

**Final Business and Regulatory Impact  
Assessment**

# **Human Tissue (Authorisation) (Scotland) Bill**

**Health Protection Division**

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**Scottish Government**  
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# Final Business and Regulatory Impact Assessment

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## 1.0 TITLE OF PROPOSAL: HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

### 2.0 PURPOSE AND INTENDED EFFECT

This Business Regulatory Impact Assessment presents a range of economic costs and benefits utilising 3 scenarios (low estimate, best estimate and upper estimate). The low estimate (do nothing) is used as a baseline against estimates of potential impact if an increase in the authorisation rate were to result from the move to a soft opt out system of organ and tissue donation.

#### 2.1 Objective

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 point<sup>1</sup>. It is important therefore that as much as possible is done to maximise the number of donors, particularly as only around 1% of people die in circumstances where they can become a deceased organ donor<sup>2</sup>.

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.

Authorisation is an important factor which often affects whether donation, and ultimately transplantation, can proceed. Although Scotland has the highest proportion of people registered on the NHS Organ Donor Register (ODR) in the UK (46%<sup>1</sup> compared to a UK average of 38%<sup>3</sup>), surveys show that the majority of Scots support donation<sup>4</sup>. We know, 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) the family overrode the authorisation the person had previously given<sup>5</sup>. It is important, therefore, to look at ways in which we 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.

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 they have authorised donation before they died, or if their nearest relative authorises the donation on their

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

<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.

<sup>3</sup> [https://nhsbtdeb.blob.core.windows.net/umbraco-assets/1616/united\\_kingdom.pdf](https://nhsbtdeb.blob.core.windows.net/umbraco-assets/1616/united_kingdom.pdf)

<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'.

<sup>5</sup> Data provided by NHSBT

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. This would mean that where the person was not known to have expressed 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’).

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).

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 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*<sup>6</sup> (the Plan). The introduction of a soft opt out system of donation will add to these existing efforts.

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.

## 2.2 Background

To support and encourage donation a range of non-legislative measures are already being taken forward. In 2013, the Scottish Government published *A Donation and Transplantation Plan for Scotland 2013-2020* which sets out the ways in which the Scottish Government hopes to improve donation and transplantation in Scotland. It builds on the progress made by implementing the recommendations of the UK Organ Donation Taskforce. The monitoring of implementation of the Plan is overseen by the Scottish Donation and Transplant Group.

The Plan identifies five priorities the Government wishes to deliver: increasing the number of people who have made their wishes about organ donation known; increasing the availability of organs; making every donation count; ensuring NHSScotland supports donation and transplantation; and ensuring the public in Scotland is informed and engaged about donation and transplantation. Significant progress has been made in increasing numbers and delivering meaningful improvements through recommendations in the Donation and Transplant Plan, for example:

- high profile publicity campaigns to encourage people to join the Organ Donor Register;
- internationally recognised schools educational resource pack to increase awareness of pupils about organ and tissue donation;
- work with Kidney Research UK which trains volunteers from South Asian communities to

<sup>6</sup> <http://www.gov.scot/Resource/0042/00427357.pdf>

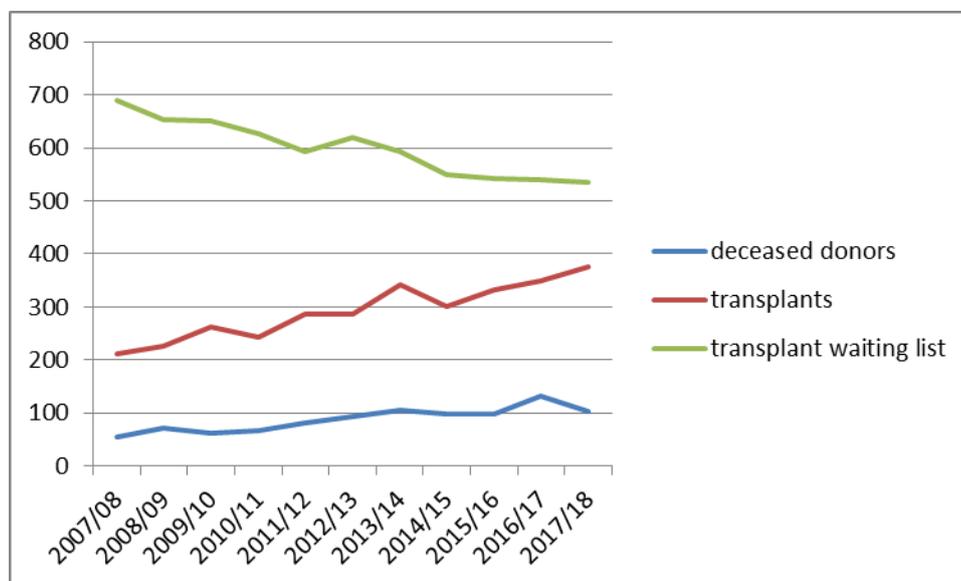
- become peer educators to increase awareness of kidney disease and organ donation;
- dedicated regional manager for Scotland to manage the Specialist Nurses for Organ Donation and to take forward key initiatives to help increase donation.

Since the start of the plan of improvement in 2008 there has been:

- an 89% increase in deceased donor numbers in Scotland (up from 54<sup>5</sup> to 102<sup>1</sup>)
- a 78% increase in the number of lifesaving transplant operations from deceased donors undertaken for patients living in Scotland (from 211<sup>5</sup> to 375<sup>1</sup>)
- a 22% decrease in the number of people resident in Scotland on the active transplant waiting list (689<sup>5</sup> to 534<sup>1</sup>).

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 donors<sup>1</sup> 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 we continue to do all we can to increase donation and transplantation.

**Figure 1: changes in number of deceased organ donors in Scotland, transplants and those on the waiting list over time<sup>5</sup>**



### 2.3 Rationale for Government intervention

The Purpose of the Scottish Government is to focus Government and public services on creating a more successful country, with opportunities for all of Scotland to flourish, through increasing sustainable economic growth. Encouraging people to support organ and tissue donation and increasing the number of donors will contribute to realising our Purpose by contributing to two of our

## Strategic Objectives:

- **HEALTHIER** - The introduction of a soft opt out system of organ and tissue donation aims to support a Healthier Scotland and in particular support the Purpose target of increasing healthy life expectancy in Scotland.
- **WEALTHIER & FAIRER** - It will also to some extent, over the longer term, help support the Purpose target of maintaining our position on labour market participation as the top performing country in the UK. This is because increasing the number of transplants undertaken will allow more people to get back into work.

## 2.4 Evidence Base to Establish Impact of Proposed Legislation

The evidence presented in this section is based on a rapid evidence review undertaken by Scottish Government [Opt Out - Organ Donation: A rapid evidence review](#)

### 2.4.1 International evidence on the impact of opt-out

The international evidence suggests that as part of a range of measures opt out systems can increase both deceased donation and transplant<sup>7</sup>. However, there is little robust evidence that demonstrates that opt out legislation **alone** will increase deceased organ donation and transplant. The evidence highlights the importance of non-legislative factors<sup>89</sup>, which can work effectively in both, opt out and opt in systems.

