms of providing information about the potential donor. Donation happens in tragic circumstances and families must be and will continue to be treated sensitively, not only to ensure that donation continues to be supported, but because families are relied upon to provide information about medical, personal and travel history of their loved one to ensure the safety of the transplantation for the recipients. In addition, in the

³⁰ Bilgel, F, “The impact of presumed consent laws and institutions on deceased organ donation,” *European Journal of Health Economics*, vol. 13, pp. 29 - 38, 2010.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 case of tissue donation, the donor would often need to be moved to a mortuary at another hospital site after death to donate so family members need to be comfortable with this. Evidence from Wales suggests that the role of the family needs to be explained in public information and in training of those involved in donation.

58. Family involvement will also continue to be crucial to the donation process for elements of authorisation – for those in excepted categories, for purposes other than transplantation and for less common types of organ/tissue. In line with the approach in the 2006 Act, in these scenarios the nearest relative will be able to authorise donation as long as it was not against the person's wishes. To optimise the opportunity for the potential donor's views to be taken into account when authorisation is being considered, the Bill provides that it is not solely the knowledge of the nearest relative in regard to the potential donor's views which is relevant but that of any others. As such, whoever is authorising must have regard to information provided by others as to the potential donor's views.

Express authorisation by adult

59. The best way to make sure that a decision to opt in to organ and tissue donation is known is to record the decision on the ODR; this can be done online, by telephone or by post. When registering an authorisation on the ODR this is specifically for transplantation, rather than the other purposes e.g. research. An authorisation on the ODR can be given for all transplantable organs and tissue or tick boxes can also be used if a person prefers to identify which specific organs and tissue authorisation is given for. For example, if someone did not wish their heart or eyes to be removed that person would not tick these boxes. As under the current legislation, provision in the Bill will prevent the removal or use of organs and tissue which have not been authorised.

60. However the Bill reflects that people should not be unduly restricted in how to make an authorisation, and allows written authorisations to be made elsewhere. In practice this will most likely be via a donor card - other written decisions about donation are rare, but the Bill permits a written authorisation in any form. This enables an individual to make a specific written authorisation covering any of the purposes listed in section 3 and any specific organs or tissue. For example if an individual wanted to donate specific organs/tissue for transplantation and research purposes this could be specified in a written note.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

61. As well as recording an authorisation people are also encouraged to tell their family of their decision. By doing so, the family are aware of that decision, and in the event that family members find themselves in circumstances where their loved one is a potential donor, that increases the chance of the family supporting the individual's decision to become a donor. This aspect of family knowledge and support makes it important to retain an ability to opt in, even in a deemed authorisation system.

62. Another reason it is important to discuss donation decisions with family is that families may be called upon to make certain decisions about what should happen to organs and tissue in the event that transplantation cannot go ahead due to medical reasons. In these cases the family could authorise donation of the organ/tissue for the other important purposes listed in section 3, such as research or training, as long as it was not against the person's wishes.

Opt-out declaration by adult

63. Similar to a decision to opt in, the best way to make sure that a decision to opt out is known will be to record it on the ODR; this is possible online, by telephone, or by post. As deemed authorisation will only cover transplantation (not the other purposes), an opt-out declaration on the ODR will similarly be in relation to transplantation. In terms of purposes other than transplantation, when it is established that there is an opt-out declaration in place on the ODR, as long as there is no evidence that the potential donor has had a change of mind, the donation process will stop. The family will not be asked about authorisation for the other purposes listed in section 3.

64. An opt-out declaration on the ODR will encompass all organs/tissue. This reflects the aim of enabling decisions about donation to be simple, and that if there were tick boxes for certain organs/tissue on both the opt in and opt out sections of the ODR it may create confusion. If an individual does not wish to donate a particular type of organ or tissue, but is happy to donate other types, that can be made clear by the person opting in, but only ticking the relevant boxes.

65. In practice it is likely that the vast majority of opt-out declarations will be made on the ODR. However the Bill reflects that people should not be unduly restricted in how to make an opt-out declaration, and it permits written declarations to be made elsewhere. This enables a person to make an opt-out declaration in writing for any of the purposes in section 3 and also for particular organs/tissue. Where a person has made an opt-out

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018. A declaration of this kind, for specific organs/tissue, and potentially also for specific purposes, deemed authorisation for transplantation may be applicable for other organs/tissue. For example if a person makes a written declaration opting out of donation of the heart for research purposes, the provisions in the Bill will enable authorisation to be deemed for organs/tissue not included in the opt-out declaration – in this case that would mean authorisation would be deemed for transplantation of the commonly donated types of organ/tissue (which would include the heart, as the opt-out declaration is not with regard to transplantation). The nearest relative would be able to authorise donation of organs/tissue for other purposes providing it was not against the person's wishes, however the nearest relative would not be able to authorise for donation of the heart for research purposes since there is an opt-out declaration in force.

66. As well as recording an opt-out declaration people will also be encouraged to tell their family of their decision. By doing so, the family members will be aware of that decision in the event that they find themselves in circumstances where their loved one is a potential donor. Making an opt-out decision on the ODR is the best way to ensure that NHS staff are made aware of the decision if the person becomes a potential donor. However SNODs or TDCs will be required to speak with the family and ascertain if the individual recorded an opt-out decision another way e.g. by making a written statement.

Validity of oral express authorisations or opt-out declarations

67. Currently section 6 of the 2006 Act provides that a decision to authorise donation can be made verbally (e.g. by telephone). However, it is not clear to whom such a verbal authorisation can be made to make it valid. The Bill will now provide that to be valid an oral express authorisation or opt-out declaration must be made to the register organisation; in practice the UK ODR administered by NHSBT.

Change of mind

68. If someone makes an express authorisation or declaration to opt out of organ or tissue donation on the ODR that person can change the decision on the ODR at any time; the ODR will reflect their latest decision and record the date that was made. However, in line with the proposals in the consultation and the views of those who responded to the consultation, the aim is to respect the wishes of the individual. Therefore, the Bill provides a safeguard for those persons who have made an express authorisation or opt-out declaration, and who subsequently changed their mind, but had not got round to updating their decision on the ODR.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

69. For example a person may have opted out on the ODR but afterwards decided in favour of becoming a donor following the experience of a family member or friend who received a transplant, but not got round to formally recording that latest decision. This could be a change of mind in its entirety – from opting out for all organs/tissue to opting in for all organs/tissue, or could be a change of mind for particular parts, or for particular purposes if these have been specified. Where evidence is provided which would convince a reasonable person of the change of mind, the effect is that the decision is treated as withdrawn to the extent of the change of mind, and the remainder of the express authorisation or opt-out declaration would remain in place, respecting the donor's decision.

70. It is likely the number of persons who make a decision on the ODR and do not get round to subsequently change their decision will be few. However, in such cases, the SNOD or TDC would explore with the family or any other relevant person with information the circumstances which led to the person changing their decision. The Bill will provide that if the SNOD or TDC considers that a reasonable person would be convinced that the information represented the potential donor's latest view, it enables donation to either go ahead or not to proceed in accordance with those views.

