

# **Organ and Tissue Donation and Transplantation**

**A consultation on increasing  
numbers of successful donations**

**December 2016**



**Scottish Government**  
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## **Foreword**

Organ and tissue donation and transplantation is an incredible development in modern healthcare. It is genuinely life-changing and one of the greatest gifts a person can give. Organ and tissue donation saves and improves lives. It allows people to lead full and happy lives, return to work, and contribute to society.

While the NHS in Scotland, with the amazing help of donors and their families, has already achieved a huge amount in increasing numbers of organ and tissue donors, we need to continue doing more in order to help reduce the numbers of people in Scotland waiting for transplants or dying waiting.

Much work is already in progress to help with this – we are already delivering meaningful improvements as a result of our *Donation and Transplantation Plan for Scotland, 2013-2020*. However, this consultation looks at two ways we could 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 Scottish Government has agreed to consider 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. We will also be monitoring the progress in Wales carefully to learn lessons from their experience of introducing a new opt out system.

Our presumption is in favour of taking an opt out system forward as part of a long-term process of culture change to encourage people to support donation. However, I am keen to hear your views on these proposals and others in this consultation so I would encourage you to respond to the questions we raise. Whatever the outcome of this consultation, rest assured the Scottish Government will continue to work both within Scotland and with our partners across the UK to increase organ and tissue donation and to allow more people to benefit from life-saving or life-changing transplants.

**Aileen Campbell**  
**Minister for Public Health and Sport**

## Introduction

Organ and tissue transplantation can save and significantly improve lives, but at present there are insufficient donors to meet the number of organs needed by people on the transplant waiting list, as well as the need for tissue transplants. This consultation seeks views on ways in which we can increase the number of organ and tissue donors and transplants in Scotland. We have already made good progress in increasing organ donation and transplantation in Scotland over recent years, with an 83% increase in the number of people who donated organs after their death in Scotland between 2007-08 and 2015-16. In 2015-16 there were **183 organ donors in Scotland** (99 who had died and 84 living donors) and 415 people from Scotland received transplants. However, despite these successes, there were still 542 people on the active transplant waiting list in Scotland, waiting for an organ.

### Background – What is organ and tissue donation?

Over the past few decades, surgical advances have allowed hospitals to remove organs from one person – a donor – and then transplant each of the organs into a person who needs a new organ. Donors who donate their organs after they die can **potentially save the lives of up to nine people<sup>1</sup>**.

Only a small proportion of people (less than 1%<sup>2</sup>) die in circumstances where it is possible for them to be an organ donor. At the moment, it is only possible to donate if you die in a hospital – normally in a Critical Care area (for example an intensive care unit) - and, even then, there may be a number of reasons why organ donation is not possible, such as medical reasons (if some or all of the organs are not functioning well) or for legal reasons (where there is an investigation into the cause of death and the Procurator Fiscal may not be able to allow some or all organs to be donated).

Therefore, this makes it very important that, where a person has died or has an unsurvivable brain injury, and where they could be a potential donor, they are identified as such and the procedures necessary to enable possible donation are initiated.

In Scotland, donors who have just died (known as deceased donors), can donate:

- Kidneys
- Liver
- Heart

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<sup>1</sup> While most donate fewer organs, it is possible for one patient to potentially save or transform the lives of up to 9 people: 2 kidneys, heart, 2 lungs, pancreas, small bowel and 1 liver, which can in some cases be split in two and transplanted into 2 people (this does not include lives saved or transformed by tissue donation)

<sup>2</sup> *Taking Organ Transplantation to 2020 – A UK Strategy* 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.

- Lungs
- Pancreas (including for islet cells)
- Small bowel (or multi visceral organs where a patient needs a transplant of several organs – this can include for example the stomach or spleen as well as the small bowel)

In addition to organs, donors can also donate **tissue**. This includes: eyes, tendons, heart valves, bone and skin. Such tissue can be used in anything from severe eye disease to reconstructive surgery and skin grafts. Donated tissue can significantly improve the lives of others – and in some cases, such as heart valves, saves lives. Unlike organs, which in most cases need to be transplanted within a few hours of the donor's death, it may be possible to donate tissue up to 48 hours after a person has died. Therefore, even if a person cannot be an organ donor, they may still be able to donate tissue. In this consultation, where we refer to measures to improve organ donation from people who have died, this would normally also include increasing tissue donation.

Over half of all donated organs in Scotland come from people who have died (deceased donors), but it is also possible for living people to donate some organs. Most living organ donors donate one of their two kidneys as it is possible to live healthily with just one kidney. It is also possible for a living donor to donate a part of their liver or occasionally their lung, but this happens less often. Some living people also donate some of their bone, for example if they have a hip replacement operation. The Scottish Government and NHS Scotland are working on a project to encourage an increase in the numbers of living kidney donors, but this consultation paper focuses on ways of increasing donation from deceased donors.

### **How does organ and tissue donation currently work in Scotland?**

While Scotland has its own legislation governing organ and tissue donation and transplantation – currently the Human Tissue (Scotland) Act 2006 - organ donation and the allocation of organs to transplant recipients is managed across the UK by NHS Blood and Transplant (NHSBT). Organs need to be carefully matched to a recipient, taking into account things like the blood group, age, weight and the tissue type of the donor and potential recipient. This is important to give the best possible chance for a transplant to be successful. If an organ is not a good match with the recipient, there is a significant risk that it won't function effectively.

NHSBT is responsible for managing the UK's national transplant waiting list and for matching and allocating organs on a UK-wide basis. While this means that some organs from donors in Scotland may go to people in other parts of the UK (and occasionally elsewhere in Europe), it also means that people in Scotland may receive an organ from elsewhere in the UK or the rest of Europe.

If someone is dying or dies in circumstances where they could be an organ donor,

for example in an intensive care unit or occasionally an emergency medicine department, a Specialist Nurse for Organ Donation (SNOD) will check to see if the patient has authorised donation themselves. People can formally authorise donation by joining the NHS Organ Donor Register, or can make someone close to them aware of their donation wishes. At this point, a sensitive discussion with the patient's family will start to take place with regard to donation.

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 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. SNODs also work hard to support the donor's family during this difficult time and to answer any questions the family has.

The organs are then retrieved by a completely different team of specialist surgeons who are not otherwise involved in the care of the patient. Organs are always removed with the greatest care and respect. They are then stored in fluid and usually kept cool to help preserve them and transported to whichever hospital or hospitals will carry out the transplant(s). As soon as possible, a separate team of surgeons will then transplant each organ into the patient who is going to receive it.

While donated organs can normally be retrieved at most acute hospitals, there are three transplant units in Scotland, which each have specialist facilities dedicated to the transplantation of organs into recipient patients:

- The Royal Infirmary of Edinburgh (liver, kidney, pancreas and islet cell transplants)
- The Queen Elizabeth University Hospital, Glasgow (kidney transplants)
- The Golden Jubilee National Hospital, Clydebank (heart transplants)

Most Scottish patients have their transplant undertaken in one of the three Scottish transplant units. However, a small number of Scottish patients receive their transplant in other parts of the UK. These usually relate to rarer transplants where it is in the best interest of patients to receive transplants in specialist centres. These treatments are fully paid for by NHS Scotland.

Meanwhile, 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.

## Progress made so far

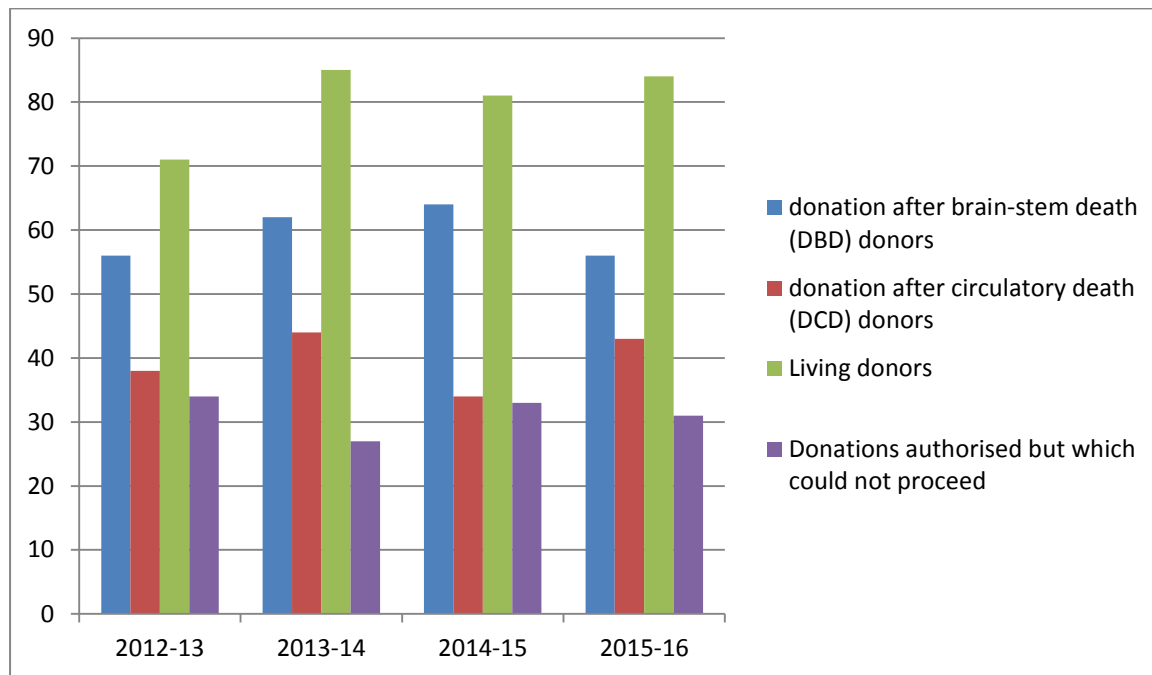
Considerable progress started being made after the publication of the UK Organ Donation Taskforce's report in 2008. In 2007-08 there were only 54 deceased donors in Scotland and 209 transplants from deceased donors. In particular, the development and training of dedicated SNODs to approach families, along with other improvements to the hospital infrastructure available to support donation, started to increase deceased donations. In 2013, the Scottish Government published [A Donation and Transplantation Plan for Scotland 2013-2020](#). This set out 21 recommendations to increase donation and transplantation, building on the earlier Taskforce report.