This section outlines research which suggests opt-out is effective and outlines its limitations.

A wide range of international evidence highlights that there is an association between countries with opt out legislation and higher rates of deceased organ donation and greater willingness to donate<sup>1011</sup>. Illustrating that opt out systems can be successful. There is however a degree of uncertainty as to the size of these associated increases, with studies reporting opt-out legislation is associated with increases in deceased organ donation rates of 13 – 18 %<sup>12</sup> and 25 – 30%<sup>13</sup>. In contrast, several countries with the lowest numbers of deceased donors in Europe (Bulgaria, Turkey, Cyprus and Greece), also have opt out<sup>14</sup> which might indicate that that opt-out alone does not always lead to a high level of donations and that the relationship is more complex and dependent on other factors. Evidence as to why opt out has not been as successful in some nations as others is limited, but Bilgel (2012) study suggests that the impact of the opt out legislation in Greece was limited by a lack of medical staff and transplant units. The impact of infrastructure changes is discussed further below.

<sup>7</sup> Welsh Government, “Opt out organ donation: An international review,” Welsh Government, 2012.

<sup>8</sup> 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.

<sup>9</sup> Welsh Government, “Opt out organ donation: An international review,” Welsh Government, 2012.

<sup>10</sup> Welsh Government, “Opt out organ donation: An international review,” Welsh Government, 2012.

<sup>11</sup> Abadie, A, Gay, S, “The impact of presumed consent legislation on cadaveric organ donation: A cross country study,” in *NBER*, 2004.

<sup>12</sup> Bilgel, F, “The effectiveness of transplant legislation, procedures and management,” *Health Policy*, vol. 110, pp. 229 - 242, 2013.

<sup>13</sup> Abadie, A, Gay, S, “The impact of presumed consent legislation on cadaveric organ donation: A cross country study,” in *NBER*, 2004.

<sup>14</sup> Palmer, M. & Jones, I., 2012. *Opt-out systems of organ donation: International evidence review*, Cardiff: Welsh Government

Whilst a few before and after studies provide some indication of success, these are limited and it is not possible to rule out the influence of other known or unknown factors<sup>15</sup>. Often changes to opt-out system occur with other changes, such as increased infrastructure changes, making it impossible to establish the impact of the legalisation alone. Rithalia et al (2009)<sup>16</sup> identified five before and after studies, which represented the experience of three different countries: Austria, Belgium and Singapore. Following the introduction of opt out organ donation legislation the studies found an increase in organ donation rates. The evidence of increase in organ donation in Austria was from 4.6 to 10.1 donors per million population per year in the four years after the introduction of presumed consent. However the largest increase was to 27.2 per million in the five years after introduction of infrastructure changes, such as full time transplant coordinators. The study therefore indicates that whilst presumed consent legislation change can influence an increase in organ donation registration, it cannot be viewed as a panacea; infrastructure changes seem to have a greater impact on organ donation.

Experimental research conducted in artificial setting provides some indications of how opt-out potentially increases donations<sup>17 18</sup>. Potentially, individuals in opt out systems attribute less personal cost to donating their organs than in opt in systems, and simply framing organ donation as the default may increase individuals' willingness to donate. Caution should be applied when applying this evidence to real world settings.

There is encouraging evidence to support the use of opt out, however it is currently impossible to infer that an increase is due to the opt out legislation alone and the evidence highlights the importance of other factors in driving increases.

### **Other important factors**

Evidence suggests that in order for opt out to be effective in contributing to an increase in donation rates it has to work as part of a package of measures<sup>1920</sup>. Family consent, use of a register, media coverage, public/staff support and staff training have all been suggested as important factors in ensuring the success of opt-out. Further, it is important to guard against any harm to the progress made so far as international experience shows that if it is not implemented carefully donation rates can be negatively impacted. Chile experienced an increase in family refusals and a decrease in donation rates following the implementation of opt-out legislation<sup>21</sup>. 70% of the population were unaware of the legislation change and this was highlighted as a key factor in the lack of success of the legislation<sup>22</sup>. Moreover, Brazil had to withdraw the implementation of its opt-out legislation largely due to an increase in medical mistrust and public anxiety<sup>23</sup>.

<sup>15</sup> Rithalia, A. et al., 2009. A systematic review of presumed consent systems for deceased organ donation. *Health Technology Assessment*, 12(26).

<sup>16</sup> Rithalia, A. et al., 2009. A systematic review of presumed consent systems for deceased organ donation. *Health Technology Assessment*, 12(26).

<sup>17</sup> Davidai, S. Gilovich T. Ross, L, "The meaning of default options for potential organ donors," *PNAS*, vol. 109, no. 38, pp. 15201-15205, 2012.

<sup>18</sup> Dalen, H and Henkens, K, "Comparing the effects of defaults in organ donation systems," *Social Science & Medicine*, vol. 106, pp. 137 - 142, 2014.

<sup>19</sup> Welsh Government, "Opt out organ donation: An international review," Welsh Government, 2012

<sup>20</sup> 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.

<sup>21</sup> Dominguez, J and Rojas, J, "Presumed Consent Legislation Failed to Improve Organ Donation in Chile," *Transplantation Proceedings*, vol. 45, pp. 1316 - 1317, 2013.

<sup>22</sup> World Health Organization, "Increasing organ donation by presumed consent and allocation priority: Chile," *Bulletin of the World Health Organization*, vol. 93, pp. 199 - 202, 2015.

<sup>23</sup> Csillag, C, "Brazil abolishes "presumed consent" in organ donation." *Lancet*, pp. 352-1367, 1998.

Currently, Spain has the highest rate of organ donors in the world and utilises an opt-out system which was introduced in 1979. However, the rate of organ donation only increased, from 14.3 to over 43.4 donors per million population in 2016, with the creation of Organizacion Nacional de Trasplantes in 1989. In particular, the introduction of well-trained transplant coordinators and public health campaigns helped influence this dramatic increase in deceased donors; suggesting infrastructure could be a primary factor in the increase.

It is clear from the evidence that both context and non-legislative measures are important in the success of organ donation systems, but there are positive indications to suggest that opt-out legislation can contribute to increasing deceased donation as part of package of wider measures. Further detail on the evidence can be found in a rapid evidence review undertaken by Scottish Government in 2018 'Opt out organ donation: A rapid evidence review'.

#### **2.4.2 Evidence from Wales**

The *Evaluation of the Human Transplantation (Wales) Act: Impact Evaluation Report*<sup>24</sup> which was published on 30 November 2017 suggests that a longer period of time is needed to draw firmer conclusions around the impact of the change in the law. The evaluation found that there had largely been limited impact on deceased donation, although it recognised that the timeframe since implementation was insufficient to firmly establish this.