71. Similarly the Bill also recognises that there may be specific circumstances which would affect whether a potential donor who has made either an express authorisation or opt-out declaration would want donation to go ahead. The Bill therefore provides an additional provision to accommodate the potential donor's views as they would relate to the specific circumstances of death where they are contrary to their recorded decision. This takes into account that some people might want to change their decision if the circumstances of their death manifest in a particular way – either after circulatory death or diagnosis of death by neurological criteria (previously known as brain-stem death) – for example for religious reasons. Where the information provided indicates particular wishes regarding the circumstances of death, donation may only proceed in the way which is consistent with the potential donor's wishes.

Deemed authorisation for transplantation as respects adult

72. Where an adult, who is not in an excepted category has neither opted out or in, the law will **deem** that the adult has authorised donation for transplantation of common types of organs and tissue. It is the intention that it is the views of the potential donor which should determine whether or not authorisation is deemed, rather than those of the family.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

73. To address the possibility that a person may not have opted out even if the person did not want to be a donor, the Bill will provide that authorisation will not be deemed if information is provided which evidences that the potential donor objected to donation. This information could be provided by the family members or anybody else who may hold it. The SNOD or TDC will explore the circumstances of the objection with whoever is providing it. The Bill will provide that if the SNOD/TDC considers that a reasonable person would be convinced by the information that the potential donor's latest view was that the person was unwilling to donate, authorisation cannot be deemed. Taking into account the experience in Wales, and the need to recognise that it is the person's decision about donation which is important, this will help ensure that it is clear that if donation does not proceed, that will be because of an objection by the individual, and not because of the nearest relative's objection.

74. As with express authorisation or opt-out declarations, there may be people who would not want authorisation to be deemed if the specific circumstances of death manifest in a particular way. The Bill therefore also provides an additional protection to prevent donation being deemed if the specific circumstances of death are not compatible for example with a person's religious belief. This takes into account that some people might not be willing to donate their organs if the circumstances of their death had manifested in a particular way – either after circulatory death or diagnosis of death by neurological criteria. Where the information provided by family or others indicates an objection to donation in the particular circumstances it may not proceed in those circumstances.

Excepted adults

75. The Bill also includes safeguards so that authorisation for donation cannot be deemed for certain categories of adults: those who have, over a significant period, lacked the capacity to understand deemed authorisation and those resident in Scotland for less than 12 months. Where an adult falls within one of these excepted categories and has not given express authorisation for donation for transplantation or made an opt-out declaration as respects donation for transplantation, the nearest relative may authorise donation as long as it would not have been against the person's wishes. Most respondents (73% of organisations and 79% of individuals) to the consultation agreed with the categories of excepted adults discussed in the following sections.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Non-resident adult: authorisation for transplantation by nearest relative

76. A person who has only relatively recently moved to Scotland cannot reasonably be expected to have sufficient awareness and knowledge of the operation of the opt-out system. The Bill will therefore provide that authorisation cannot be deemed for them – although a person who has recently moved to Scotland will still be able to opt in or opt out. If a person in this category has done neither, donation will proceed only if authorised by the nearest relative, authorisation being dependent on donation not being against the person's wishes.

77. The Bill provides that a person cannot be deemed to have authorised donation where the person has not been resident in Scotland for at least 12 calendar months. This provision reflects the consideration by the Scottish Parliament Health and Sport Committee of the proposal in the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill which proposed a minimum of 6 months. In the Stage 1 report on the Bill, the Committee noted concerns raised in evidence that 6 months may not be a reasonable time for someone coming to Scotland to acquaint themselves with the organ and tissue donation system. A person might not necessarily have to be in Scotland continuously, for example short breaks for holiday, working away on business would still count as being resident. People who come to work in Scotland only on a seasonal and regular basis (e.g. for 6 months every year) would not fall within the deemed authorisation system.

78. A wide range of views were expressed in the consultation on the issue of defining residence. Respondents highlighted practical difficulties of obtaining authorisation for organ or tissue donation from family members living overseas or cultural, and religious and language barriers which would need to be overcome. Some respondents also commented that students studying in Scotland might not see themselves as resident in Scotland; in the case of people such as students, whether or not they were treated as resident would be likely to depend on whether they live in Scotland for the majority of the year.

79. In practice, and as is the case currently, organ or tissue donation would only be able to proceed if there was either an express authorisation by the potential donor or an authorisation from a nearest relative. So if a relative is either unwilling or unable to authorise, donation will not proceed.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Adult incapable of understanding deemed authorisation: authorisation for transplantation by nearest relative

80. The Bill recognises that a person who lacks capacity to understand deemed authorisation cannot reasonably be expected to have made a choice in favour of donation by not opting out. People will be affected in different ways; some with conditions that cause intermittent incapacity before capacity is lost completely, others with lifelong incapacity. The reason for the incapacity is not relevant for the Bill, only whether or not there has been lack of capacity over a significant period of time.

81. The proposal in the Bill provides that, in the absence of the adult opting in or out, the nearest relative can authorise donation provided that the person was not unwilling to donate. In addition, the provisions also recognise the requirements and principles of the United Nations Convention on the Rights of Persons with Disabilities, the Mental Health Care and Treatment (Scotland) Act 2003 and the Adults with Incapacity (Scotland) Act 2000 by requiring the nearest relative to also have regard to the past wishes and feelings of the potential donor which are relevant to donation, as far as they are known. This allows for circumstances where a person may have had a view on donation, but subsequently lost capacity (unless the person had previously actively opted in or out to donation, in which case the previous self-authorisation would still apply as under the current legislation).

82. The Bill provides that a potential donor falls within this excepted category only where the lack of capacity has existed over a significant period of time. The Bill is not prescriptive as to what a significant period is as it is likely to vary from case to case, but it should be long enough so as to mean that the potential donor cannot have been reasonably considered to have had an understanding of the opt-out system. The provisions are flexible to allow interpretation in each individual case and to allow the SNOD or TDC to enquire into medical records and have discussion with the clinical team and the family.

83. Focus groups with a small number of people with learning difficulties as part of the consultation process recognised that capacity covered a wide range of circumstances. They took the view that, as well as having an exception in place to safeguard persons who lacked the capacity to understand the opt-out system, it was important wherever possible to also make sure that people should be supported in the first instance.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Excepted body parts: authorisation for transplantation by nearest relative

84. Deemed authorisation will apply to commonly donated types of organ and tissue e.g. heart, lungs, kidneys, liver, eyes, pancreas, small bowel, heart valves, tendons. Authorisation for donation of excepted body parts (less commonly donated types of organ and tissue) e.g. face and limbs (for transplantation or any other purpose) would be able to be given by a nearest relative, as long as it would not have been against the person's wishes to donate. It is very rare that such organs or tissue could be donated - transplantation of excepted body parts is at present not routine in the UK, therefore it is the intention to define these in regulations. This applies the same principle adopted by the Welsh Government where it was considered preferable to have a list of less commonly donated types of organs or tissue as opposed to creating a list of organs for which consent could be deemed. Respondents to the Welsh Government consultation on the regulations felt that this would reduce the possibility of unintended consequences. Responses to the recent Scottish Government consultation show that individual respondents were broadly in favour of deemed authorisation applying to all types of organ and tissue (83%), but that this was not the case with organisations with just under half supportive of this. Applying deemed authorisation to only the more commonly donated types of organ and tissue reflects a measured approach in introducing deemed authorisation, and should avoid the consequence of people deciding to opt out due to concern about donating a particular, rarely donated body part even though such donation would be extremely unlikely. The proposals would still permit donation of less commonly donated types of organ/tissue where authorisation is explicitly given.