Significant progress has already been made through implementing these recommendations, such as:

- successful and ongoing awareness-raising campaigns, which have encouraged more people to sign up to the NHS Organ Donor Register (ODR) – the proportion of the Scottish population who have joined the ODR increased from 29% in 2007/08 to 43% by October 2016;
- a project with Kidney Research UK which trains volunteers from black, Asian and minority ethnic (BAME) backgrounds to become peer educators to increase awareness of kidney disease and promote organ donation within BAME communities. This is important because families from BAME communities are much less likely to authorise organ donation, but statistically are more likely to need an organ transplant because of increased incidence of diabetes, heart disease and kidney disease;
- a schools educational resource pack has been provided to all secondary schools in Scotland. It has been recognised internationally as an important resource in increasing awareness about organ and tissue donation among young people;
- a new dedicated regional manager for Scotland is in post. Her role focuses on managing the SNODs in Scotland and taking forward key initiatives to help increase donation (previously the postholder covered both Scotland and the Northern region of England).

However, while **Figure 1** shows that numbers of organ donors has been gradually increasing overall over recent years, there is still more that can be done. Increasing the number of donors further remains a challenge, particularly given that fewer than 1% of people die in circumstances where they can donate.

**Figure 1 – numbers of organ donors and non-proceeding donors in Scotland by financial year<sup>3</sup>**



The Scottish Government, the Scottish Donation and Transplant Group and the dedicated Regional Manager for Scotland are taking forward a number of new initiatives, including:

- a project to raise awareness of and increase kidney donations from living donors in Scotland;
- considering piloting a model of designated requesters in two or more hospitals, which is based on an approach used in Australia where only clinicians and SNODs who have had specialist training approach families for authorisation of donation, to see if this helps increase authorisation rates further (currently any SNOD or clinician can approach a family about authorising organ donation);
- updating the existing agreement between the Scottish Donation and Transplant Group and the Crown Office and Procurator Fiscal Service (COPFS) which seeks to minimise the number of occasions when Procurators Fiscal are unable to allow donation to proceed due to needing a full post mortem examination of the potential donor's body;
- the Scottish Government will be working with clinicians, SNODs and NHSBT to explore opportunities for children or very young babies to donate their organs. This is a very sensitive subject, but we know that parents can draw some comfort from the fact that some good has come out of the tragic death of their baby or child;
- in 2015-16, 19 families refused to authorise donation because they felt the process was going to take too long. NHSBT is therefore working to try to shorten

<sup>3</sup> Source – NHS Blood and Transplant (NHSBT)



donation processes generally and also to see if donation processes can potentially be undertaken in a different order to allow for quicker, limited donations (of only kidneys and possibly also the liver) in cases where families would otherwise refuse authorisation due to concerns about the length of time the process will take. This trial might help increase donations in at least some extra cases in future.

### **Summary of areas considered in the consultation paper**

This consultation is split into two sections. They cover different parts of the organ donation process, but are closely linked: the hospital identifying and referring potential donors and then the donation being authorised by the family. Delivering real increases in the number of donors and transplants will require progress in both of these areas.

The **first chapter** seeks views on alternative ways of potentially increasing the proportion of cases where organ and/or tissue donation is authorised. This looks at the pros and cons of an opt out system allowing authorisation to be deemed in certain circumstances, with safeguards – that is where, for most people, unless they have opted out of organ or tissue donation or their family know they did not want to donate their organs or tissue, donation can be deemed to be authorised. Such a system could potentially help tackle the problem of people ‘not getting around’ to making their wishes known.

Other potential options, 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), were considered carefully, but have not been included in this consultation because they were not considered practical and raised significant ethical concerns. The option of a ‘mandated choice’ system – where everyone would be legally required to make clear whether or not they wished to be a donor – was also considered, but not included 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.

The **second chapter** looks at whether we should encourage hospital clinicians to refer to a SNOD patients who are expected to die in an intensive care unit or emergency department in circumstances which would potentially enable them to be an organ donor. This would also include referring most patients dying elsewhere in a hospital to a TDC, to consider further whether they could be a donor. Such an approach could help tackle the problem of people who have expressed a wish that they want to be a donor not being referred to a SNOD or TDC at the point of death. While in some of these cases it may not be possible for the person to be a donor for medical reasons, this would help ensure that, where needed, a case was considered by a transplant surgeon – in many cases, the person may at least be able to donate some organs or tissue.

# Chapter 1 – Increasing Authorisation for Organ and Tissue Donation

## Introduction

This chapter explores whether an ‘opt out’ system would increase the number of cases where donation is authorised – either through the explicit permission of the donor who has died, through the support of the family, or where authorisation can be deemed to be in place. Under Scottish legislation (the Human Tissue (Scotland) Act 2006), organs and tissue can only be donated from someone who has died if either the person themselves ‘authorised’ donation before they died – for example by joining the NHS Organ Donor Register (ODR) or by carrying a donor card – or if their nearest relative authorises the donation on their behalf.

The legislation does permit organs or tissue to be donated without needing the family’s permission, if the person who has died has already authorised it. However, in practice, the support of the family is key to providing background information on the potential donor to enable the transplant surgeons to decide whether their organs or tissue are likely to be safe for transplantation. Therefore, currently donation would not proceed if the family were not content to authorise donation. Families are much more likely to authorise donation if their loved one was known to have wanted to be a donor. This is known as an ‘opt in’ system.

While authorisation is only one of several steps in enabling donation (and ultimately transplantation) to go ahead, it is important as each year a significant proportion of families refuse authorisation for their loved one’s organs to be donated – in 2015-16 in 43% of cases in Scotland where family members were approached about donation authorisation was not given or the family overrode the authorisation the person had previously given themselves. That is despite surveys suggesting the great majority of Scottish people support organ donation<sup>4</sup>, even if many of them do not get around to joining the ODR.

There are a number of different models of consent/authorisation used in different countries throughout the world. Most countries either use an opt in system, like the current Scottish system (where explicit authorisation or consent is needed), or an opt out system (where donation can usually take place unless someone has explicitly stated that they don’t want to be a donor) and there can be a range of variations within these systems.

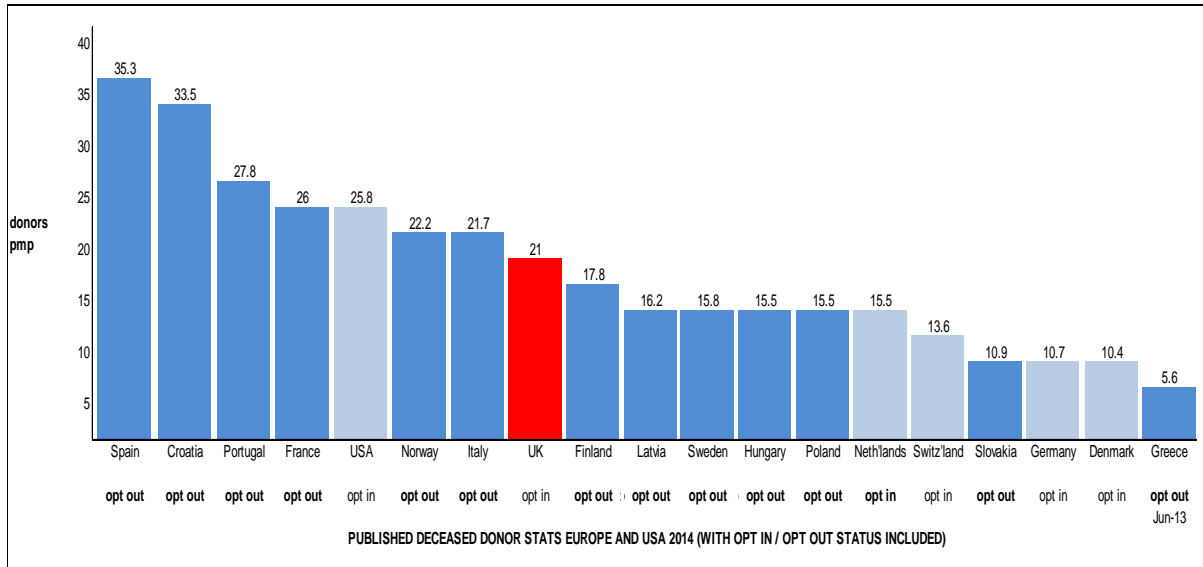
The chart below shows that numbers of organ donors per million people in the population varies dramatically across different European countries, although it is not always the case that those countries with opt out systems have higher donation

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<sup>4</sup> For example, in a survey 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’

rates. This is because donation rates are affected by a wide range of factors – authorisation (or consent) for donation is just one of them.

**Figure 2 – Deceased organ donors per million population in key countries – September 2014<sup>5</sup>**



### The current opt in system

Keeping the current system remains an option. As noted in the introduction, there are a number of other initiatives being taken forward through the Scottish Donation and Transplant Group (SDTG) to help increase donation rates, which do not need changes to the current legislation.