Evidence from Wales shows that prior to the introduction of the opt out system in Wales in December 2015, there had been an increase in the number of people who have opted in to the NHS organ donor register. In 2014/2015 the share was 34% of the Welsh population. The increased continued post opt out and in 2015/2016 the share was 36% of the population; further increase was experienced in 2016/2017 with a share of 38% of the population. However, it is too soon following the introduction of the system in Wales to determine whether the increase can be attributed to introduction of the legislation. Overall public awareness of the legislation also increased.

Associated with the change in legislation there has also been an increase in the percentage of people who have opted out on the organ donor register. 2014/2015 the percentage was 0% of the population; (as there was no option to opt out); in 2015/2016 the percentage increased to 5% of the population and in 2016/2017 the percentage further increased to 6% of the population opted out. Although this number is increasing, slightly, this suggests that people are able to make an informed decision about whether or not to opt out.

The overall consent rate for deceased donation in Wales has increased from 54% in 2013/14 to 64% in 2016/17. It is still too early to judge the impact on deceased donor rates; it is also difficult to estimate how much of this change is due to the introduction of the legislation and the communication campaign that was introduced with it. Overall the Welsh study concludes that it is too soon to draw firm conclusions.

#### **2.4.3 Public opinion**

The most recent Scottish survey shows that the majority of the public are supportive of an opt out system. The TNS survey 2016 found that 59% agreed that "everyone should be presumed to be willing to be a donor unless they register a wish otherwise".

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%

<sup>24</sup> The Welsh Government. *Evaluation of the Human Transplantation (Wales) Act: Impact Evaluation Report*. 2017.

were against. A further 21% said they ‘needed more information to decide’. Another Wales-based survey indicated a greater proportion of respondents supported the move to an opt out system than were against it. The Welsh Government also conducted public surveys where they found that the public support in Wales for opt out increased after implementation of the legislation, from 49% in 2012 to 67% in 2015. Therefore this suggested that the Welsh public were supportive of opt out prior to legislation change.

However some groups within the population were not so supportive of the legislation change. In 2010 interviews with UK leaders of the main faith and belief organisations found that the majority supported an opt in system and wanted to retain this over an opt-out system<sup>25</sup>. There is insufficient data on the representative views of the religious populations themselves due to the small numbers involved and caution should be applied in drawing inferences. Although a survey of Western Muslims (British, European, North American and Oceanic geography) on attitudes to organ donation found that only 26% of respondents agreed with the concept of presumed consent (or ‘opt out’). This compared with 55% who did not, and 20% who did not know<sup>26</sup>.

### **3.0 CONSULTATION**

#### **3.1 Within Government**

As well as Better Regulation Unit and Health and Social Care Analysis, Health Protection Division had direct contact and discussion with the following divisions and agencies which has informed the development of the proposals:

- SG Family and Property Law
- SG Looked After Children Unit
- SG Adults with Incapacity Policy Review
- SG Cohesive Communities
- NHS Blood and Transplant (NHSBT)
- Scottish National Blood and Transfusion Service (SNBTS)
- NHS National Services Division
- NHS Health Scotland
- NHS Healthcare Improvement Scotland (Scottish Health Council)
- Population Healthcare – Welsh Government
- Population Health – UK Government

#### **3.2 Public Consultation**

The Scottish Government carried out a public 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.

<sup>25</sup> Randhwa, G, Brocklehurst, A, Pateman R, Kinsella S and Parry V, “‘Opting-in or opting-out?’—The views of the UK’s faith leaders in relation to organ donation,” *Health Policy*, vol. 96, pp. 36 - 44, 2010.

<sup>26</sup> Sharif, A; Jawad, H; Nightingale, P; Hodson, J; Lipkin, G; Cockwell, P; Ball, S; and Borrow, R (2011) ‘A quantitative survey of Western Muslim attitudes to solid organ donation’, *Transplantation Vol 92:10*

Notification of the consultation was sent to 260 stakeholder groups and the consultation was launched by Aileen Campbell MSP, Minister for Public Health and Sport and accompanied by a news release which received wide media coverage in newspapers and broadcast news.

The consultation responses were independently analysed and the analysis was published on 28 June 2017 [Analysis of Responses to Consultation on Organ and Tissue Donation and Transplantation](#)

There were a total of 824 responses to the consultation, including a petition with 18,500 signatures in support of moving to an opt out system (which was counted as a single response). A significant number of respondents were individuals (95%).

The consultation responses showed strong support for moving to a soft opt out system from individuals (84%) and overall (82%). The responses from organisations, including those representing health professionals, are more mixed (53% support) but where this is not support, or no view on opt out in principle, there remains support for the system as proposed in the consultation if it is introduced.

### **3.2.1 Qualitative research**

In addition to the public consultation, Focus groups were carried out with young people and people with learning difficulties to understand what they thought about particular elements of the proposals and what should be taken into consideration as they are developed. The focus groups were facilitated by the Scottish Health Council and a summary of each group is below. Link to full report [Gathering Views on Organ Donation](#)

#### Young people

Two groups took part. Overall the first group felt organ and tissue donation and transplantation was an important issue and they were in favour of the soft opt out system. They agreed that 16 was an appropriate age to give authorisation to donate; however they felt that it was still important for younger teens to learn about organ donation and have discussions with their parents. It was also thought to be essential that people have the right to change their mind at any time. All participants thought it was a good topic to learn more about and would like to be kept informed through school, social media, adverts and a formal letter informing them (should the soft opt out system go ahead).

The second group also found the topic interesting and important and indeed something young people should have an opinion on and to have that opinion heard. Whilst the general feeling of the group was that the age groups identified in the proposal seemed to be right, some participants thought that “maturity” was more important than age in being able to make such decisions. The group felt that it was important to be able to change your mind and it was equally important that parents should respect the wishes of their children. In relation to updating them with information, it was identified that perhaps the message should continue to be dispersed in a range of ways, including the range of social media used by this age group, structured sessions during school sessions and by using the Young Scot rewards website.

#### People with learning difficulties

People First worked with the Scottish Health Council to carry out two focus groups. The participants in the first group had an interest in the topic of organ donation and would welcome the opportunity to discuss it in their own group and with their family and friends. They also acknowledged that there needs to be more conversation in general about major health issues and decisions, such as organ donation or blood donating, etc. This should come from the Scottish Government in conjunction with

the local NHS health board. They unanimously agreed that any printed media must be in an easy ready format (prepared in consultation with those with learning difficulties). The group also felt that “supported decision making” must be taken into consideration, so that the individuals can make an informed decision, and not feel that their families are taking ownership.