Authorisation for purpose other than transplantation by nearest relative

85. The Bill retains the ability for a nearest relative to authorise donation for purposes other than transplantation where the adult has given an express authorisation for transplantation, provided it would not have been against the person's wishes. This is so that if authorised organs/tissue cannot be used for transplantation due to medical reasons, the organ/tissue can go on to be used for the other purposes listed in section 3, such as research, rather than being unused or disposed of.

86. Similarly, as deemed authorisation will only apply to transplantation, the Bill will require that in deemed authorisation cases the removal of organs or tissue for other uses in section 3(1) of the 2006 Act for research, education or training, or audit or quality assurance will require authorisation

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 by the nearest relative, again provided it would not be contrary to the person's wishes.

Chapter 3 - Authorisation by or on behalf of a child

Authorisation by child 12 years of age or over

87. Children 12 years of age or over but under the age of 16 will continue to be able to authorise donation and the Bill will provide for them to do so in exactly the same ways as for adults. The consultation sought views on the appropriate age from which deemed authorisation should apply and the responses included a range of views on this point and also views on the age at which authorisation should be able to be given by a child. The largest proportion thought that express authorisation should be required for all children under 16 and the Bill proposals reflect this, while also maintaining the age thresholds in the 2006 Act.

88. In addition, two focus groups were held with young people aged 12 to 19 years which asked about the age from which deemed authorisation should apply. The young people taking part in the focus groups expressed a range of views about what the appropriate age would be, both for self-authorisation and deemed authorisation. Overall both groups thought that 15-16 years would be an appropriate age for deemed authorisation to start from.

89. Where a potential donor aged 12 or over, but under 16, has made neither an authorisation or opt-out declaration, a decision about whether to authorise donation will fall to a person with parental rights and responsibilities (PRRs) for the child. Authorisation can only be given where it would not be against the child's wishes to donate. Additionally, where a child has given an authorisation for transplantation, a person with PRRs will be able to authorise for purposes other than transplantation, provided it would not have been against the child's wishes. As with adults, in order to optimise the opportunity for the potential donor's views to be taken into account when authorisation is being considered, the Bill provides that it is not solely the knowledge of the person with PRRs which is relevant with regard to the potential donor's views but also that of others, for example other family members who may have discussed donation with the child. Therefore, in making a decision on whether to authorise, the person who may do this must have regard to information provided by others as to the potential donor's views.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Opt-out declaration: child 12 years of age or over

90. The Bill will provide that a child of 12 years of age or over but under the age of 16 can record a decision not to become a donor after their death and that this can be made in exactly the same ways as for adults. Although children are not subject to deemed authorisation, enabling a child to make an opt-out declaration ensures legal parity between opt in and opt out decisions.

Change of mind

91. As with adults, the intention is to give effect to the donation decision of the potential donor. The Bill therefore does not provide for an 'override' by parents where a child has recorded a decision. However parents and others who are close to the child will be able to provide information which evidences the child's views, so that in the case where the potential donor has opted in or out the child's most recent known views will determine whether donation ultimately proceeds or not.

92. Also as with adults, the Bill will provide a safeguard for children who have made an authorisation or opt-out declaration, and subsequently changed their mind but not got round to updating their decision, for example on the ODR. The SNOD/TDC would explore with the parent or any other relevant person with information the circumstances which led to the child changing their decision. The Bill provides that if a reasonable person would be convinced that the information represented the potential donor's latest view, this would allow donation to either go ahead or be prevented in accordance with those views.

93. The Bill also includes provision for children to accommodate the potential donor's views as they would relate to the specific circumstances of death where they are contrary to their recorded decision. Where the information provided indicates particular wishes regarding the circumstances of death, donation may only proceed in the way which is consistent with the potential donor's wishes.

Authorisation by person with parental rights and responsibilities: child under 12 years of age

94. Authorisation for a child under 12 years of age will continue to remain the responsibility of a person with PRRs. However, the Bill also aims to reflect the United Nations Convention on the Rights of the Child (UNCRC), and brings authorisation for these children in line with how the regime works for children 12 years of age or over. Therefore it includes a new requirement that a person with PRRs will not be able to authorise the

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 removal of the organs or tissue from a child under 12 years of age if the person with PRRs has actual knowledge that the child was unwilling to have their body parts removed in this way. As with adults, in order to optimise the opportunity for the potential donor's views to be taken into account when authorisation is being considered, the Bill provides that it is not solely the knowledge of the person with PRRs which is relevant and recognises that others may also have information.

Authorisation by other persons: children

95. The Bill includes provision to deal with the very rare cases where there is no person with PRRs immediately before the child's death, or when those with PRRs are incapacitated. For example if parents and child are simultaneously critically ill and are expected to die, this could be as a result of a car crash. Whilst this occurrence will be incredibly rare, this issue has been raised by NHSBT and the opportunity has been taken to enable authorisation to be given in this type of situation.

96. It is intended that in these very rare cases authorisation will be able to be given by a nearest relative or another adult with a close relationship with the child, in line with the approach in other parts of the UK, under the Human Tissue Act 2004. Those people who are able to provide authorisation are set out in a hierarchy which is similar to the "nearest relative" hierarchy for adults in section 50 of the 2006 Act but which takes into account the familial circumstances particular to a child.

97. In practice, if it was established that there was no person with PRRs or that person is incapacitated, then a sensitive discussion led by the SNOD/TDC would take place with the relatives at the bedside. In the same way as for an adult potential donor, the highest ranking person on the hierarchy would be identified by the SNOD/TDC and asked to consider authorising donation. The same requirements apply when authorisation is being considered by a person entitled to authorise in these circumstances, as when authorisation is being considered by a natural person with PRRs. These requirements include the duty to enquire as to the child's views, the principle that authorisation could only be given where donation would not be against the child's wishes, and that it is not solely the knowledge of the person providing authorisation which is relevant in regard to the potential donor's views but also that of others.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Functions of local authority with parental rights and responsibilities

98. The 2006 Act does not currently permit local authorities who hold PRRs for a child to authorise donation upon death. This was considered during the 2006 Bill, but did not proceed due to concerns³¹ about the appropriateness of local authorities in Scotland having this power, albeit that this is in place in England and Wales. Given the 2006 Act has now been in place for over 10 years, it was considered appropriate to review this.

99. In order to explore this issue further the consultation sought views on local authorities being able to authorise donation for a child for whom it holds PRRs if no parent is available. The largest proportion of both organisational and individual respondents thought that local authorities should be able to authorise donations in these circumstances. However, a relatively large minority of both groups (25% and 29% respectively) thought that local authorities should not be able to authorise donations.

100. A focus group and small survey were also held with care-experienced young people to hear their views on the proposal. Those in the focus group had mixed views on who was most appropriate to make a decision on donation and the discussion reflected the differing individual circumstances and need for flexibility in any approach. Those responding to the survey were supportive of allowing a local authority to authorise donation. They were also asked if views should be sought from others to inform the donation decision and had mixed views on this point.