The current opt in system has the advantage of avoiding donation proceeding in cases where the family thinks the potential donor may have objected, but the donor never explicitly raised any concerns, or potentially in cases where it would cause distress to the family. Also, the current system – along with the SDTG’s initiatives – has been shown to be effective at increasing numbers of donors and transplants, and is well understood by NHS staff and families. One survey this year also suggested that it may be more popular amongst the Great British public than an opt out system<sup>6</sup>. While our current system is an opt in system, people in Scotland can also already choose to actively make clear they do not wish to be a donor by registering to ‘opt out’ via the [Organ Donation Scotland](http://www.organdonation.scot.nhs.uk) website.

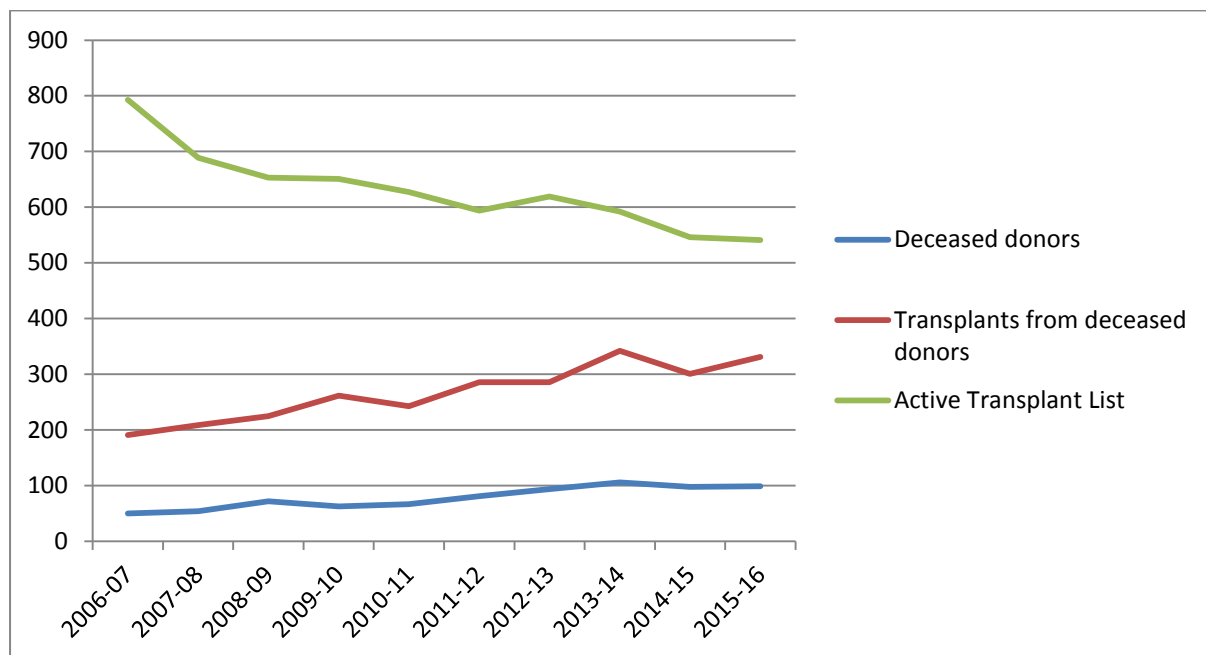
<sup>5</sup> See Council of Europe Transplant Newsletter September 2015: [https://www.edqm.eu/sites/default/files/newsletter\\_transplant\\_2015.pdf](https://www.edqm.eu/sites/default/files/newsletter_transplant_2015.pdf)

<sup>6</sup> See <https://www.ipsos-mori.com/researchpublications/researcharchive/3728/Wishes-of-organ-donors-should-take-priority-over-wishes-of-their-families-public-says.aspx> - a survey of 1001 adults in Great Britain (but this does not provide a breakdown of responses provided by those in Scotland). 49-50% favoured the current opt in model, while 37-42% favoured an opt out/deemed consent model.

### A soft opt out system

There has already been significant debate about whether or not there should be an opt out system of organ donation in Scotland. International evidence as to whether or not an opt out system in itself makes any significant difference to numbers of organ (or tissue) donors is unclear and subject to debate.

**Figure 3 – changes in number of deceased organ donors in Scotland, transplants and those on the waiting list over time<sup>7</sup>**



Rates of organ donation can be higher in countries with opt out systems, although it is often unclear whether it is the opt out system itself or other factors (such as developments in donation and transplant resourcing, prioritisation in hospitals or awareness raising amongst the public) which have helped increase donation rates. For example, Spain currently has the highest organ donation rates in the world (approx. 35 donors per million population) and is often quoted as an example of an opt out system working well. However, Spain only observed a significant increase in donation numbers after improvements to their infrastructure, and many years after the legal basis for opt out had been introduced. It is also worth noting that, due to differing donation procedures, a significant proportion of donors' organs in Spain are not transplanted<sup>8</sup>. In addition, as shown in Figure 2, Scotland and the rest of the UK already have higher donation rates per million population than some of the countries operating opt out systems.

<sup>7</sup> Source – NHS Blood and Transplant (NHSBT)

<sup>8</sup> For example, in 2014, an average of 24% of donated kidneys in Spain were not used for transplant because no transplant centre would accept them. This is compared to only 10% in the UK because in the UK no organs are removed from a donor unless they have already been accepted by a transplant hospital as being suitable for one of their patients.

A 'soft' opt out system was introduced in Wales in December 2015 and there have been mixed indications so far about the impact this legislative change has had. It is not yet clear if the new system is likely to lead to an overall increase in consent rates and donors. Data from NHSBT shows there were 25 deceased donors in Wales from April to September 2016, compared to 60 in 2014-15 and 64 in 2015-16. It is however too early to draw meaningful conclusions from the first short period of operation.

While the evidence from other countries is often inconclusive, given the increasing levels of public interest in developing an opt out system, the Scottish Government would consider the introduction of an opt out model if such a step would be supported by the general public and by stakeholders, and if it can be introduced in a way that will do no harm – either to the public perception of organ donation and trust in the NHS, or to the operation of processes required to take donation forward.

The existing UK NHS Organ Donor Register (ODR) allows anyone in Scotland to either opt in or to register their wish not to donate (often referred to as 'opting out'), by confirming if they do or don't want to be an organ or tissue donor when they die (people can also opt in on a qualified basis if they are willing to donate certain organs or tissue, but not others). A change to an opt out system of donation could legally permit donation to proceed where authorisation can be 'deemed' on the basis that a person has not opted out by recording that wish on the ODR, or by otherwise noting in writing that they did not wish to donate their organs and/or tissue.

However, there would be likely to be significant concerns that such a rigid opt out system – sometimes called a 'hard' opt out system - might lead to people becoming donors even if they would not have wanted to. It may be they had not got round to opting out or were not able to understand that they needed to opt out.

Therefore, it is likely that a 'soft' form of opt out system would be more acceptable, one that 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. These safeguards would have to be structured in a way that was not overly complex and did not cause delays to the organ donation process. An overly complex or time-consuming process will lead to donations being unable to proceed. Too many administrative obstacles would also mean that there would be little or no difference in practice from the current Scottish opt in system.

**Question 1 – what do you think of the principle of a soft opt out system for Scotland?**

**Question 2 - are there any changes you would make to the current 'opt in' authorisation system, other than moving to opt out?**

**Question 3 – where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor’s family opposes the donation?**

**How soft opt out could work in Scotland**

A workable soft opt out system would be expected to involve the following three ‘steps’<sup>9</sup>:

1. high profile **awareness-raising campaigns**, for at least twelve months before introduction of the new system and on a regular basis after implementation. This would be designed to ensure as many people as possible think about organ and tissue donation, discuss it with their families and either opt in or, if they don’t want to be a donor, opt out. It would be important to ensure these campaigns take account of the needs of people who either speak little or no English and people with disabilities or learning difficulties who may need extra support to understand the new system and/or to opt out if they want to. Efforts would also need to be made to allow people who may be harder to reach to opt out if they want to, including prisoners and others who may not have access to the internet. Education and training for a range of healthcare professionals and other professional groups involved would also be required during this time.
2. **deemed authorisation** - in the event of death of someone in hospital in circumstances where their organs or tissue could potentially be donated (and they were not in any of the ‘excepted’ categories under step three below), a Specialist Nurse for Organ Donation (SNOD) or a Tissue Donor Co-ordinator or person who takes authorisation for eye donation (TDC) would undertake the following checks to help them reach decisions:
  - if the person had registered as opting out, no donation could proceed (unless the family provided evidence that the person had confirmed in writing more recently that they had changed their mind);
  - if the person had registered as opting in, the family would be informed and SNODs/TDCs would start the process of examining the feasibility of donation (unless again the family provided evidence that the person had confirmed verbally or in writing more recently that they had changed their mind);
  - if the person had not registered any decision on the ODR, a SNOD/TDCs would approach the person’s family to discuss the fact that the person was not on the ODR and therefore, in the absence of other information, would

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<sup>9</sup> Note – this is just a summary of steps and steps 2 and 3 would be considered at the same time. Authorisation procedures would not be taken forward in cases where there were already known medical reasons why the person could not be a donor. These procedures would also not be taken forward if the Procurator Fiscal refuses to consent to any donation – NHS staff must inform the Procurator Fiscal under certain circumstances, such as if the death was suspicious.

be deemed to have authorised donation. The family or friends would be asked if their relative/friend had expressed any objections to organ donation. If the person was not known to have expressed any objections then the assumption would be that donation could proceed; **this would count as 'deemed authorisation'**;

- however, there could potentially still be scope for donation not to proceed if it was clear that proceeding would cause distress to the family (and lead to them potentially refusing to provide the important background information which is needed in most cases to decide if it is safe to proceed with donation and subsequent transplant). In Wales, families can still refuse to allow donation to proceed even where the legislation would allow donation to proceed on the basis of deemed consent and this has happened already;
- in the relatively rare cases where the person did not have any family or close friends – or at least none who were contactable within the necessary timeframe – then, if they did not come under any of the explicit authorisation categories below, donation could be considered to be authorised unless the person had opted out. However, in these cases, NHS staff would still need to consider whether or not they had sufficient information on the patient and his or her medical history to be sure the organs or tissue would be safe to transplant. In some cases, they may still be able to proceed where sufficient information is available from medical records.