The second group thought it was important that people should have a choice and there should be more done to increase the awareness of donation so families have the conversation and make a choice and it is not left to the bereaved family member. The group thought that it feels slightly ‘forced’ upon if put in to law. The group thought it was important that information is in a format that is easier to understand, rather than it being assumed that people cannot understand it. The group thought family members or advocates could have a conversation with individuals about donation in a way that is understood, or medical professionals could do the same and add the decision onto medical records. The group suggested lots of ways to communicate the change, including through talking mats and organisations like People First. The group advised against relying on social media alone as some people don’t have access, and thought although it might be a good idea, giving information out when people fill in forms on other issues may cause stress. The group thought a ‘blanket’ letter similar to those about voting in elections would be unhelpful.

### **3.3 Business consultation**

It is not envisaged that the legislation will result in any impacts on businesses.

## **4.0 OPTIONS**

### **4.1 Sectors and groups affected**

#### **Background**

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.

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.

## **4.2 Costs and Benefits**

As a result of the introduction of the Bill it is anticipated that the organisations and individuals affected will include: families of donors, recipients, families of recipients, the Health Service (transplant facilities including staff and other hospital services), wider society and government. The costs and benefits of a change of legislation for organ donation will be wider than just the operational costs and benefits that a potentially wider pool of authorised donors will have. The costs and benefits will also apply to potentially extending the life of additional organ recipients. A range of economic and financial costs and benefits have been presented below for the different options.

**Option 1 - Do nothing.** The do nothing option will not alter the status quo in legislative terms. This option will provide the baseline against which the impact of the introduction of this legislation will be measured.

### **Option 2 – Soft opt-out system for organ donation.**

This option proposes a soft opt out system for organ and tissue donation. Under this option adults (except for those in certain categories) could be deemed to have authorised donation if they have not opted out, but it allows for family members to advise of any objection the individual had to donation; meaning that donation wouldn't proceed if the potential donor would not have been willing to donate.

It is not possible to identify with any certainty the impact on organ donor numbers and transplants as a result of the opt out system. Any increase could also be attributable to other measures underway to increase organ donation and transplantation, for example: the use of novel technologies. Therefore, growth might not necessarily be directly attributable to the introduction of the opt-out system. Nevertheless, a cost benefit analysis has been undertaken which estimates the number of additional donors which may be attributed to an opt-out system can be found below.

For the purposes of this analysis, increases in activity are assumed to be as a result of the policy only, and are net of any long term trend or targets. Note that, any increase in activity is assumed to take place in the first year after implementation and is then assumed to be constant (a constant incremental difference from the baseline) in subsequent years. This is due to the underlying complexities and year-on-year variation which make it difficult to predict more accurate long-term trends.

### **Costs**

The financial cost of the Bill will fall mostly to the Scottish Government through direct funding of public information across the population and costs of evaluation of the opt out system. Other costs will fall to bodies funded indirectly by the Scottish Government i.e. NHS Blood and Transplant (NHSBT), which is responsible for the NHS organ donor register, for Specialist Nurses for Organ Donation, for retrieval services across the UK and for eye donation, NHS National Services Scotland's Scottish National Blood Transfusion Service (SNBTS), which is responsible for tissue services (excluding eye donation) and its National Services Division (NSD), which commissions transplant services for Scottish Patients.

The NHS Blood and Transplant (NHSBT) and the Scottish National Blood Transfusion Service

(SNBTS) have provided an assessment of the likely impact of an introduction of a presumed authorisation system – or soft-opt out – for organ and tissue donation in Scotland.

The analysis presented here utilises 3 main scenarios:

- Low estimate: the “do nothing” scenario which sees no increase in donors or transplants
- Best estimate: the central estimate of NHSBT’s modelling, in which the authorisation rate in Scotland increases to 65%, with an estimated **12 new donors, and 28 successful organ transplants per annum.**
- Upper estimate: also based on NHSBT’s estimate under a 65% authorisation rate, but utilising the upper end of the possible range, with an estimated **24 new donors and 59 successful organ transplants per annum.**

In order to capture the impact of the proposed new system for organ donation it is necessary to measure what the costs and benefits of this change will be in relation to option one or ‘do nothing’ option. This is in effect the baseline or ‘counterfactual’ against which we will assess the impact of option 2 (the ‘preferred option’).

Future projections of costs were discounted at 3.5<sup>27</sup>% and benefits, measured in Quality Adjusted Life Years (QALYs) at 1.5<sup>28</sup>% to derive Present Costs and Present Values.

The costs of the Bill are predicated on the costs of preparation for implementation of the soft opt-out system. As such, Year One (2019-20) will consist of a preparation and implementation phase for training public awareness etc. with implementation at some point during Year Two (2020-21). Please note that for costings purposes, a start date for the implementation of opt out of 1 April 2020 has been assumed, although implementation may well start later in that year (in which case there would be a proportionate reduction in the recurring costs for 2020-21).

## Public Information

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 organ donor register. The campaigns are supplemented throughout the year by targeted information, for example for students, on-going social media activity, an internationally-recognised schools educational pack and work undertaken by Kidney Research UK peer educators to raise awareness of organ donation among South Asian communities, as well as information being provided at public events.

In addition to the current duty, the Bill will also require Scottish Ministers to promote public awareness of the implications of the circumstances in which authorisation may be deemed. This 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 and on a regular basis after implementation of the legislation.

In developing public information, research will be undertaken to gauge people’s understanding of the

<sup>27</sup> As per Treasury Green Book Guidance

<sup>28</sup> Following Department of Health guidance

opt out system and to ensure accessibility for different groups e.g. people with disabilities 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. Focus groups held with school pupils, 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.

For children about to reach the age of 16 there will also be a need to provide information on an on-going basis about the organ and tissue donation system e.g. through direct mailing so that they are aware of the implications. Feedback from focus groups with young people identified individual mailing as one of the preferred methods of communication.

Costs on the Scottish Government for public information and awareness raising for the new system, including pre commencement awareness (Year 1 and 2), are estimated in Table 1.

<b>Table 1</b>	<b>Year 1 2019-20 £ (m)</b>	<b>Year 2 2020-21 £ (m)</b>	<b>Year 3 2021-22 £ (m)</b>	<b>Year 4 2022-23 £ (m)</b>	<b>Year 5 2023-24 £ (m)</b>	<b>Total</b>
*Public information: development and delivery	0.45	1.405	0.535	0.425	0.275	<b>3.09</b>

\*These figures are additional to the £0.250 already allocated annually for public information under the current system. Year 6 costs are estimated at £0.275. From year 7 recurring costs will be approximately £0.425 which includes the £0.250 already allocated under the present system.

- Year 1 includes - research, evaluation design of materials including engagement with organisations to develop and test materials for the general public and specific groups, and production of all materials required for campaign delivery.
- Year 2 includes - direct mailing to all households at a cost of approximately £800,000, and additional media for public information at a cost of approximately £400,000
- Year 3 includes - public information campaign and direct mailings to those about to reach their 16<sup>th</sup> birthday at an approximate cost of £200,000 around 50,000 people and additional media for public information at a cost of approximately £300,000.
- Years 4, 5 - includes additional media (approximately £200,000 and £100,000 respectively).