101. Following this consultation and taking into account the views of care-experienced young people, the Bill will permit local authorities who hold PRRs to authorise donation for a child in its care by removing the current exclusion. The provisions of the Bill would in future allow donation to be authorised where appropriate. The change proposed in the Bill would be with the intention to provide the same opportunity for looked after children as that which is afforded to non-looked after children to become a donor. This would also be in line with UNCRC. The current lack of parity is particularly apparent for children under 12 who are not permitted to authorise their own donation so, if the local authority holds PRRs in the

³¹ <http://archive.scottish.parliament.uk/business/committees/health/reports-05/her05-19-05.htm#RGROP>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 event that the child could become a donor, the donation cannot be authorised even if it is the child's stated wish.

102. In practice, the local authority would only be asked to make a donation decision where there is nobody else with PRRs. Provision will also require local authorities to consult relevant parties who have a relationship with the child, including the child's parents (wherever possible), and to have regard to the views of the child, where they are known.

103. The local authority would already be involved in the on-going care and support to ensure the wellbeing of the child, and those other parties involved with the child would likely also be present. By holding PRRs the local authority is required to take decisions on behalf of a child for many aspects of life. However these decisions are not taken in isolation but in discussion with family members and those who have day to day care of the child. In the event that a child for whom the local authority holds PRRs is likely to die, the local authority would be involved in the end of life pathway for the child. Therefore in circumstances where donation could be considered the local authority would be required to take into account the views of the child, if these had been known and the views of the parents and any other relevant parties, for example those with day to day care of the child. It would be expected that these discussions would take place supported by and guided through the process by the SNOD at the time the end of life pathway was being discussed; with all parties involved. Authorisation by the local authority for donation would either be given or withheld on the basis of those discussions.

104. The number of deceased donors in Scotland who were children or babies is low, with a total of 34 across Scotland since the introduction of the 2006 Act.³² Given the proportion of those children for whom a local authority will hold PRRs, cases where there is local authority involvement will be very infrequent. Data on the number of potential child donors where the local authority holds PRRs is not collected; however NHSBT estimates that since the 2006 Act came into force there have been fewer than 10 such potential donors in Scotland. These cases may be infrequent, but it is still considered important that the opportunity to donate is extended to as many people as possible.

³² Data provided by NHSBT

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Chapter 4 – Authorisations: general

Power to make further provision about express decisions

105. In order to take account of any future developments with the ODR, or more broadly about methods to provide authorisations or opt-out declarations, the Bill provides that Scottish Ministers may make regulations about the manner in which and to whom such authorisations or opt-out declarations may be made.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Withdrawal by person who is blind or unable to write

106. The 2006 Act makes provision in relation to authorisations made by a person who is blind or unable to write, setting out the requirements that must be fulfilled. In order to take account of the situation where a nearest relative or person with PRRs is providing authorisation on behalf of a potential donor, the Bill makes similar provision in relation to these individuals and importantly continues to reflect the needs of those persons as the system changes.

Removal and use of a body part for quality assurance purposes

107. There is a need to use donated tissue as part of quality assurance processes, to ensure that equipment used in processes relating to donation and transplantation of tissue is working effectively. Such processes are required as part of directions made by, or licensing requirements imposed by, the Human Tissue Authority in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007, which implement various European Directives relating to the quality and safety of tissues and cells for human application, including transplantation. Currently tissue used for quality control purposes is authorised under the “audit” purpose in section 3(1). However in order to make clearer the use of tissue for these purposes, the Bill provides that “quality assurance” is included as a purpose for which body parts may be removed and used in accordance with the Act.

Removal of part of body of deceased person: further requirements

108. Under the current system, before organs or tissue can be removed for transplantation or other purposes the person who proposes to carry out or authorise the removal must ensure that the correct authorisation from either the potential donor or nearest relative is in place. The Bill will require the person carrying out the removal of organs and tissue to be satisfied before the removal take place that the appropriate records relating to the specific donation are in place. These records include that the correct authorisation by the person or nearest relative is in place, that the authorisation is for the removal and use of the part for the purpose in question; that due regard has been taken to ensure that in the case of deemed authorisation donation is not for a person in an excepted category; unless the nearest relative has authorised donation within the provisions of the Act.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Chapter 5 – Pre-death procedures relating to transplantation

109. In line with the overall aim of the Bill, which seeks to increase the number of organ and tissue donors and transplants in Scotland, it is also important to ensure that the processes which support donation and transplantation work well and are underpinned by a clear legal framework. This includes ensuring there are clear processes for authorisation for medical procedures which may be carried to help facilitate successful transplantation, and requirements which must be satisfied before these procedures can be carried out.

110. The Bill therefore sets out how these procedures may be authorised. This is primarily based on authorisation for donation, but will also require Scottish Ministers to ensure that information will be publicly available so that people will know what will be involved in the donation process and how these procedures are authorised.

Background

111. Currently, almost 40% of deceased donation in Scotland happens after a person has died following circulatory death (“DCD”). This is where the donor has been pronounced dead following cessation of the heart and respiratory activity. Donation after diagnosis of death by neurological criteria (“DNC”), where the donor has been pronounced dead using neurological criteria accounts for the rest of deceased donation. In the past most donation proceeded with DNC donors however, there has been a significant increase in donors who have donated following circulatory death in recent years. In 2017/18 there were 41 such donors from a total of 102 deceased donors overall.³³ The increase in this type of donation is as a result of developments in clinical practice and processes and is now a very important element of organ donation in Scotland.

112. In practice, to enable safe and successful transplantation, organs have to be removed immediately after the death of a DCD donor, and quickly transported to the transplanting hospital. This means there are significant time constraints and some of the vital tests which are necessary to ensure that the organs are likely to be successfully transplanted, and are a good match for the transplant recipient, need to be carried out shortly before death. These can include blood and urine tests, and may include x-rays or tests on the heart such as an electrocardiogram or echocardiogram.

³³ <https://nhsbtdbe.blob.core.windows.net/umbraco-assets/1068/scotland.pdf>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

All of these tests, or procedures, might be considered to be routine, as blood and urine tests would normally be carried out on a patient as part of their routine care. For example, all patients in intensive care will have had a urinary catheter inserted, meaning that urine samples taken for the purposes of organ donation can be taken in a non-invasive way. Similarly, blood samples taken for the purposes of organ donation are likely to be taken from an existing line.

113. These sorts of procedures would only be carried out where the person has previously made clear a wish to donate, or where their family has authorised donation. In all cases the person's family is consulted and steps are taken to ensure the family is aware and comfortable with the tests being carried out.

114. There are also other tests, and procedures, which would not so commonly be part of the routine care of a patient who may go on to become a DCD donor, but which could, if they were carried out, improve the potential for transplantation of donated organs, and might include procedures such as bronchoscopies,³⁴ which may be helpful in ascertaining the suitability of lungs for transplantation, or the administration of certain medications to improve the flow of blood to organs.

Developments

115. DCD donation has been carried out in Scotland and the rest of the UK since 2003. It began to expand significantly after Guidance was issued by the former Chief Medical Officer in 2010 ("CMO Guidance")³⁵ which provided reassurance around the carrying out of some of these tests – including blood tests on a potential donor where it was clear that the person, or their family, were happy for that person to be a donor. Similar Guidance was issued by the Department of Health for England and Wales in 2009,³⁶ but this reflected the different legal regimes in those countries for

³⁴ A bronchoscopy is used to enable a small sample of cells from inside the lungs to be removed by passing a thin tube through the mouth or nose, down the throat and into the airways of the lungs.