**Question 4 – if there was a soft opt out system, what do you think of the proposed checks above?**

**Question 4(a) - if you think these are not sufficient, what other checks would be needed (apart from those set out under step 3 below)?**

**Question 5 – in any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family?**

3. In cases where someone dies and checks made by SNODs or TDCs suggest that they may fall into any of the following categories, donation (of either organs or tissue or both) could only be authorised with **explicit authorisation**, either from the person themselves or from their family:
  - someone who, over a period of time before their death, did not have capacity to take a decision on donation (see further details below on who this would cover);
  - a child under a certain age – we would still view it as appropriate for children of 12 years old or over to be able to self-authorise their own donation if they wish, but it may not be appropriate for someone's authorisation to be 'deemed' unless they are at least 16 years old;

- anyone who had not been resident in Scotland for at least 12 months before their death. It is proposed that this would be a relatively straightforward assessment of whether or not their 'main' home had been in Scotland for 12 months or more, but they would not necessarily need to live there all the time – for example, students or members of the armed forces would count as resident if they were generally in Scotland over 50% of the year even if they stayed somewhere else during their holidays or had periods working abroad during that time.

We are acutely aware of the importance of ensuring any opt out system takes account of the rights of people who are unable to make their own decisions. In hospital immediately before their death, almost all potential donors would be considered 'incapable' of making their own decisions, but these separate explicit authorisation provisions would only be expected to apply where the person suffered from incapacity over a period of time before their death due to a mental disorder or physical disability – with the result that they cannot be considered to have been capable of taking a decision on organ donation for some time before their death. This would probably mean it is likely they could not have made their own decisions for more than a year before their death. However, it might also be appropriate for the system to allow the flexibility to require explicit authorisation as appropriate in certain cases where a person's lack of capacity was over a shorter period. This would recognise that they may not have had sufficient ability or understanding to make their views on organ donation known. We are therefore keen to hear your views on when a person should be classed as not having capacity to make their own decisions under this provision (see question 7 below).

If a potential donor falls into any of the three 'excepted' categories above:

- Similar procedures would apply to the current ones in that donation would normally only be authorised in these circumstances where a family member provides authorisation on the person's behalf. The Human Tissue (Scotland) Act 2006 already defines who would be classed as the person's nearest relative (if there is no family member, the decision can be made by a friend of long-standing);
- However, if the adult or child had opted out of donation then their view would be respected. If they had opted in, then that should be sufficient to authorise a donation if they were 12 years old or over (particularly for anyone who had been living in Scotland for less than twelve months or if the person had opted in at a time when they did have the capacity to make that decision). However, there would still be scope for donation not to proceed if it was clear that proceeding would cause distress to the family or if the family and/or medical records made sufficiently clear that the person did not have the capacity to understand what they were doing at the point they opted in and the family did not agree to authorise donation;



- In cases where the person was not known to have expressed a view either way, the nearest relative would be asked to decide whether or not to authorise donation. As happens under the current system, they should base their decision on what they think their relative would have wanted in cases where it is possible to know this. In cases where it is not possible to know what the person might have wanted, their nearest relative would need to make their own decision;
- In the case of children, it would be the child's parent(s) or another person with parental responsibilities and rights who would decide. For looked-after children, a local authority currently cannot authorise donation if no parent is available, although there may be a case for reconsidering this restriction – for example, in England and Wales where a person in a local authority has parental responsibility for a child in care then the local authority staff member can give consent to donation.

The potential approach set out above would involve SNODs, TDCs and/or clinicians (or in some cases eye donation specialists if only eye donation is being considered) needing to make a judgement about a potential donor's situation in order to decide whether or not they fall into one of the categories where explicit authorisation is required. They would normally be the ones deciding whether or not explicit authorisation would be required, although they would consult their senior managers in NHSBT or SNBTS if they were unsure in a particular case. Given the limited timescales available to seek authorisation for donation, it might not always be possible, for example, to be sure if a person had been resident in Scotland for more than twelve months or if they had sufficient capacity to make their own decisions about donation before coming to hospital. Therefore, we would propose that detailed guidance and training should be provided for SNODs, TDCs and other healthcare workers before the implementation of any opt out system. We would also propose that, where there is some doubt about whether or not a person falls into one of the 'excepted' categories, explicit authorisation should always be sought from the person's nearest relative.

**Question 6 – if there was a soft opt out system, what do you think about the categories of people set out above for whom explicit authorisation would still be needed from the person themselves or family member?**

**Question 6(a) – if these are not sufficient, why do you think this?**

**Question 7 – in what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?**

**Question 8 – under what age do you think children should only be donors with explicit authorisation?**

**Question 9 – for children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for the child to authorise donation for the child if no parent is available?**

**Donations of less common types of organs or tissue under an opt out system**

While this model of deemed authorisation could cover the more common types of organ and tissue donation, it may still be appropriate to only allow for more rare and novel types of tissue or organs to be donated with explicit authorisation from either the donor themselves or their family. For example, it is now possible for limbs to be transplanted; it is also possible to undertake facial tissue transplants, although this is not currently carried out in the UK. In the Welsh opt out legislation, there is a list of these rarer types of organs or tissue – referred to as ‘excluded material’ – where express consent is still required for it to be donated<sup>10</sup>. A similar provision could be considered in any future Scottish legislation to specify the types of organs and tissue where deemed authorisation either could or could not be used.

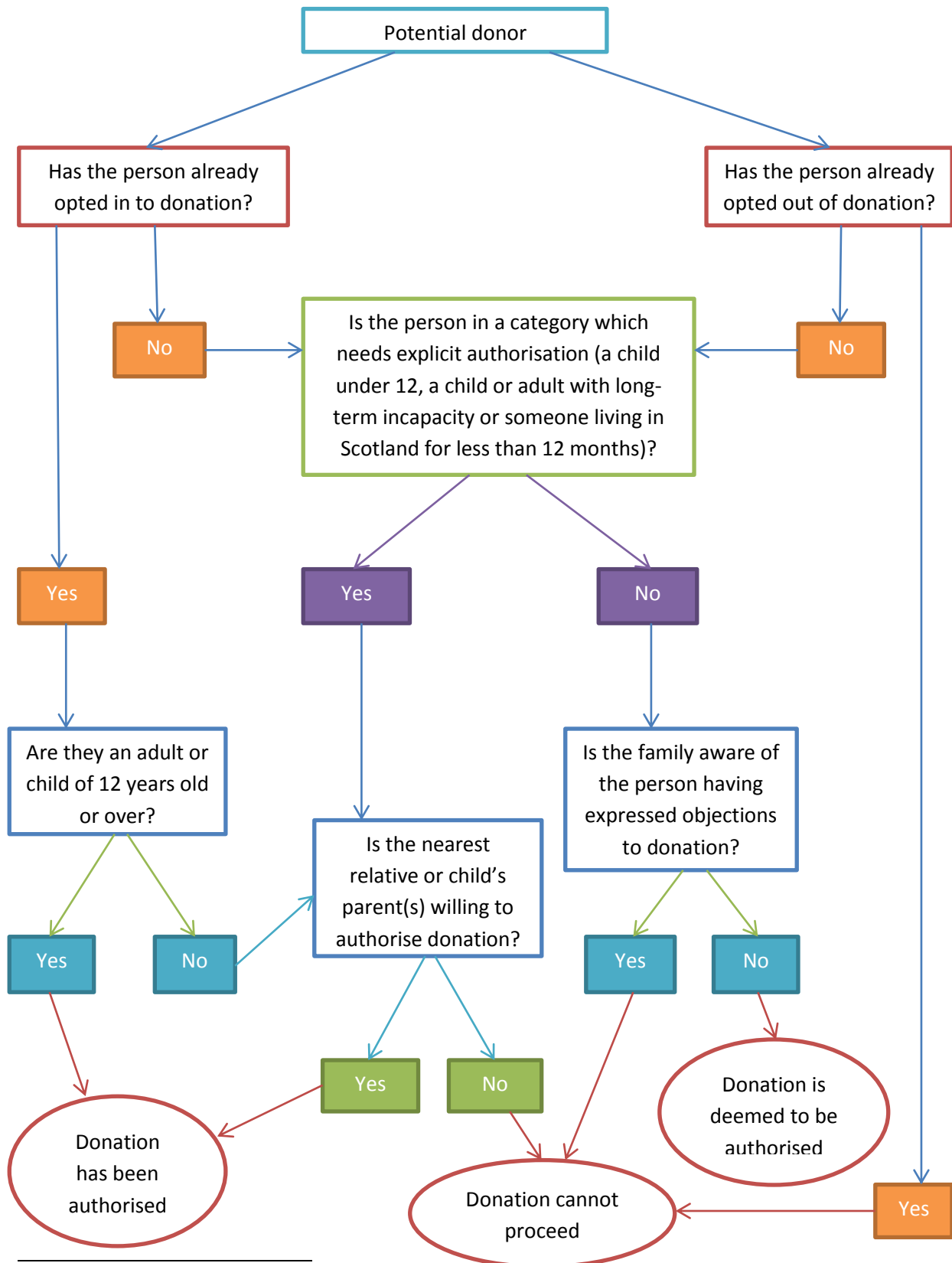
In addition, we would propose that any deemed authorisation approach would only apply to donation where this is for transplantation. It would not apply to donation for research purposes as this could still only happen with explicit authorisation from the donor or their family. While donation for research remains very important and there is significant demand for such organs, we do not feel this is sufficient to allow organs to be removed on the basis of deemed authorisation only.