### *Evaluation*

Organ donation and transplantation rates are subject to on-going monitoring. Information gathered and published by NHSBT is used to identify trends in authorisation and qualitative information for example: analysis of approaches by Specialist Nurses for organ donation will be used to gauge understanding by donor families of the system, as well as being used to inform training and improvement.

In addition, representative surveys to track public understanding and attitudes toward donation will be undertaken, including using information currently gathered as part of the evaluation of public information campaigns. The effectiveness of the processes in place as a result of the legislation will be evaluated through a process evaluation, used to improve implementation. The additional costs associated with evaluating the impact of the legislation will fall on the Scottish Government and have

been estimated as £91,500 spread over years. An impact evaluation will be conducted over a 10 year period to establish the impact of the new system.

## **Costs on Other Bodies, Individuals and Businesses**

### *NHS Blood and Transplant*

While Scotland has its own legislation governing deceased organ and tissue donation, the Organ Donor Register, 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, offering, acceptance and retrieval of organs for transplantation on a UK-wide basis. While this means that some organs from donors in Scotland go to people in other parts of the UK, it also means that people in Scotland receive organs from elsewhere in the UK. In the three years from April 2014 to March 2017, 44% of organs from deceased donors in Scottish hospitals went to transplant units in Scotland.

### *NHSBT Implementation costs (Table 2)*

The Scottish Government provides funding to NHSBT for these services via funding provided to NHS National Services Scotland's National Services Division. It is estimated that NHSBT will incur costs for implementation of the soft opt out system estimated at £376,000 in year 1 and 2. The costs include £163,000 for development and delivery of training; including a half time project management/training and development post in the lead up to and for one year following implementation of the soft opt out system. This position will ensure that clinical staff directly involved in the donation and transplantation process are trained and understand the soft opt out system. It will also be responsible for wider engagement with Organ Donation Committees and clinical teams across NHS Boards not directly involved in organ donation, to raise awareness of the opt out system; ensuring consistent messages and information. Additional costs of £213,000 have been factored in for training of the Organ Donor Register call centre staff and additional mailing, based on experience from the introduction of the system in Wales associated with increased registrations on the Organ Donor Register (both from those opting in and opting out).

However, the recent announcement by the UK Government that it will support legislation aimed at introducing an opt out system in England has resulted in an increase across the UK in registrations to opt out of organ and tissue donation on the assumption that the law in Scotland and England has already changed. This may potentially require some of the anticipated costs resulting from the Bill for the Organ Donor Register staff and additional mailing to be brought forward in part, including potentially incurring some additional costs ahead of Parliamentary consideration. This may however be necessary to make sure that any opt out registrations are processed promptly in order to ensure the Register is always up to date. The workload of the ODR team will continue to be monitored closely with NHSBT.

### *NHSBT Recurring costs (Table 2)*

To reflect lessons from the introduction of the soft opt out system in Wales, NHSBT intends to introduce the role of Specialist Requester to help with the introduction of opt out. This is with the intention of maximising authorisation from the start; learning lessons from the experience of introducing opt out in Wales. A lower level of approaches to families was experienced in Wales in potential deemed authorisation cases. (This was at the same time triage and screening was introduced so all UK approach rates went down at this time). Recent pilot schemes of specialist requesters have

shown an increase in authorisation rates under the current “opt in” system in England, in particular where requesters have been involved in significant numbers of approaches to families.

Currently Specialist Nurses for Organ Donation (SNOD) lead on the whole organ donation and much of the tissue donation process from solid organ donors, from the approach to the family to the point the dispatch of organs to transplant units. The Specialist Requestor would assume the role of navigating and supporting the family through the authorisation process. Doing so would allow the SNOD to focus on the clinical side of the process where donation is authorised, for example: arranging the appropriate tests and donor characterisation, liaising with transplant centres and co-ordinating the organ retrieval process. Specialist requester resource would be expected to start in 2019-20 in order to allow for training and development of experience prior to the introduction of an opt out system, with an anticipated recurring cost of up to £257,000 per annum.

Provisional recurring costs of up to have also been factored in to cover the increased registrations on the Organ Donor Register and to cover any additional costs which may arise from a potential increase in non-proceeding donors (where the donation is authorised and the retrieval team travel to the hospital, but unfortunately it is unable to proceed).

Recurring costs of £114,000 per annum from 2020-21 have been included for increased retrieval team and SNOD activity.

The phasing of costs reflect the need to be prepared in advance of commencement of the soft opt out system.

<b>Table 2</b>	<b>Year 1 2019-20 £ (m)</b>	<b>Year 2 2020- 21 £ (m)</b>	<b>Year 3 2021-22 £ (m)</b>	<b>Year 4 2022-23 £ (m)</b>	<b>Year 5 2023-24 £ (m)</b>	<b>Total £ (m)</b>
<b>Non recurring costs</b>						
Implementation (one off)	0.330	0.046	0	0	0	0.376
<b>Total</b>	<b>0.330</b>	<b>0.046</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0.376</b>
<b>Recurring costs</b>						
Specialist requestors	0.257	0.257	0.257	0.257	0.257	1.285
ODR team - additional staff & mailing costs	0.040	0.040	0.040	0.040	0.040	0.2
Retrieval team costs - transport & consumables (up to)	0	0.085	0.085	0.085	0.085	0.340
SNOD costs (extra on call & transport costs) (up to)	0	0.029	0.029	0.029	0.029	0.116
Additional Retrieval & SNOD costs for non-proceeding donors (up to)	0	0.037	0.037	0.037	0.037	0.148
<b>Total recurring</b>	<b>0.297</b>	<b>0.448</b>	<b>0.448</b>	<b>0.448</b>	<b>0.448</b>	<b>2.089</b>
<b>Grand total</b>	<b>0.627</b>	<b>0.494</b>	<b>0.448</b>	<b>0.448</b>	<b>0.448</b>	<b>2.465</b>

Note – recurring costs are subject to a number of uncertainties and therefore are estimates only. In particular, costs for retrieval teams and SNOD on call and transport costs, along with the additional

costs for non-proceeding donors, will be subject to negotiation with NHSBT and the other UK health departments. Based on NHSBT estimates for additional donors due to the opt out system, it should be possible to manage donation for these donors within existing resources. However, as previously noted, there would also be expected to be additional donors not resulting from the opt out system (due to other initiatives being undertaken). Therefore, when the additional anticipated donor numbers due to opt out are combined with other additional donors, there may be a need for additional funding as indicated in the table to cover the opt out costs.

Over the longer term opt out is expected to increase numbers of eye donors in Scotland in order to help meet demand. Currently Scotland imports more corneas from the rest of the UK for patients in Scotland than are provided by Scottish deceased donors – for example in, 2016/17, 282 corneas were donated in Scotland, but 338 corneal transplants were performed for patients resident in Scotland. However, other than training for staff (which is covered in the overall training costs for NHSBT) there are not expected to be additional costs associated with this as NHSBT charges hospitals for providing corneas for transplant on a cost recovery basis.