<https://www.nhs.uk/conditions/lung-cancer/diagnosis/#bronchoscopy-and-biopsy>

³⁵ [http://www.sehd.scot.nhs.uk/cmo/CMO\(2010\)11.pdf](http://www.sehd.scot.nhs.uk/cmo/CMO(2010)11.pdf)

³⁶ https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/138313/dh_109864.pdf

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 people who are not capable of consenting to this type of medical procedure.

116. However, even since 2010 there have been further developments in medical practice which mean that DCD donation has increased, and is likely to continue to do so. There is also the potential that procedures, including the use of certain medication, could further improve the likelihood of successful transplantation.

117. The introduction of the opt-out system also means that the basis upon which a person can authorise donation is changing, so it is also relevant to consider how authorisation for procedures can be given where authorisation for donation has not been expressly given by a potential donor.

Legal framework

118. The current legal framework in Scotland which supports authorisation for donation, set out in the 2006 Act, and the Adults With Incapacity (Scotland) Act 2000 (“AWI Act”) (which provides a framework for consent to medical treatment where people are incapable of expressing their own decisions), does not specifically envisage circumstances where a person is on a pathway to donate their organs for transplantation and is not in a position to consent to the procedures which will facilitate this.

119. It is recognised in the CMO Guidance that the basis for consent to the tests and procedures for the purposes of transplantation specifically, should be considered further. In addition, the 2013-2020 Plan, in recognising the growing importance of DCD donation, also noted that while the CMO Guidance provided initial helpful clarification, it did not provide a general solution and recommended that changes should be made after consultation.

Authorisation

120. The Bill therefore sets out a framework for authorisation for pre-death procedures which may be carried out for the purposes of transplantation, including that authorisation for some procedures can be deemed in certain circumstances. This takes account of the introduction of the opt-out system, and the addition of deemed authorisation for donation for transplantation.

121. The responses to the consultation suggest that many people may be happy to donate without giving an express authorisation, and that they

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 apply the same principle to routine procedures which are necessary to ensure successful transplantation – particularly as without certain tests donation is unlikely to be able to proceed. The Bill also makes it clear that the framework only applies to those procedures which are for the primary purpose of transplantation, so will not apply to any of the on-going treatment a person may receive in intensive care, even if that treatment may also, as a secondary impact, contribute to successful donation.

122. The provisions reflect the different ways in which authorisation for donation can, and will be able to, be made. The Bill not only provides that authorisation for procedures may be deemed where authorisation for donation for transplantation is deemed, it will also make clear that authorisation for procedures can also be deemed where express authorisation for donation has been given. It will also allow a person to expressly authorise the procedures. A “nearest relative” or person with PRRs (or other person in a common calamity scenario) who is entitled to authorise donation in respect of a child will also be able to authorise procedures, but only if the person is satisfied that it would not be contrary to the individual’s previous wishes.

123. Before the opt-out system is in place, authorisation will be able to be given expressly by the person themselves, by the nearest relative or person with PRRs (in the case of a child), who can authorise donation. This allows a framework for authorisation for the procedures to be in place quickly, but will also allow time for public information to be developed and provided alongside the public information for opt out enabling authorisation for procedures to be inferred at the same time opt out is introduced.

124. This issue does not directly affect tissue only donation as, for example, eyes can be retrieved from a donor up to 24 hours after the patient’s death, while other forms of tissue can be donated up to 48 hours after death. This means the necessary tests can be carried out following the death of the patient. However, for completeness the proposed framework will cover both organ and tissue donation for transplantation.

Types of procedure

Type A procedures

125. The Bill will enable routine types of procedure to be prescribed by Scottish Ministers in secondary legislation, after consultation (“Type A procedures”). This will allow the list to fully reflect current practice. It will also be able to be amended, again after consultation, as experience in recent years with developments in practice demonstrates the need for

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 flexibility and an ability to respond to medical progress. Setting out these procedures ensures that there is transparency about what may be involved as part of the donation process, and therefore what a person is authorising. To supplement this, and to ensure that people know about these procedures and that authorisation may be inferred, there will also be duty on Ministers to promote information and awareness about what procedures may be carried out as part of the donation process and how these are authorised.

Type B procedures

126. In addition to what may be considered to be more routine procedures (which will be prescribed as Type A procedures), there are also procedures which could be carried out, including the administration of some forms of medication, but they may not be of a type where people would assume that they are consenting to them by simply authorising donation (“Type B procedures”). The Government recognises that some people may be entirely content for these sorts of procedures to be carried out if it will improve the likelihood of successful transplantation. To enable these kinds of procedure to be carried out, Ministers will also be able to set these out in secondary legislation along with how they may be authorised, and safeguards over and above those which will apply to routine procedures – depending on the nature of the procedure in question. This power will also only be able to be exercised after consultation. This is a further measure which will allow the overall process for donation to keep pace with medical developments but also provide reassurance about how these more novel procedures may be authorised.

Safeguards

127. The Bill also sets out the circumstances in which pre-death procedures may be carried out, and certain requirements which must be met for all pre-death procedures. This ensures that there are sufficient and robust safeguards against premature or unnecessary procedures, and that it is clear both for the public and medical professionals when the procedures may be carried out

128. In all cases where pre-death procedures may be undertaken, a decision will have been taken that the person is likely to die imminently and that, if the person is receiving life sustaining treatment, this will be withdrawn. This is a familiar part of the end of life pathway, and it is only after this point that discussions about donation are carried out. At all times, individuals will be treated as a patient and will remain under the care of health professionals who work within an ethical framework and where

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

patient care is a priority. However, to reflect current practice and also reassure and make clear that these procedures are not undertaken without consideration of the impact on the patient, or their wishes, the Bill provides that they may only be carried out if necessary and are not likely to cause any harm or more than minimal discomfort. They can also not be carried out if it is known that the person would not have consented and, in line with the general approach in the Bill, if they would have been contrary to the person's wishes and feelings, so far as these are ascertainable. The Government is of the view that this reflects the high standard of care that is already given to people who are potential donors and these provisions are not aimed at introducing any new requirements which medical professionals do not already meet in practice.

Children

129. The Bill will continue to allow a person with PRRs to authorise medical procedures for a child, including pre-death procedures. However, the approach to authorisation for donation for transplantation more generally, which allows children 12 years of age or over to make formal decisions about donation, is also taken into account. Therefore the Bill provides that where children 12 years of age or over but under the age of 16 authorise donation, authorisation of pre-death procedures will also be able to be deemed.

130. The safeguards will apply, including protections against premature or unnecessary procedures. The Bill also provides the procedure is not authorised if the child would not have wanted it to be carried out, and it similarly cannot be given by a person with PRRs if the child would not have wanted it to be carried out. There are corresponding duties to inquire in relation to the child's view of pre-death procedures as there are in relation to donation, so it is clear that those close to the child can provide information about the child's views

Consultation

131. This matter was considered in the public consultation which included the proposals for a soft opt-out system, and people were asked about tests and other procedures which are carried out now and could be carried out in future. A significant majority of respondents (84%-93%) thought that the common tests (tests on blood, urine, chest secretions, and heart, as well as x-rays) should be able to be carried out on potential donors. A similarly high number of respondents also thought that medication could be given to patients in certain circumstances to improve the chance of successful donation and transplantation. These tests and procedures were therefore

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 broadly welcomed – with some respondents noting in particular that if not carried out donation might not proceed and transplantation might not be successful. The Bill therefore seeks to support this broadly-held public view that the NHS should support donation where possible. The issue of pre-death procedures has been further discussed through the SDTG sub-group, and separately with representatives of the Scottish Intensive Care Society. The approach set out in the Bill has been developed as a result of these discussions.