**Question 10 – in any opt out system, what provisions do you think should apply to the less common types of organs and tissue?**

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<sup>10</sup> See the Human Transplantation (Excluded Relevant Material)(Wales) Regulations 2015 at [http://www.legislation.gov.uk/wsi/2015/1775/pdfs/wsi\\_20151775\\_mi.pdf](http://www.legislation.gov.uk/wsi/2015/1775/pdfs/wsi_20151775_mi.pdf)

**Figure 4 - Flowchart of authorisation pathways for potential organ and tissue donors<sup>11</sup>**



<sup>11</sup> Note – this flowchart is based around donations of ‘standard’ organs and tissue for transplantation – it does not cover either donations for research or the proposals around rarer types of donation – in both cases explicit authorisation from either the donor or their family would be needed.

## Benefits and disadvantages of this soft opt out model

This process would have potential benefits in a number of cases by permitting organs to be donated in cases where a person is in favour of donation, but has not got around to signing up to the Organ Donor Register. It may also in some cases make things easier for relatives by taking away much of the pressure in making what can be a very difficult decision, but still giving them the chance to object if they know that their relative did not want to be a donor. If there is sufficient ongoing awareness-raising through a range of media to ensure that people who do not want to donate have sufficient opportunity to easily opt out, then it may be acceptable to authorise donation on the basis that the person has chosen not to opt out.

**Table 1** below sets out the reasons given why families refused authorisation for organ donation in 2015-16. In 28 cases, the family said their relative had previously expressed a wish not to donate. The table also shows that in all the other cases, the donations could potentially have been 'deemed' to be authorised, assuming they did not fall into an excepted category where explicit authorisation was needed. However, it is likely that a majority of others would also not ultimately proceed because either a) explicit authorisation would be needed, b) because the family might override the deemed authorisation or c) due to medical reasons.

**Table 1 – Reasons given why families did not provide authorisation – 2015-16**

Reason	No of DBD donors	No of DCD donors
Patient previously expressed a wish not to donate	7	21
Family were not sure whether the patient would have agreed to donation	<5	13
Family did not believe in donation	<5	<5
Family felt it was against their religious/cultural beliefs	<5	-
Family was divided over the decision	-	<5
Family felt the patient had suffered enough	<5	7
Family did not want surgery to the body	<5	5
Family had difficulty understanding/accepting neurological testing	<5	<5
Family felt the length of time for donation process was too long	<5	16
Family concerned that organs may not be transplanted	-	<5
Strong refusal - probing not appropriate	<5	5
Other	<5	11
<b>Total refusals</b>	<b>23</b>	<b>85</b>

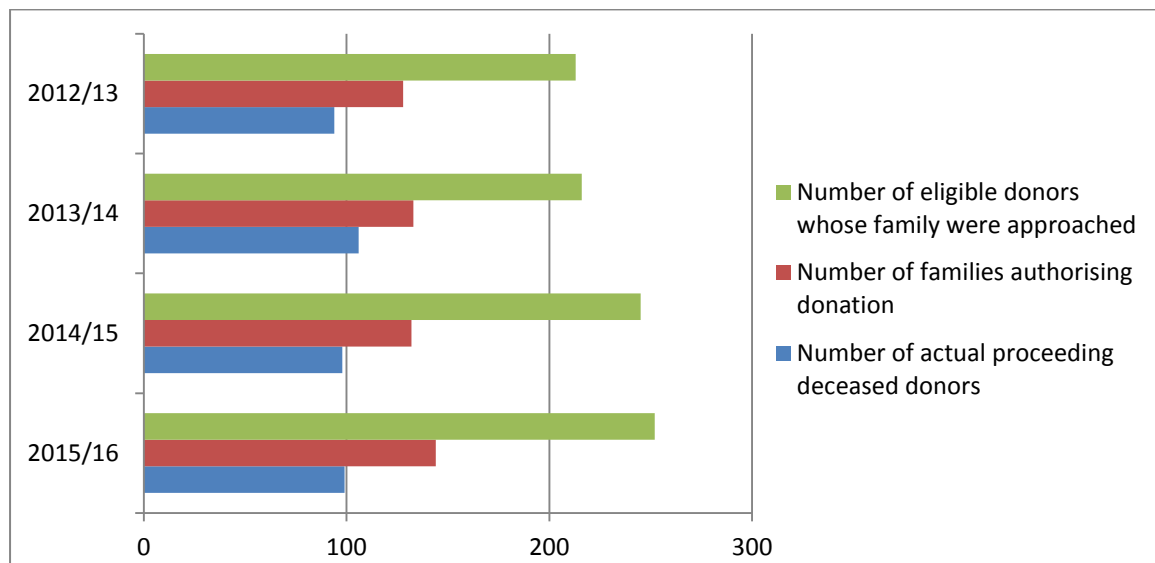
Source – NHS Blood and Transplant (NHSBT) – covers approaches in Scottish hospitals

Note – where fewer than 5 families refused for a particular reason, this has been marked <5 in order to help protect their identities

DBD donors are ones who have been diagnosed as brain dead, while DCD donors are ones who will be certified as dead after their heart stops beating and they have stopped breathing.

However, clearly such a deemed authorisation approach could carry risks. Deemed authorisation would be a legal authorisation. Nonetheless, it is still likely to be difficult to assume it is accepted that someone authorises their donation just because they have not opted out. The model above however aims to provide sufficient safeguards for the groups of people who are less likely either to be able to sufficiently understand the meaning or implications of opting in or out or may be unaware of the legislation due to not having been in Scotland for very long.

**Figure 5 – numbers of families approached compared to those giving authorisation and actual donor numbers**



**Source - NHSBT – Note that families are only approached where initial checks based on the information the Critical Care unit has suggest the person’s organs are likely to be suitable for donation**

**Figure 5** above suggests that an opt out system has the potential to increase authorisation rates, which in turn could increase the number of people who actually go on to donate organs. However, it is impossible to judge to what extent authorisation or actual donations would increase as more people are likely to opt out of donation (under the current system, only 1146 people in Scotland had so far opted out at the end of September 2016) and some would still need explicit (rather than ‘deemed’) authorisation. Based on the Welsh experience, it is likely that a number of families would also still refuse to support the donation and clinicians would feel unable to proceed.

Regardless of the amount of awareness-raising, there are still likely to be a significant number of people not in any of the listed categories needing explicit authorisation who would neither opt in or out – this is often likely to be either because they don’t want to think about death or don’t think it will happen to them for a long time or just because they don’t get round to it. In Wales, the level of awareness of their new opt out legislation is high as a result of their awareness-

raising campaign. As a result, they have made clear to people that anyone who neither opts in or out of donation is still making an **active choice** to allow their organs to be donated. As at 31 March 2016, 165,129 people in Wales had opted out of donating their organs (just over 5% of the population), while 1,113,090 had opted in.

Surveys suggest the great majority of people do support donation (70% of people in an August 2016 survey<sup>12</sup>). It could also be argued that if people have been given sufficient information, it is their responsibility to explicitly opt out if they don't want to be a donor, but there is still a possibility a model based on 'deemed' authorisation leads to people becoming donors when they actually would not have wanted to donate. This could risk being viewed by some as the state taking people's organs, rather than people actively choosing to give them. Any such perception could lead to a loss of trust in the NHS and the system more widely, which might actually lead to an increase in numbers of people choosing to opt out. It could also lead to conflict with families, which would be likely to put SNODs, TDCs and doctors in a very uncomfortable position and make it difficult for them to gather sufficient information from the family about the patient's lifestyle to be reassured the organs or tissue will be safe to transplant. In such cases, NHS staff would often decide not to proceed with donation even if the legislation permitted it.

As suggested above, a model which allows for authorisation if someone has not opted out, but still recognises and allows for donation not to proceed if it is likely to cause severe distress or conflict with the family should help increase authorisations to some extent, but avoid the opt out system being too rigid.

### **Pre-death tests for potential donors**

There also needs to be consideration for potential Donation after Circulatory Death (DCD) donors<sup>13</sup> to determine whether or not 'deemed authorisation' of donation 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. If these were not allowed or were only permitted with explicit authorisation from the patient or their nearest relative then this is likely to prevent successful organ donation proceeding, even if the authorisation for donation could be deemed. Given time constraints in the organ donation process, it is vital that a number of tests have been carried out before treatment is withdrawn from a DCD patient to ensure that the organs are likely to be safe to transplant and are a good match for a transplant recipient. Organs need to be removed from the patient very soon after their death and be transplanted into a recipient within a few hours or

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<sup>12</sup> Survey of 1032 people by TNS on behalf of the Scottish Government as part of the Organ Donation 2016 campaign evaluation – 70% agreed with the statement “*as organ donation saves lives, we should all register to be organ donors*”

<sup>13</sup> Note – this issue does not apply in the same way for donors who donate after being diagnosed as brain-stem dead (DBD donors). While tests also need to be carried out on DBD donors, they are only done after it is confirmed that the donor is dead.

a transplant will not be successful. DCD donation normally also requires NHS staff to plan the timing of withdrawing the patient's treatment (in discussion and agreement with the patient's family) in order to allow for the necessary tests and other checks to be carried out, for the recipients of each of the organs to be identified and for the team of retrieval surgeons to arrive at the donating hospital.