### *Scottish National Blood Transfusion Service (SNBTS) (Table 3)*

SNBTS, part of NHS National Services Scotland, is responsible for retrieval, processing and storage of tissue in Scotland (excluding eyes for which donation processes are currently managed by NHSBT). The main tissue retrieved from deceased donors in Scotland by SNBTS is tendons and heart valves. SNBTS also receives deceased donor pancreata for processing into islet cells for transplant. The current supply of tendons is largely sufficient to meet demand in Scotland and therefore there are no plans to increase current rates of tendon retrieval. However, there is strong demand for heart valves, in particular pulmonary valves, as demand in Scotland is likely to increase in future. Therefore SNBTS would hope to work with NHSBT (as many tissue donors are also organ donors) to increase heart valve retrieval in Scotland.

Costs identified reflect the need for preparation for implementation

<b>Table 3</b>	<b>Year 1 2019-20 £ m</b>	<b>Year 2 2020-21 £ m</b>	<b>Year 3 2021-22 £ m</b>	<b>Year 4 2022 -23 £ m</b>	<b>Year 5 2023-24 £ m</b>	<b>Total £ m</b>
*Staff costs and training - up to	0.062	0.118	0.118	0.231	0.231	0.76
*Test & Consumables - up to	0.009	0.018	0.018	0.036	0.036	0.117
<b>Total</b>	<b>0.071</b>	<b>0.136</b>	<b>0.136</b>	<b>0.266</b>	<b>0.266</b>	<b>0.875</b>

### Assumptions

- Year 1- Staff costs - funding at 50% (assumes staff would be appointed mid-way through the year to allow for training and getting up to speed).
- Year 1-3 - 1 whole time equivalent (WTE) Nurse band 6 for and increase to 2 WTE in Year 4
- Year 1-3 - 1.5 WTE Scientist band 6 for and increase to 3.0 WTE in Year 4

\*Staffing and consumables costs will increase in accordance with activity

## *Costs of Transplantation*

All solid organ transplant services in Scotland are nationally commissioned through NHS National Services Scotland's National Services Division (NSD). Indicative targets for deceased and living organ donation were agreed between NHSBT and the four UK Health Departments until 2019/20. The indicative target to 2020 was 606 transplants for Scottish patients, for which funding is nominally allocated to Scottish units (funding for more rare types of or paediatric transplants carried out with Scotland is normally paid on a one-off basis to the unit carrying out the transplant). As noted, organs from deceased donors are allocated on a UK-wide basis. Therefore, while some organs from Scottish donors are allocated to patients living in Scotland, any increase in Scottish deceased donor numbers would not lead to a proportionate increase in Scottish transplant numbers as Scottish transplant numbers depend on deceased donor numbers across the UK as a whole. It is therefore unlikely that the introduction of a soft opt out system in Scotland would in the first few years result in transplant units exceeding 606 transplants for Scottish patients as this would require both a significant increase in deceased donors and the number of organs per donor which could be used. For example in 2016-17 there were 431 patients in Scotland who received transplants (348 of which were from deceased donors), although for planning purposes units were resourced to meet an estimated target of 527 transplants for Scottish patients (413 of which were anticipated to be from deceased donors). Therefore, while there is still significant work for units in preparing for deceased donor transplants which unfortunately do not proceed for a range of reasons, there should still be some capacity for units to increase the number of transplants carried out with current planned resourcing levels.

This will be reviewed in planning future transplant numbers and resource requirements beyond 2020 in preparing a successor to NSD's commissioning strategy 'Commissioning Transplantation to 2020<sup>29</sup>', particularly as other developments e.g. in other parts of the UK or in the use of novel technologies, have the potential to increase transplant numbers beyond the estimated additional transplant numbers due to the opt out system.

Similarly NHSBT, which co-ordinates organ retrieval for Scotland is funded to carry out more retrievals than currently take place, in line with the 2020 deceased donor targets. Therefore it is unlikely in the short term that retrievals will increase beyond the level currently funded and whilst these have been estimated for in Table 2 for year 2 they will be subject to negotiation.

### **Five Year Discounted Cost Projections based on potential impact of an opt out system of donation**

The main costs surrounding the implementation of the soft opt-out system are derived from the need for awareness raising and education and from increases in resourcing costs for NHSBT and SNBTS.

It is assumed that, even for the baseline scenario, there would be an associated increase in costs from current activity, due to the fact that provisions in staffing would be made for implementation, even though these would result in no additional transplants (worst case scenario). The best estimate and higher estimate scenarios assume higher staffing and non-staffing recurring cost requirements associated with increased activity.

Total transplant costs were based on estimates on average costs per case provided by National Services Division of £61,956 per transplant. For the reasons set out above, we have not assumed additional costs for transplantation will result from the opt out system alone in the first couple of years. However, taking account of the fact that there are likely to be additional transplants not relating to opt out in addition to approximately 28 per year attributed to the opt out system, it is estimated that additional real terms funding may be needed from year 4 onwards to account for units being unable to increase transplantation further without additional resources. This will be discussed further with

<sup>29</sup> See <http://www.nsd.scot.nhs.uk/publications/ServiceReviews/CTT2020%20final%20report.pdf>

transplant units.

Total awareness raising and campaign costs were provided by Scottish Government and include media, public relations, production of promotion materials and other items.

Total evaluation costs include attributable costs of the Social Attitudes Survey and anticipated periodic costs for process evaluation, were supplied by Health and Social Care Analysis.

Future projections of costs were discounted at 3.5<sup>30</sup>% to derive an overall estimate of Present Cost in years one to five. These range from £5.27m for the baseline, to £13.74 m for the best estimate, up to £22.54 m for the high estimate scenarios.

### Baseline – no incremental change

Baseline estimate (low/now incremental change in transplants) £m	yr1	yr2	yr3	yr4	yr5	total non- discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
NHSBT - Total Non-Recurring Costs	£0.33	£0.05	£0.00	£0.00	£0.00	£0.38
NHSBT - Total Recurring Costs	£0.30	£0.30	£0.30	£0.30	£0.30	£1.48
<b>NHSBT - Total</b>	<b>£0.63</b>	<b>£0.34</b>	<b>£0.30</b>	<b>£0.30</b>	<b>£0.30</b>	<b>£1.86</b>
SNBTS - Staff total	£0.06	£0.12	£0.12	£0.12	£0.12	£0.53
SNBTS - Non-staff total	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00
<b>SNBTS - Total</b>	<b>£0.06</b>	<b>£0.12</b>	<b>£0.12</b>	<b>£0.12</b>	<b>£0.12</b>	<b>£0.53</b>
<b>Total transplant cost</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>
<b>Total awareness raising campaigns costs</b>	<b>£0.45</b>	<b>£1.41</b>	<b>£0.54</b>	<b>£0.43</b>	<b>£0.28</b>	<b>£3.09</b>
<b>Total evaluation costs</b>	<b>£0.02</b>	<b>£0.04</b>	<b>£0.03</b>	<b>£0.01</b>	<b>£0.00</b>	<b>£0.09</b>
<b>Annual total, non-discounted</b>	<b>£1.16</b>	<b>£1.90</b>	<b>£0.98</b>	<b>£0.85</b>	<b>£0.69</b>	<b>£5.57</b>
<b>Annual total, discounted at 3.5%</b>	<b>£1.16</b>	<b>£1.84</b>	<b>£0.91</b>	<b>£0.76</b>	<b>£0.60</b>	
<b>Present Cost years 1-5</b>						<b>£5.27</b>