Chapter 6 - Duty to inquire

132. Under the current opt-in system SNODs and TDCs have a primary role in making the approach to the family of a potential donor to provide information about organ and tissue donation. In making that approach the ODR will be checked to ascertain if the person had recorded a decision to donate or not to donate, the family will also be asked if there was any known change to the decisions made by the potential donor. In cases where a person had not recorded a decision on the ODR the nearest relative will also be asked if the views of the potential donor with regard to organ and or tissue donation are known.

133. Involvement of families is crucial to the on-going success of the organ donation system and this will continue under the opt-out system. However, to ensure the interests of the potential donor are safeguarded at all times, and to ensure there is a clear and effective mechanism in place for relatives and others who are entitled to provide information to exercise their rights, the Bill will place a duty on health workers to make inquiries. This duty reflects the existing good practice described above and will provide for inquiries to be made as to:

- whether a potential donor has given an authorisation for donation and if so the extent of the authorisation;
- whether the potential donor has made an opt-out declaration and if so the extent of the declaration;
- in the case of an adult, whether the nearest relative has any information about the potential donor's most recent views in relation to donation. Inquiries must also be made of anybody who wishes to provide such information and anybody else the SNOD considers appropriate;
- in the case of a child, whether a person with PRRs has any information about the potential donor's most recent views in relation to about donation. Inquiries must also be made of

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

anybody who wishes to provide such information and anybody else the SNOD considers appropriate;

- in the case of a child where there is nobody with PRRs or those people with PRRs are incapacitated, whether the highest ranking person has any information about the potential donor's most recent views about donation. Inquiries must also be made of anybody who wishes to provide such information and anybody else the SNOD considers appropriate;
- in the case of a child where a local authority holds PRRs, whether it, in consultation with those it is required to consult has any information about the potential donor's most recent views about donation. Inquiries must also be made of anybody who wishes to provide such information and anybody else the SNOD considers appropriate;
- the potential donor's most recent views in relation to pre-death procedures;
- whether the potential donor falls within an excepted category (where authorisation would otherwise be deemed).

Alternative Approaches

134. No single measure will radically increase donation rates, rather action is required on every single part of the donation pathway in order to drive continuous improvement, and there is already a package of measures in place which are delivering improvements. We know that a higher proportion of people in Scotland are in favour of becoming a donor, than the proportion who have taken the step of joining the ODR to give their authorisation. Authorisation is a key factor which affects whether donation, and ultimately transplantation can proceed and therefore it is important that as much as possible is done to potentially increase the proportion of cases where organ and/or tissue donation is authorised, including introducing a soft opt-out system.

Retaining the current opt-in system

135. Retaining the current opt-in system of organ and tissue donation is no longer an option that has significant public support. Attitudes towards organ donation have shifted over recent years. A survey undertaken in 2016 found that 58%³⁷ agreed that “everyone should be presumed to be

³⁷ Unpublished: TNS Organ Donation 2016 Campaign Evaluation (September 2016) – Q1/5: How much do you agree or disagree that:

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 willing to be a donor unless they register a wish otherwise”. In addition, in 2016 while the Scottish Parliament was unable to support the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill 2016 there was still broad support for the principles of a soft opt-out system. As a result the Scottish Parliament recommended that the Scottish Government should consult on further methods to increase organ donation, and on a workable opt-out system for authorisation of donation. This is why the Scottish Government accepted the previous Committee’s recommendation to consult in detail. Of the 824 individuals and organisations who responded to the consultation 82% supported a move to a soft opt-out system.

136. The intention to introduce legislation for the soft opt-out system of organ and tissue donation is therefore set against this background of public support with the aim of changing public attitudes towards donation over the longer term and within the context of the measures that are already in place or underway to increase organ donation.

137. There would likely be significant concerns that the introduction of a rigid or ‘hard’ opt-out system might lead to people becoming donors even if they would not have wanted to, for example if they had not got round to opting out or were not able to understand that they needed to opt out. Ultimately this could damage trust in donation and harm donation and transplantation. Therefore, a ‘soft’ form of opt-out system, which provides additional safeguards to ensure donation does not proceed in cases where the family knew that their loved one did not want to be a donor is preferable.

138. Alternatives to moving to an opt-out system, such as a reciprocity system (where in cases of equal medical need, a person who had joined the ODR would get priority over someone who had not), have been considered carefully, but are not considered practical under the current UK-wide allocation system and given significant ethical concerns. The option of a “mandated choice” system – where people would be legally required to make clear whether or not they wished to be a donor – was also considered, but discounted as it raised significant issues about how people could be forced to make such a decision, as well as significant practical issues in establishing and enforcing a system to collect everyone’s views.

Everyone should be presumed to be willing to be an organ donor unless they register a wish otherwise

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

139. As well as moving to a soft opt-out system the consultation also sought views on issuing CMO guidance to encourage clinicians to refer patients who are expected to die in circumstances which would potentially enable them to be an organ or tissue donor to refer them to a SNOD or TDC. This was supported in the consultation responses and will be taken forward in due course.

Consultation

140. The Scottish Government carried out a formal consultation over 14 weeks from 7 December 2016 to 14 March 2017. The consultation sought views on increasing numbers of successful donations in Scotland. The consultation looked at two ways to potentially increase numbers of deceased organ and tissue donors – by seeking to increase numbers of referrals and by seeking to increase the number of times when donation is “authorised” to proceed. In particular, the consultation looked at the introduction of an opt-out system of donation if this can be developed in a way which will do no harm to trust in the NHS or to the safety of transplantation. The consultation included proposals for the operation of a soft opt-out system and sought views on this.

141. The consultation responses were independently analysed and the analysis was published in June 2017. There were a total of 824 responses to the consultation, including a petition with 18,500 signatures in support of opt out (which was counted as a single response). A significant number of respondents were individuals (94%).

Respondent type	Number	%
Individual	778	94%
Organisation	45	5%
Petition	1	0%
Total	824	100%*

* Percentages do not total 100% due to rounding.

Organisation type	Number	%
NHS and / or local authority organisations	14	31%
Professional groups and regulatory bodies	12	27%
Charity, voluntary sector or patients’ rights groups	11	24%
Faith groups	8	18%
Total	45	100%

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

142. The results show that most individuals (84%) supported the principle of a soft opt-out system, while organisations were divided in their views (53% in favour vs 47% opposed). Among organisations, voluntary sector groups were largely in support of the principle of a soft opt-out system while faith groups were mainly opposed.