Currently, up until the point of death, for adults, the legislation governing support provided to and any tests carried out on patients, such as potential donors who are unconscious and therefore unable to express their own decisions at the time, is the Adults with Incapacity (Scotland) Act 2000. At the moment, a number of tests are carried out prior to death, although this currently only happens where either the donor themselves has previously made clear that they wish to be a donor or where the donor's family has authorised the donation on their behalf. In all cases, the SNODs or other medical professionals ensure the donor's family is aware of and comfortable with any tests being carried out. However, we are in the process of considering whether, in the future, people joining the ODR need to have more detailed information and a greater awareness about what tests might potentially be needed if they were to become a donor.

Currently in Scotland, a number of tests are already being carried out as part of the routine care of the type of patients who might go on to become DCD donors. All patients in an Intensive Care Unit already have an existing line placed in their artery which allows blood samples to be taken without needing further injections. Similarly all patients in Intensive Care will have had a urinary catheter inserted as part of their care so this also allows for urine samples to be taken in a non-invasive way. However, in a number of cases, additional tests will be needed, depending on which organs are being considered for donation, on the patient's medical circumstances and on, for example, any countries the potential donor had visited recently. Normally, this would not include tests which would be considered invasive. Tests such as bronchoscopies have very occasionally been carried out – and on the rare occasion this happens, the test is done with the support of relatives who have authorised the donation and in a way that minimises the possibility of the patient experiencing any discomfort. We would propose that, in future, bronchoscopies should not be carried out, unless it was clear that the donor themselves had indicated in advance that they were willing to consent to that sort of test.

**Question 11 – which tests do you think medical staff should be able to carry out on a donor before they withdraw life-sustaining treatment to check if their organs or tissue are safe to transplant, both where a patient's authorisation for donation is 'deemed', as well as where the donation is explicitly authorised:**

- **a) Blood tests?** - for tissue typing to find a good recipient match, to detect any infections, such as HIV or Hepatitis, or for testing the patient's blood gases to check how well the lungs function;
- **b) Urine tests?** - to check if the patient has any infections;

- **c) X rays?** - to check for any undiagnosed medical problems;
- **d) Tests on a sample of chest secretions?** - taken via a tube to test how well the lungs function. Chest secretions are often removed from patients in Intensive Care as part of their treatment to help make them more comfortable so would be removed anyway as part of their care – this would therefore involve testing samples of the secretions that have been removed;
- **e) Tests on the heart such as an ECG (electrocardiogram) or ECHO (echocardiogram)<sup>14</sup>?** – these tests check if the heart is functioning well.

**Question 12 – if you answered no to some or all options in question 11, are there any circumstances when particular tests could be permitted?**

**Question 13 – where it is agreed a patient’s condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given<sup>15</sup>?**

### **Authorised representatives (also known as proxies)**

In England and Wales, it is possible for people to nominate one or two representatives to make decisions about donation for them when they die. This is not an option at present in Scotland. In reality, very few people have nominated a representative (only 57 people in England and Wales had done so as at 31 March 2016) and including representatives in the chain of decision-making could make donation processes more complex and lengthy. Firstly, this is because it may be difficult to contact the representative(s), particularly if they have changed their contact details. Secondly, it is normally vital to keep the family involved as, unless they have been estranged from the donor for many years, they may have important information on the potential donor’s history and lifestyle that will help doctors and SNODs or TDCs to decide if the person’s organs or tissue are likely to be safe for transplanting. In addition, if a person is capable of nominating a representative, there are very few cases where they would not be capable of also deciding whether or not they wish to donate, so it is unlikely that a representative would be needed.

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<sup>14</sup> Currently in Scotland these tests are not required for DCD patients as hearts are only donated by patients diagnosed as brain-stem dead. However, DCD heart donation has been trialled in some hospitals in England and might potentially be extended to include some Scottish donors in future.

<sup>15</sup> For example, a patient may be given a drug such as Noradrenaline to improve their blood pressure – maintaining or increasing the dose of this after the decision has been taken to withdraw life sustaining treatment will help improve the blood flow to the organs. If antibiotics are used to treat an infection which the donor has, that will help mitigate any impact of the infection on the organ transplant recipient(s)



It has been suggested that looked-after children are one category of people who might benefit from being able to nominate a representative, although again if the child is able to make the decision to nominate a representative they are probably sufficiently mature to opt in or opt out (if they are 12 years old or over then they could be a donor under the current system without needing permission of a parent or other person with parental responsibility if they are signed up to the ODR). Local authorities are not currently permitted to authorise donation for children in their care (see the section on an opt out system).

In addition, people who are estranged from their families or who know their family have very different views about donation from their own may also not want family members to make decisions for them, but again if they are able to nominate a representative, they should also be able to make their own advance decisions about donation in almost all cases. In cases where no partners or family members are available, the legislation already permits a friend of long-standing to authorise organ or tissue donation.

Therefore, on balance, we do not think that authorised representatives would be necessary. The evidence from England and Wales suggests they are very rarely appointed and have not been used. The Scottish Parliament has already considered this point when it debated the Human Tissue (Scotland) Act 2006, but it decided, at that time, that appointed representatives were unnecessary. Given that including them in the process would create potential delays and conflicts with families, we propose not to include them, but would be grateful for views on this.

**Question 14 – what do you think about allowing people to appoint one or more authorised representatives to make decisions for them?**

**Question 14(a) – if you think this should be allowed, in what circumstances do you think an authorised representative would be useful?**

**Question 15 – do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?**

## Chapter 2 – Increasing Numbers of People considered as Potential Organ and Tissue Donors

### Introduction

It is already accepted that, as part of good end-of-life care, everybody should have the option to be a donor, particularly if they have expressed a wish to do so. This is both for the wider public good by helping deliver much-needed transplants, but also as it can, in time, help grieving families to know that something positive has come from the tragic loss of their loved one.

The number of referrals to the Special Nurses for Organ Donation (SNODs) has increased by 85% since 2011/12, despite a decline in numbers of people dying in circumstances where they could be organ donors. Therefore progress is already being made in identifying potential opportunities for donation. However, there are still some potential donors who are missed each year because the clinical teams caring for the patient do not consider donation and do not contact a SNOD or Tissue Donor Co-ordinator (TDC), mainly for patients who die after circulatory death.

**Figure 6 – proportion of total cases which met existing referral criteria that were referred to Specialist Nurses for Organ Donation – 2015-16**

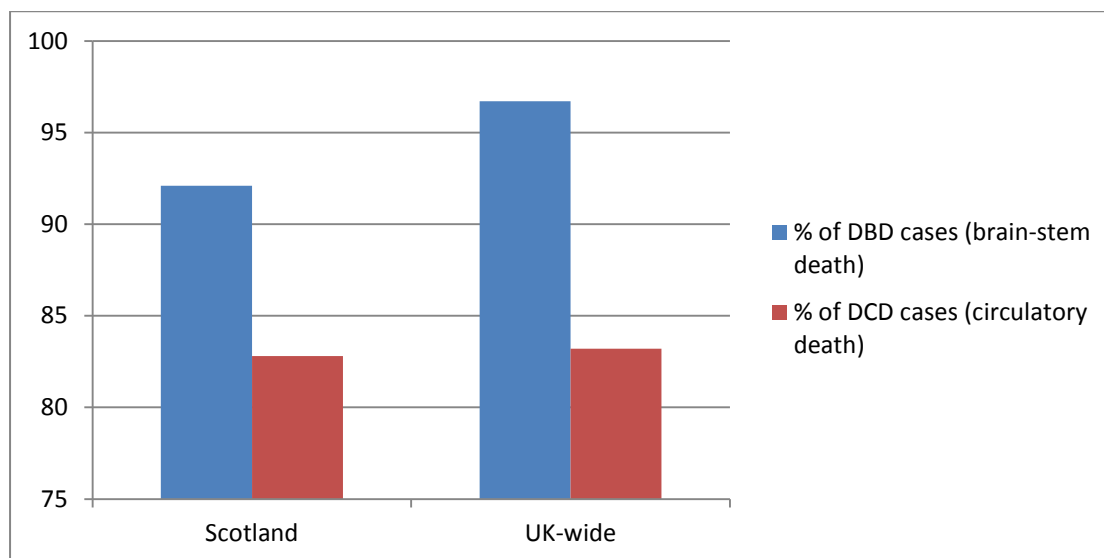


Figure 6 above shows that 17% of potential DCD patients in Scotland were not referred to the SNODs in 2015-16 – some of those patients were on the Organ Donor Register (ODR). While Scotland's performance is not significantly lower than the UK average, there is still scope for improvement as around 20 referrals of potential donors are being missed each year. Meanwhile, for tissue donation, while there are fairly good referral rates from some hospital units, many patients who could be tissue donors are not referred by the relevant hospital departments.

In some cases, this lack of referral was due to an oversight by clinical staff who had not thought about donation – for tissue donation this seems to be common due to

lack of awareness of the possibility of tissue donation, as well as, for example, staff in areas such as Emergency Departments feeling they are too busy to refer a patient. Further, in some cases, even though the patient met the current criteria for referral for donation, clinicians seem to have assumed the patient would not be a suitable donor. This is either because of health issues which may make the patient's organs/tissue unsuitable for transplantation or because the clinicians thought that the length of time between withdrawing treatment and the patient's death would be likely to mean the patient's organs would not be viable for transplantation. Organ or tissue donation should be considered in every case where the patient does not have any 'absolute' contraindication to donation i.e. where they definitely could not donate any of their organs<sup>16</sup> or tissue - for example if the patient was over a certain age (currently organs cannot be donated from those who are 85 years old or over, although it may be possible to donate corneas from patients who are older) or has certain 'live' cancers. For most patients, it may often be possible for at least some organs or tissue to be donated.