### Best estimate

Best estimate £m	yr1	yr2	yr3	yr4	yr5	total non- discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
NHSBT - Total Non-Recurring Costs	£0.33	£0.05	£0.00	£0.00	£0.00	£0.38
NHSBT - Total Recurring Costs	£0.30	£0.45	£0.45	£0.45	£0.45	£2.09
<b>NHSBT - Total</b>	<b>£0.63</b>	<b>£0.49</b>	<b>£0.45</b>	<b>£0.45</b>	<b>£0.45</b>	<b>£2.46</b>
SNBTS - Staff total	£0.06	£0.12	£0.12	£0.23	£0.23	£0.76
SNBTS - Non-staff total	£0.01	£0.02	£0.02	£0.04	£0.04	£0.12
<b>SNBTS - Total</b>	<b>£0.07</b>	<b>£0.14</b>	<b>£0.14</b>	<b>£0.27</b>	<b>£0.27</b>	<b>£0.87</b>
<b>Total transplant cost</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£1.73</b>	<b>£6.94</b>	<b>£8.67</b>
<b>Total awareness raising campaigns costs</b>	<b>£0.45</b>	<b>£1.41</b>	<b>£0.54</b>	<b>£0.43</b>	<b>£0.28</b>	<b>£3.09</b>
<b>Total evaluation costs</b>	<b>£0.02</b>	<b>£0.04</b>	<b>£0.03</b>	<b>£0.01</b>	<b>£0.00</b>	<b>£0.09</b>
<b>Annual total, non-discounted</b>	<b>£1.17</b>	<b>£2.07</b>	<b>£1.15</b>	<b>£2.88</b>	<b>£7.93</b>	<b>£15.19</b>
<b>Annual total, discounted at 3.5%</b>	<b>£1.17</b>	<b>£2.00</b>	<b>£1.07</b>	<b>£2.60</b>	<b>£6.91</b>	
<b>Present Cost years 1-5</b>						<b>£13.74</b>

<sup>30</sup> as per Treasury Green book guidance

### Higher estimate

High estimate £m	yr1	yr2	yr3	yr4	yr5	total non- discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
NHSBT - Total Non-Recurring Costs	£0.33	£0.05	£0.00	£0.00	£0.00	£0.38
NHSBT - Total Recurring Costs	£0.30	£0.51	£0.51	£0.51	£0.51	£2.35
<b>NHSBT - Total</b>	<b>£0.63</b>	<b>£0.56</b>	<b>£0.51</b>	<b>£0.51</b>	<b>£0.51</b>	<b>£2.73</b>
SNBTS - Staff total	£0.06	£0.12	£0.23	£0.23	£0.23	£0.87
SNBTS - Non-staff total	£0.01	£0.02	£0.04	£0.04	£0.04	£0.13
<b>SNBTS - Total</b>	<b>£0.07</b>	<b>£0.14</b>	<b>£0.27</b>	<b>£0.27</b>	<b>£0.27</b>	<b>£1.01</b>
<b>Total transplant cost</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£0.00</b>	<b>£3.66</b>	<b>£14.62</b>	<b>£18.28</b>
<b>Total awareness raising campaigns costs</b>	<b>£0.45</b>	<b>£1.41</b>	<b>£0.54</b>	<b>£0.43</b>	<b>£0.28</b>	<b>£3.09</b>
<b>Total evaluation costs</b>	<b>£0.02</b>	<b>£0.04</b>	<b>£0.03</b>	<b>£0.01</b>	<b>£0.00</b>	<b>£0.09</b>
<b>Annual total, non-discounted</b>	<b>£1.17</b>	<b>£2.14</b>	<b>£1.35</b>	<b>£4.87</b>	<b>£15.68</b>	<b>£25.19</b>
<b>Annual total, discounted at 3.5%</b>	<b>£1.17</b>	<b>£2.07</b>	<b>£1.26</b>	<b>£4.39</b>	<b>£13.66</b>	
<b>Present Cost years 1-5</b>						<b>£22.54</b>

### Benefits

The positive health impact of receiving an organ can be measured in QALYs<sup>31</sup>. Patients who receive transplants on average benefit from longer life years and experience an improvement in quality of life relative to those patients whose conditions are managed with medical treatment. Following NICE methodology, one year of perfect health (equal to one QALY) is valued at £60,000.

The Welsh Government, in its impact assessment for the “Human Transplantation (Wales) Bill”, used the following QALY values in their impact assessment. Multiplying these values by the value for 1 QALY year yields the following results:

Increase in QALYs gained from transplant		
		£ value
kidney	4	£240,000
liver	13	£780,000
heart	7	£420,000
lung	4	£240,000
<b>average</b>	<b>7</b>	<b>£420,000</b>

\*source: Scottish Government calculations and Welsh Government impact assessment

Using the average QALY figure as a maximum (i.e £420,000), we can then calculate the additional QALY values for the additional number of transplants as follows. These range from £0 for the baseline, to £45.33m for the best estimate, up to £95.51m for the high estimate scenarios.

It is important to note that these estimates of benefits are non-cash releasing and are a monetary representation of the value of a life saved, extended or improved only.

<sup>31</sup> Quality Adjusted Life Years - A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.

Baseline – no incremental change

Baseline estimate (low/now incremental change in transplants)	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
<b>Total QALYs gained</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	<b>0</b>	
<b>Total QALYs, years 1-5</b>	<b>0</b>					
QALY monetary value (£m)	£0	£0	£0	£0	£0	£0
QALY monetary value, discounted at 1.5% (£m)	£0	£0	£0	£0	£0	£0
<b>Present Value, years 1-5 (£m)</b>						<b>£0</b>

Best estimate

Best estimate	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
<b>Total QALYs gained</b>	<b>0</b>	<b>196</b>	<b>196</b>	<b>196</b>	<b>196</b>	
<b>Total QALYs, years 1-5</b>	<b>784</b>					
QALY monetary value (£m)	£0.00	£11.76	£11.76	£11.76	£11.76	£47.04
QALY monetary value, discounted at 1.5% (£m)	£0.00	£11.59	£11.41	£11.25	£11.08	£45.33
<b>Present Value, years 1-5 (£m)</b>						<b>£45.33</b>

Higher estimate

High estimate	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
<b>Total QALYs gained</b>	<b>0</b>	<b>413</b>	<b>413</b>	<b>413</b>	<b>413</b>	
<b>Total QALYs, years 1-5</b>	<b>1,652</b>					
QALY monetary value (£m)	£0.00	£24.78	£24.78	£24.78	£24.78	£99.12
QALY monetary value, discounted at 1.5% (£m)	£0.00	£24.41	£24.05	£23.70	£23.35	£95.51
<b>Present Value, years 1-5 (£m)</b>						<b>£95.51</b>

Additional benefits from theatre use and workforce productivity

*Theatre productivity*

Additional benefits can be assumed to be derived from increased efficiencies in theatre throughput if an increase in available organs results in an increase in the successful delivery of organs for transplantation.