Respondent type	Supports principle	Does not support principle	Total
NHS and / or local authority	4	5	9
Charity, voluntary sector or patients' rights groups	8	1	9
Professional groups and regulatory bodies	3	3	6
Faith groups	1	5	6
Organisation total	16	14	30
Organisation percentage	53%	47%	100%
Individual respondents	644	127	771
Individual percentage	84%	16%	100%
Total (organisations and individuals)	660	141	801
Total percentage	82%	18%	100%

143. In general, respondents agreed that, if an opt-out system were introduced, the proposed checks set out in the consultation paper were sufficient to decide whether the donation should proceed. Two-thirds (67%) of organisational respondents and 86% of individual respondents indicated agreement. However, four out of the six faith groups thought the checks outlined were not sufficient. Those who did not think the checks were sufficient were generally opposed to the principle of an opt-out system and concerned about the practice of deemed authorisation. Occasionally, this group of respondents suggested additional checks that could be included and many of these focused on a situation in which an individual's family or friends were unable to be contacted or identified.

144. The consultation also considered the implications of an opt-out model for some groups, such as those with significant mental impairments and also those for whom English is not their first language. It sought views on any equalities impacts of the proposals which has informed the Equality Impact Assessment and the Children's Rights and Wellbeing Impact Assessment and this has helped inform the development of the Bill.

145. In summary the responses show:

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

- Majority support overall (82%) for moving to a soft opt-out system, with higher support from individuals (84%) than organisations (53%).
- Majority support overall (85%) for the checks to ascertain if someone is eligible for deemed authorisation, with higher support from individuals (86%) than organisations (67%).
- Majority support from individuals and overall (79%) and organisations (73%) for the categories of people for whom explicit rather than deemed authorisation should apply (i.e. those with incapacity; children; those who have been resident in Scotland less than 12 months).
- Majority support from individuals (83%) and overall (81%) for donation proceeding when the family is opposed in cases where the patient is on the ODR. The majority of organisations (64%) were opposed.
- Majority support from individuals (57%) and overall (55%) for a deemed authorisation donation proceeding when it causes distress to the family. The majority of organisations (72%) were opposed.
- Majority support overall (84-93% depending on test type) for ante mortem tests, with similar levels of support from organisations and individuals.
- Majority support overall (92%) for administering treatment to the potential donor to aid successful transplantation with slightly higher support from individuals (92%) than organisations (89%).
- Majority support overall (88%) for issuing CMO guidance to encourage referrals, with slightly higher support from individuals (88%) than organisations (81%).
- Majority of organisations (55%) and around a fifth of individuals (18%) and overall (19%) said they could identify impacts or implications for particular equalities groups.

Focus groups

146. In addition to the formal consultation, further in-depth qualitative research³⁸ was carried out in conjunction with the Scottish Health Council

38

http://www.scottishhealthcouncil.org/publications/gathering_public_views/organ_donation.aspx

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 with specific groups of people who would be impacted by the legislation. Focus groups and a small survey were carried out with young people (aged 12 to 19), people with learning difficulties and care experienced young people in order to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed. Key findings from these groups were as follows.

147. Young people were supportive of a soft opt-out system of donation; they expressed a range of views about what the appropriate age would be, both for self-authorisation and deemed authorisation and overall both groups thought that 15-16 would be an appropriate age for deemed authorisation to start from. The young people thought that they should receive a personal letter to tell them about soft opt out prior to their 16th birthday, so this is expected to form part of the awareness raising campaign.

148. People with learning difficulties felt that wherever possible they should be given the support to understand the organ and tissue donation system and be enabled to make their own decisions and those with powers of attorney or guardians should not be able to make the donation decision where there is capacity for someone to understand donation; accessible information in different formats co-produced by people with learning difficulties should be provided to explain donation.

149. Care-experienced young people expressed some concern over the principle of an opt-out system and about people being informed enough for it to work. Those in the focus group had mixed views on who was most appropriate to make a decision on donation and the discussion reflected the differing individual circumstances and need for flexibility in any approach. Those responding to the survey were supportive of allowing a local authority to authorise donation. They were also asked if views should be sought from others to inform the donation decision and had mixed views on this point.

Faith groups

150. All the responses from faith groups were supportive of people being able to make a choice about whether to donate. Most expressed a wish to retain the current opt-in system – there were a mixture of views from some respondents but only one of the eight responses was supportive overall of the introduction of a soft opt-out system of donation.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

151. As part of the consultation process Scottish Government officials have met some of the faith groups which responded to the consultation in order to understand better the concerns and to explain the proposals in more detail. This has helped to provide a degree of reassurance about the proposals and how they would operate in practice, particularly in relation to the safeguards although there remains opposition in principle to moving to an opt-out system.

152. Faith Groups are keen to continue to play a role in supporting donation and want to ensure that public awareness and information is afforded the priority and on-going resource necessary required to ensure that the population and groups within the population have accessible information to inform their decision. The Faith Groups that officials met have offered to provide factual information about the opt-out system to their congregations in order to help explain the system and what the choices will be.

153. The impact on the faith/belief equality group has been considered as part of the Equalities Impact Assessment.

Effects on Equal Opportunities, Human Rights, Island Communities, Local Government, Sustainable Development Etc.

Equal opportunities

154. Respondents to the Consultation who commented on the Equality impacts and implications of the system showed support for the proposed safeguards for those with mental impairments, children and those who would be resident in the country for less than 12 months who would potentially adversely affected by an opt-out system, if such safeguards were not in place. Respondents also commented generally from a third party perspective on the impact on those with religious belief. A few respondents including faith organisations had a direct interest in this issue. Comments fell into three categories; that some people may be opposed to organ donation for religious or cultural reasons, that the handling and burial of the deceased may need to be considered and that the issue of explicit consent was crucial for some who believed in the sanctity of the human body. Other responses highlighted the potential impact on hard to reach groups such as those with limited English or those hard to reach and socially disadvantaged.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

155. Respondents also identified positive impacts and implications for black and ethnic minority groups where organ donation rates were particularly low for a range of reasons e.g. lower levels of awareness, religious and cultural beliefs and practices or prevalence of particular health conditions which meant they were over represented on the transplantation list. Positive impacts were also identified for those with long term health conditions or disabilities if there was an increase in the availability of organs and tissue.

156. Some respondents did not think that there would be any equality impacts or implications as they thought the system in terms of risks and benefits would apply equally to all groups as the right to opt out applied to everyone, they thought the safeguards and proposals, for the opt-out system adequately dealt with potential equality issues; or they thought being a member of an equality group was not relevant to the issue of organ donation.

157. An Equalities Impact Assessment (EQIA) has been carried out and will be published on the Scottish Government website at <http://www.gov.scot/Publications/Recent>

158. The EQIA concludes that none of the proposals are discriminatory. There are safeguards included in the Bill to address equalities issues, including not applying deemed authorisation to certain groups of people on the basis that they might not reasonably be expected to have sufficient awareness, knowledge or understanding about the operation of the opt-out system to understand the implications of not opting out. This is balanced with a continuing ability for people (aged 12 or over) in these groups to make a donation decision if they wish. There is also a safeguard which will mean that, where an individual is subject to deemed authorisation, families can advise of a known objection the potential donor held, meaning donation would not proceed. There is also a safeguard which will mean that if an individual would have views about whether or not donation should proceed in the particular circumstances of death, for example in relation to religious belief, donation may only proceed where it is compatible with those views.