Hospital doctors may sometimes have concerns that the patient's health problems might be such as to make a particular patient unsuitable to be an organ/tissue donor. However, clinicians who are not dealing with organ/tissue transplantation on a daily basis are not necessarily experts in determining whether there are any contraindications to organ or tissue donation. It is the staff who deal with organ and tissue donation and transplantation on a daily basis who are the experts in this field and the ones who can best advise whether or not organs and/or tissue from a particular patient would be suitable for transplantation. Therefore, it is always best for the patient's case to be referred to the SNODs or TDCs early on to investigate if donation is possible, even if the doctor caring for the patient thinks it is unlikely. In some cases, the patient will indeed not be suitable for donation and he/she will be quickly ruled out after a telephone conversation with the SNOD or TDC; in other cases however, the patient may be able to successfully donate.

A limited system has been implemented in Scotland where the relevant Regional Clinical Lead for Organ Donation will require an NHS Board's donation committee (which is there to help support donation in their area) to investigate and provide an explanation, especially if a person who was pronounced brain-stem dead in an intensive care unit and was on the ODR was not referred to a SNOD.

### **Proposals to reduce numbers of missed referrals**

If all patients in critical care areas were referred either at the point a doctor decides to carry out brain-stem death testing (for potential donation after brain-stem death (DBD) cases) or at the point the doctor documents the decision to withdraw treatment (for potential donation after circulatory death (DCD) cases) this would be likely to **increase the number of organ donation referrals in Scotland by around 20-30 each year**. We would consider whether the guidance should provide specific

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<sup>16</sup> See the NHSBT policy note at [http://www.odt.nhs.uk/pdf/contraindications\\_to\\_organ\\_donation.pdf](http://www.odt.nhs.uk/pdf/contraindications_to_organ_donation.pdf)

clinical triggers which should lead to an organ donation referral<sup>17</sup>. While not all of these patients would become actual donors, a proportion of them should do. For tissue donation, doctors should also refer patients who die outwith Critical Care Units as tissue donation can still take place up to 48 hours after the patient has died (or up to 24 hours in the case of eye donation)<sup>18</sup>.

Therefore, greater encouragement should be given to all hospital doctors to **refer any patient for consideration as an organ and/or tissue donor if they are expected to die in a critical care area and are under the age of 85**, with other parts of hospitals also encouraged to refer those who have recently died for consideration as a potential tissue donor. Greater awareness raising of organ and tissue donation and the role of SNODs and TDCs among staff working across hospitals could be helpful in making staff who have never or rarely been involved in donation more aware of the advice and support that SNODs or TDCs can provide. While some staff working in Intensive Care Units will be very familiar with organ donation, others in Emergency Departments may be much less familiar with it. Similarly, staff in other hospital departments are not always aware of the potential for tissue donation.

When a patient is referred to the donation service, the local SNOD or TDC will discuss the patient's key health issues with the clinician by telephone to decide if any absolute contraindications to donation apply and to check whether the patient had either opted in or opted out on the ODR. If there are any health concerns which might prevent a particular organ/tissue being donated, the SNOD or TDC would speak to transplantation medical staff to get their view on whether or not the organ(s) or tissue could be transplanted.

To help encourage further increases in referrals, the Chief Medical Officer (CMO) could for example issue guidance to hospitals to encourage them to refer all patients who meet the criteria above – either as a potential organ or tissue donor. As SNODs and TDCs work closely together, staff would only need to refer a patient to one or other, not both. In cases where this did not happen and the patient was on the ODR, there may be a case in some circumstances for the Regional Clinical Lead for Organ Donation asking the relevant hospital to investigate the circumstances. That would help those hospitals to learn lessons for the future and address any issues identified locally, such as around lack of awareness of organ and tissue donation or misunderstandings about what constitutes a contraindication to donation.

The CMO's guidance could also re-emphasise the importance of all hospital staff doing what they can to facilitate donation, stress that SNODs and TDCs are there to

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<sup>17</sup> For example there are some existing guidance documents which set out suggested clinical triggers for considering donation, such as the National Institute for Health and Care Excellence (NICE) guidance for England on improving donor identification

<https://www.nice.org.uk/guidance/cg135/chapter/1-recommendations>

<sup>18</sup> Note – outside the central belt of Scotland, currently heart valves and corneas are the only tissue that can be donated. Within the central belt, tendons and skin can also be donated.

support hospital staff, and encourage clinicians to always involve SNODs or TDCs in approaches made to families about donation. On average in 2015-16, SNODs were involved by doctors in only 69% of approaches to families in Scotland, although involvement rates improved during the second half of the year (across the UK they were involved in 83% of cases). Authorisation rates are significantly higher where a SNOD is involved in the approach discussions with the family.

The proposed CMO guidance has advantages in that it can be implemented relatively quickly and encourages all potential donors to be fully considered, even if it is later agreed that the person would not be a suitable donor for medical or other reasons. Some clinicians may have concerns that it could put additional work pressure on them and other NHS staff and lead to difficult discussions with families. However, given that these proposals would only be expected to lead to around 20 to 30 extra cases each year across Scotland where families would be approached about organ donation, it is unlikely to place individual departments under significant extra pressure. There would also be a likelihood of some extra approaches to families about donating tissue only (where the patient has been ruled out as a potential organ donor), but these would all be carried out by the TDCs. It is worth noting that, for example, the North West region of England already has a 'required referral' policy for hospitals – evidence from the operation of this policy could be considered in developing any new CMO guidance.

Strengthened guidance on referrals should help generate greater awareness and lead to more referrals to the donation service. It would reduce the risk of referrals being missed due to an oversight and some of these patients could reasonably be expected to become donors. It would also promote consistency in practice across NHS Boards and promote equity in the approach taken across Scotland. For those patients who are on the ODR, referral helps to ensure that attempts are made to see if their wish to be a donor can be taken forward. Where the person cannot be an organ donor for medical reasons, the referral may still help enable them to be a tissue donor instead.

**Question 16 – what do you think about providing CMO guidance to encourage clinicians to refer almost all dying or recently deceased patients – particularly those who are under 85 years old - for consideration as a potential organ or tissue donor?**

**Question 17 – what do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor co-ordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?**

## Equalities Impact Assessment

If there are proposed changes to legislation as a result of the findings of this consultation, the Scottish Government will be carrying out a number of Impact Assessments, including an Equalities Impact Assessment. We are required to carry out an Equalities Impact Assessment in order to ensure compliance with our duties under the Equality Act 2010 and associated regulations. The Equalities Impact Assessment aims to ensure that any new Scottish Government policies or legislation help promote opportunities where possible for a range of equalities groups and at the very least avoid any discrimination or other unfair treatment of any particular groups of individuals, based on, for example, their gender, race, religion or disability.

We do not feel that the proposals in this consultation would be likely in most cases to impact on individuals in any equalities group differently from others, although there are some specific provisions for children and adults who do not have the capacity to understand or make their own decisions about organ or tissue donation – likely to be those with serious disabilities – to help protect their interests. There may also be some implications for some people from minority ethnic groups if they do not have a good understanding of English, as well as those with visual or hearing impairments, in ensuring that they are sufficiently aware of any changes that may be adopted in relation to a deemed authorisation system.

We would be grateful for your views on any equalities impacts to ensure that they can be fully considered as part of the Impact Assessment.

**Question 18 – do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? If yes, please provide details.**

In the question above, equalities groups should be taken to mean any different impacts the proposals might have on any particular groups of people based on their:

age  
being pregnant or on maternity leave  
disability  
gender reassignment  
race  
religion or belief  
sex, or  
sexual orientation

Please note, we will also be carrying out a Children's Rights and Wellbeing Impact Assessment, which will take account of responses to a number of the earlier questions in this consultation, where those relate to children (either directly or indirectly).

## How to respond and what happens next

### Responding to this Consultation

We are inviting responses to this consultation by **14 March 2017**.

If you only wish to answer some of the questions, feel free to do so. If you wish to make additional comments that relate to organ and tissue donation and transplantation, but are not directly relevant to any of the questions, please add in your comments at the end of your response.

Please respond to this consultation using the Scottish Government's consultation platform, Citizen Space. You can view and respond to this consultation online at <https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation>

You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of **14 March 2017**.

If you are unable to respond online, please complete the Respondent Information Form (see "Handling your Response" below) to:

email: [Organ\\_donation\\_scotland@gov.scot](mailto:Organ_donation_scotland@gov.scot)

or write to us at:

Organ and Tissue Donation consultation  
Scottish Government  
Health Protection Division  
St Andrew's House  
Regent Road  
Edinburgh EH1 3DG

### Handling your response

If you respond using Citizen Space (<http://consult.scotland.gov.uk/>), you will be directed to the Respondent Information Form. Please indicate how you wish your response to be handled and, in particular, whether you are happy for your response to be published.

If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form attached included in this document. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.

All respondents should be aware that the Scottish Government is subject to the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

## **Next steps in the process**

Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public at <http://consult.scotland.gov.uk>. If you use Citizen Space to respond, you will receive a copy of your response via email.

Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so.

## **Comments and complaints**

If you have any comments about how this consultation exercise has been conducted, please send them to [sharon.grant@gov.scot](mailto:sharon.grant@gov.scot).

## **Scottish Government consultation process**

Consultation is an essential part of the policy-making process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.

You can find all our consultations online: <http://consult.scotland.gov.uk>. Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.

Consultations may involve seeking views in a number of different ways, such as public meetings, focus groups, or other online methods such as Dialogue (<https://www.ideas.gov.scot>).

Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise, the responses received may:

- indicate the need for policy development or review
- inform the development of a particular policy
- help decisions to be made between alternative policy proposals
- be used to finalise legislation before it is implemented

While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

If you have any questions about responding to the consultation, please email [organ\\_donation\\_scotland@gov.scot](mailto:organ_donation_scotland@gov.scot) or call us on 0131 244 9228. You can also use these contact details if you would like to request a copy of this consultation in a different format.