The analysis assumes that these benefits will take effect from year 3 onwards – with years 1 and 2 absorbed by existing capacity. The benefits represent a non-cash release of productivity improvements as expressed by the proportionate inverse of the surgery cost.

Whilst this is an estimate of the potential productivity benefits, there are multiple influencing external factors, such as staff rota and the baseline theatre capacity and operating schedules which will impact on the exact outcomes for theatre productivity.

Baseline – no incremental change

Baseline estimate (low/now incremental change in transplants)	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
Total productivity improvements in theatre utilisation	£0.00	£0.00	£0.00	£0.00	£0.00	£0.00
<b>Present Value, years 1-5 (£m)</b>						<b>£0.00</b>

## Best estimate

Best estimate	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
Total productivity improvements in theatre utilisation	£0.00	£1.68	£1.62	£0.00	£0.00	£3.30
<b>Present Value, years 1-5 (£m)</b>						<b>£3.30</b>

## Higher estimate

High estimate	yr1	yr2	yr3	yr4	yr5	total non-discounted
	2019-2020	2020-21	2021-22	2022-23	2023-24	yr1-yr5
Total productivity improvements in theatre utilisation	£0.00	£3.53	£3.41	£0.00	£0.00	£6.94
<b>Present Value, years 1-5 (£m)</b>						<b>£6.94</b>

## Workforce productivity

At a societal level, there can also be assumed to be gains in productivity if recipients of successful organ transplants are able to contribute economically for an increased duration after the operation. Again, multiple factors, such as the age of the recipient and the capacity for employment will play a role. Detailed information on transplant recipients' employment is limited, and therefore has not been included in the costings. 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<sup>32</sup>.

## Net Present Values

Having estimated the discounted costs and benefits, we can now estimate the Net Present Value (NPV – the difference between Present Benefits and Present Costs). A positive NPV indicates that the benefits outweigh the costs. For the baseline (worst case scenario), the NPV is negative, as there are assumed increases in costs due to implementation, with no additional benefit from increased number of transplants.

Both Best estimate and higher estimate scenarios are net positive.

Summary Costs and benefits: Net Present Values (NPVs) £m	Baseline estimate (low/now incremental change in transplants)	Best estimate	High estimate
<b>Present Value (PV), years 1-5</b>	£0.00	£45.33	£95.51
<b>Present Cost (PC), years 1-5</b>	£5.27	£13.74	£22.54
<b>Net present Value (PV-PC)</b>	<b>-£5.27</b>	<b>£31.58</b>	<b>£72.97</b>

## Including Theatre productivity

Summary Costs and benefits: Net Present Values (NPVs) £m	Baseline estimate (low/now incremental)	Best estimate	High estimate
<b>Present Value (PV), years 1-5</b>	£0.00	£48.62	£102.46
<b>Present Cost (PC), years 1-5</b>	£5.27	£13.74	£22.54
<b>Net present Value (PV-PC)</b>	<b>-£5.27</b>	<b>£34.88</b>	<b>£79.92</b>

<sup>32</sup> 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

## 5.0 SCOTTISH FIRMS IMPACT TEST

It is not envisaged that the legislation will result in any impacts on businesses.

### 5.1 Competition Assessment

It is not envisaged that the legislation will result in any impacts on businesses and therefore it is not envisaged that there will be any impacts on competition.

### 5.2 Test run of business forms

It is not envisaged that the legislation will result in any new business forms. The legislation will result in new forms for organisations working directly in organ donation, namely NHSBT and SNBTS. These will be developed jointly by the relevant organisations.

## 6.0 LEGAL AID IMPACT TEST

It is not envisaged there there will be any greater demand placed on the legal system by this legislation. Accordingly it is not considered that there will be any effect on individual's right of access to justice through availability of legal aid or on possible expenditure on the legal aid fund.

The Scottish Government Legal Team has been consulted on this subject.

## 7.0 ENFORCEMENT, SANCTIONS AND MONITORING

Not applicable

## 8.0 IMPLEMENTATION AND DELIVERY PLAN

How will the proposal be implemented and in what timescale?

The legislation will be progressed through the Scottish Parliament within the Parliamentary timetable. It is the intention that and commencement of the opt out provisions would be preceded by a 12 month public information campaign.

**9. SUMMARY** costs and benefits table for the introduction of the soft opt-out system (Including theatre productivity):

Soft opt out system	Total benefit yrs 1-5 : - economic, environmental, social (£m)	Total cost yrs 1-5: - economic, environmental, social - policy and administrative (£m)
1 (Baseline)	£0.00	£5.27
2 (Best estimate)	£48.62	£13.74
3 (High estimate)	£102.46	£22.54

The main costs surrounding the implementation of the soft opt-out system are derived from the need for awareness raising and education and from increases in resourcing costs for NHSBT and SNBTS. Future projections of costs were aggregated from years one to five to give a Present Cost\* from £5.27m for the baseline, to £13.74m for the best estimate, up to £22.54m for the high estimate scenarios.

The positive health impact of receiving an organ can be measured in QALYs (Quality Adjusted Life Years). The monetary equivalent of these measured as Present Value\* ranges from £0 for the baseline, to £45.33m for the best estimate, up to £95.51m for the high estimate scenarios. There might potentially be productivity improvements in theatre utilisation, (although there is no certainty around this which are estimated to range from £0m for the baseline, to £3.30m for the best estimate, up to £6.94m for the high estimate scenarios.

The Net Present Value (NPV – the difference between Present Benefits and Present Costs) for the baseline (worst case scenario) is negative, as there are assumed increases in costs due to implementation, with no additional benefit from increased number of transplants. Both Best estimate and Higher estimate scenarios are net positive.

\* Costs and Benefits discounted at 3.5% and 1.5% as per HMT guidance

## 10.0 DECLARATION AND PUBLICATION

I have read the Business and Regulatory Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the costs, benefits and potential impact of the Human Tissue (Authorisation)(Scotland) Bill.

Signed:



Date: May 2017

Minister's name: Aileen Campbell MSP

Minister's title: Minister for Public Health and Sport



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