159. Public information and raising awareness will be important in explaining how the system will take account of the needs of equalities groups and also in ensuring that the communication needs of different equalities groups are met. Further work will be undertaken with stakeholder groups to identify the format and content of information required to ensure as much coverage as possible.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Human rights

160. The introduction of an opt-out system, and a statutory framework for pre-death procedures, would have human rights implications as it will engage with right to respect for private and family life under Article 8 of the European Convention on Human Rights (“ECHR”), and, potentially, the right to expression of religious beliefs under Article 9 ECHR. The statutory framework provided for in the Bill constitutes a robust and proportionate approach to safeguarding and promoting human rights, while pursuing the legitimate aim of establishing an effective opt-out system for organ and tissue donation in Scotland. The establishment of such a system, and the potential benefits for those in need of organ and tissue transplantation, which may be realised through the implementation of such a system are directed to the protection of the rights and freedoms of others, and the protection of health. In particular, the system promotes the right to life, protected by Article 2 of the ECHR, as well as the right to healthcare enshrined in Article 35 of the Charter of Fundamental Rights of the European Union and in Article 12 of the International Covenant on Economic, Social and Cultural Rights of 1966. Insofar as steps taken under the provisions in the Bill may affect the Article 8 and/or Article 9 rights of potential donors and their relatives, those steps, if undertaken in accordance with the provisions in the Bill, would be justified by, and proportionate to, the legitimate aims pursued by the scheme.

161. The removal of parts of a person’s body after death, in particular, may engage Article 8 ECHR rights. In setting out clearly the circumstances in which deemed authorisation will apply, along with the safeguards aimed at ensuring donation will not proceed if that would be contrary to the wishes of the potential donor the Scottish Government’s view is that the rights under Article 8 are protected and promoted. The Bill makes it clear that reasonable steps must be taken to inquire about the person’s views about donation before it may proceed. It also enables relevant people (including family members) to provide evidence as to the willingness or otherwise of a person to donate and when this can happen. The Bill also imposes duties on Scottish Ministers to raise awareness about how transplantation may be authorised, particularly deemed authorisation.

162. Rights under Article 8 are further protected, and promoted, in the Bill by setting out a framework for authorisation of pre-death procedures. This makes it clear how and when these procedures may be authorised and sets out requirements which must be in place before they may be carried out, including that they are not likely to cause harm or more than minimal discomfort. There are also duties on Ministers to promote information and

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163. By providing a system where primacy is given to the wishes of the donor, including their religious beliefs around circumstances of death, so that this can be taken into account in determining the most recent view of the potential donor and whether donation should proceed, this also enhances the rights to express religious beliefs under Article 9 of ECHR.

164. The Bill also recognises the rights of adults who lack capacity to understand deemed authorisation. They are not subject to deemed authorisation, and a separate regime, with its own safeguards provides an appropriate and proportionate legal basis for authorisation of donation by such adults. The provisions comply with and take into account of the principles and requirements of the United Nations Convention on the Rights of Persons with Disabilities of 2006, the Mental Health (Care and Treatment) (Scotland) Act 2003 and the Adults with Incapacity (Scotland) Act 2000 and require that before a nearest relative can authorise donation that account is taken of the potential donors unwillingness to donate and past wishes and feelings about donation, if these are known.

165. The Bill also contains a separate regime in respect of children. The requirements and principles of the United Nations Convention on the Rights of the Child of 1989 are reflected in the Bill by requiring that before a person entitled to authorise donation on behalf of a child can provide such authorisation, account must be taken of the potential donor's unwillingness to donate. If authorisation is being considered by a local authority which holds PRRs, account must be taken of the views of the child, where known, and the views of the child's parent and other relevant parties.

Island communities

165. The Bill will apply to all communities across Scotland, including island communities. Whilst it is not possible to donate organs or tissue from hospitals on the islands, in some cases patients from the islands may be transferred to mainland hospitals for example if treatment in an intensive care unit is required. In cases where the patient unfortunately does not survive and dies in circumstances where donation could proceed, it would be considered for that patient in the same way as for any other patient.

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018

Local government

166. The move to an opt-out system of organ and tissue donation will have no impact on local authorities. Impacts on local authorities will be limited to the few cases which may arise if a local authority is called on to consider authorisation for a child for whom it holds PRRs, in consultation with relevant parties including the child's family and in accord with the view of the child where it is known. In practice, the local authority would only be asked to make a donation decision where there is nobody else with PRRs

167. Data is not collected on the number of children for whom a local authority solely holds PRRs. The nearest proxy that can be used to estimate the number of children captured by this provision is the number of children in the category "looked after away from home", as detailed in the Children's Social Work Statistics. In 2016-17 there were 11,131 such children,³⁹ however the number of children for whom the local authority will solely hold PRRs will be much lower as PRRs are often shared.

168. However, given the low overall numbers of paediatric deceased organ or tissue donors in Scotland, and the small proportion of those for whom a local authority will solely hold PRRs, cases will arise very infrequently and therefore the impact on local authorities is expected to be minimal. In these cases the local authority would be actively involved in the end of life pathway for the child and facilitating a donation decision would be part of that pathway. The Bill confers no obligation on a local authority to keep a record of the donation views of a child for whom it holds PRRs.

169. The formal consultation was sent to every local authority/Health and Social Care Partnership and four responses were received. Of these, one agreed that local authorities should be able to authorise donations and three responded that they "didn't know". Scottish Government officials have met COSLA to discuss the proposals and COSLA has confirmed it is content with the proposed change to enable local authorities to authorisation donation.

Sustainable development

170. A pre-screening report on the environmental impact of the Bill has been completed. This confirmed that the Bill will have minimal or no impact

³⁹ <https://beta.gov.scot/publications/childrens-social-work-statistics-2016-17/pages/1/>

This document relates to the Human Tissue (Authorisation) (Scotland) Bill (SP Bill 32) as introduced in the Scottish Parliament on 8 June 2018 on the environment and, as such, is exempt for the purposes of section 7 of the Environmental Assessment (Scotland) Act 2005.

171. There are positive social and economic benefits in to increase donation. Organ and tissue donation is seen as a gift by families of donors knowing that the loss of their family member has given life to others. Recipients and their families are grateful for the gift and to the selfless action of the donor. This relieves the stress, anxiety and the financial burden which long term incapacity has on the patient and the wider family.

172. Over the longer term wider society will benefit from a change to the culture towards supporting organ donation with the aspiration that transplant waiting lists will decrease and the demand for transplants will be met. Patients who receive transplants on average benefit from longer life and experience an improved quality of life relative to those patients whose conditions are managed with medical treatment. In addition transplant recipients are able or may be much more able to return to employment and contribute economically for an increased duration after transplant. Detailed information on transplant recipients' employment is limited. However one study has reported that approximately 80% of organ transplant recipients in developed Western Europe are able to return to full-time employment after a successful operation.⁴⁰

173. The wider impacts of an increase in transplantation will ensure that research and development can continue which in turn will identify new and improved techniques to improve the viability of organs and tissue for transplantation, resulting in better outcomes.

⁴⁰ Slapak, M. (2005). Sport and transplantation. *Annals of Transplantation*. 10(1), 62. As cited in "Commissioning Transplantation to 2020", Subgroup of the National Specialist Services Committee, Final Report, National Services Division

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Human Tissue (Authorisation) (Scotland) Bill

Policy Memorandum

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