## Consultation on Organ and Tissue Donation and Transplantation

### RESPONDENT INFORMATION FORM

**Please Note** this form **must** be completed and returned with your response.

Are you responding as an individual or an organisation?

- Individual  
 Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response.  
Please indicate your publishing preference:

- Publish response with name  
 Publish response only (anonymous) – Individuals only  
 Do not publish response

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

- Yes  
 No

## List of Questions

**Question 1 – what do you think of the principle of a soft opt out system for Scotland?**

- I support the principle of a soft opt out system in Scotland
- I do not support the principle of a soft opt out system

**Question 2 – are there any changes you would make to the current ‘opt in’ authorisation system, other than moving to opt out?**

**Question 3 – where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor’s family opposes the donation?**

- medical staff should still proceed with the donation
- medical staff should not proceed with the donation

**Question 4 – if there was a soft opt out system, what do you think of the proposed checks set out in step 2 (on pages 14 to 15)?**

- these are sufficient to decide if a donation can be deemed to be authorised
- these are not sufficient to decide if a donation can be deemed to be authorised
- don’t know

**Question 4(a) - if you think these are not sufficient, what other checks would be needed (apart from those covered in questions 6 to 8 below)?**

**Question 5 – in any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor’s family?**

- the donation should still proceed
- the donation should not proceed
- don’t know

**Question 6 – if there was a soft opt out system, what do you think about the categories of people set out under step 3 (pages 15 to 17) for whom explicit authorisation would still be needed from the person themselves or family member?**

- the categories above are sufficient
- the categories above are not sufficient
- don't know

**Question 6(a) – if these are not sufficient, why do you think this?**

**Question 7 – in what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?**

**Question 8 – under what age do you think children should only be donors with explicit authorisation?**

- under 12
- under 16
- under 18
- other (please specify)

**Question 9 – for children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available?**

- they should be allowed to authorise donation of a child's organs or tissue in those circumstances
- they should not be allowed to authorise donation of a child's organs or tissue
- don't know

**Question 10 – in any opt out system, what provisions do you think should apply to the less common types of organs and tissue?**

- deemed authorisation provisions should only apply to the more common organs and tissue (kidneys, liver, pancreas, heart/heart valves, lungs, small bowel and stomach, tendons, skin, corneas, bone)
- deemed authorisation provisions should apply to all organs and tissue

**Question 11 – which tests do you think medical staff should be able to carry out on a donor before they withdraw life-sustaining treatment to check if their organs or tissue are safe to transplant, both where a patient’s authorisation for donation is ‘deemed’, as well as where the donation is explicitly authorised:**

- **a) Blood tests?** - for tissue typing to find a good recipient match, to detect any infections, such as HIV or Hepatitis, or for testing the patient’s blood gases to check how well the lungs function;
  - yes
  - no
  - don’t know
- **b) Urine tests?** - to check if the patient has any infections;
  - yes
  - no
  - don’t know
- **c) X rays?** - to check for any undiagnosed medical problems;
  - yes
  - no
  - don’t know
- **d) Tests on a sample of chest secretions?** - taken via a tube to test how well the lungs function. Chest secretions are often removed from patients in Intensive Care as part of their treatment to help make them more comfortable so would be removed anyway as part of their care – this would therefore involve testing samples of the secretions that have been removed;
  - yes
  - no
  - don’t know
- **e) Tests on the heart such as an ECG (electrocardiogram) or ECHO (echocardiogram)<sup>19</sup>?** – these tests check if the heart is functioning well.
  - yes
  - no
  - don’t know

**Question 12 – if you answered no to some or all options in question 11, are there any circumstances when particular tests could be permitted?**

- if the person had previously made clear they wished to be a donor
- if the donor’s family provided consent on the donor’s behalf
- such tests should never be permitted before death

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<sup>19</sup> Currently in Scotland these tests are not required for DCD patients as hearts are only donated by patients diagnosed as brain-stem dead. However, DCD heart donation has been trialled in some hospitals in England and might potentially be extended to include some Scottish donors in future.

**Question 13 – where it is agreed a patient’s condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given<sup>20</sup>?**

- they should be able to provide such forms of treatment
- they should be able to provide such treatment, but only where the donor’s family provides consent
- they should not be able to provide any such treatment just to help the donation

**Question 14 – what do you think about allowing people to appoint one or more authorised representatives to make decisions for them?**

- this should be allowed
- this is not necessary
- don’t know

**Question 14(a) – if you think this should be allowed, in what circumstances do you think an authorised representative would be useful?**

**Question 15 – do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?**

**Question 16 – what do you think about providing Chief Medical Officer (CMO) guidance to encourage clinicians to refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor?**

- CMO guidance should be provided to encourage more referrals
- CMO guidance should not be provided
- other (please specify)

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<sup>20</sup> For example, a patient may be given a drug such as Noradrenaline to improve their blood pressure – maintaining or increasing the dose of this after the decision has been taken to withdraw life sustaining treatment will help improve the blood flow to the organs. If antibiotics are used to treat an infection which the donor has, that will help mitigate any impact of the infection on the organ transplant recipient(s)

**Question 17 – what do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?**

- this should be a requirement
- this should not be a requirement
- don't know

**Question 18 – do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative? If yes, please provide details.**

## **Glossary of terms and acronyms used in this consultation**

**Authorisation** – under the Human Tissue (Scotland) Act 2006, organ or tissue donation can proceed where it has been ‘authorised’, either by the donor themselves or their nearest relative. Authorisation can be given in writing (such as by joining the ODR) or by telephone. This is similar to ‘consent’, which is required in England, Wales and Northern Ireland. However, in the case of consent, the donor or their nearest relative has to have been given certain detailed information before they can consent; for authorisation, information is available if people want it, but they do not have to show they have seen the information before they can authorise donation.

**DBD – Donation after Brain-stem Death (or Brain Death)** – this is where donation takes place after two doctors have confirmed that the person is dead using neurological criteria to show that the person no longer has any brain-stem function, (where the patient is on life support and has completely and irreversibly lost the capacity for consciousness and the ability to breathe independently). The patient will usually have suffered either some form of severe head trauma, for example in a car accident, or have had a severe stroke.

**DCD – Donation after Circulatory Death** – this is where donation takes place after doctors have confirmed that the person is dead using cardio-respiratory criteria (where their heart has stopped beating and they have stopped breathing for a period of five minutes). The person will have suffered some form of critical illness and death happens after it is agreed that their life-sustaining treatment should be withdrawn because they cannot recover or breathe without life support.

**CLOD – Clinical Lead for Organ Donation** – each Scottish hospital where donation can take place has a doctor who leads on championing organ donation in their hospital and making their colleagues aware of developments in procedures or opportunities associated with donation. There are also two Regional CLODs who oversee the work of the CLODs in their area.

**HTA – Human Tissue Authority** – this is the organisation which regulates organ donation and transplantation across the UK. It carries out certain checks to ensure, for example, that no living donors are being paid to donate a kidney or any other organ.

**NHSBT – [National Health Service Blood and Transplant](#)** – a UK NHS body which coordinates preparations for organ donation and manages operations to remove organs from donors. It also oversees the allocation of organs to transplant recipients. Its staff work with NHS staff in Scottish hospitals to ensure the donation process works as smoothly as possible. The Scottish Government provides funding to NHSBT to cover its costs for delivering its service in Scotland. NHSBT also provides blood and tissue services, but these do not operate in Scotland, although they do manage Scottish eye donations (see SNBTS below for the Scottish equivalent).

**ODR – the [National Health Service Organ Donor Register](#)** – this is the UK-wide register of people who have confirmed that they agree that some or all of their organs or tissue can be donated after their death. People can either join the register online or by filling in a paper form. People can now also use the ODR to confirm if they do NOT wish to donate any of their organs, known as ‘opting out’. If someone has just died or is about to die, SNODs or TDCs (defined below) can access the register to check if that person had either signed up to the register or opted out of donation.

**Opt in system** – an opt in system of organ donation is one where donation can only proceed if there is explicit authorisation or consent for donation, either from the donor themselves or in some cases from their family. Scotland currently has an opt in system of donation.

**SDTG - [Scottish Donation and Transplant Group](#)** – this Group brings together a range of stakeholders with different interests and/or expertise to provide advice to Ministers on donation and transplantation. The Group aims to help increase donation and transplantation, particularly by implementing the recommendations in the Scottish Government’s [A Donation and Transplantation Plan for Scotland 2013-2020](#).

**Soft opt out** – this is a system of organ and tissue donation, also known as a deemed consent (or authorisation) system. A soft opt out system starts from the assumption that most adults can be a donor when they die unless they have stated that they do not wish to donate, but it normally allows for the family’s views to be taken into account in some way.

**SNBTS – [Scottish National Blood Transfusion Service](#)** – SNBTS is part of NHS Scotland and is the Scottish body which collects blood in Scotland and delivers it to Scottish hospitals so it is available, for example, where someone needs a blood transfusion. It also manages Scottish tissue donations and services, such as donations of skin, heart valves and tendons.

**SNOD – Specialist Nurse for Organ Donation (or Special Nurse – Organ Donation)** – these nurses are employed by NHSBT and work in hospitals to support donor families and, where donation is likely to proceed, they help make arrangements to ensure the donation can take place and that the organs have been allocated to transplant recipients by NHSBT.

**TDC - Tissue Donor Co-ordinator** - these nurses are employed by SNBTS and work in hospitals to raise awareness and provide teaching about tissue donation. Where donation is likely to proceed, they help make arrangements to ensure the donation can take place.





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