

## SPICe Briefing

# Transplantation (Authorisation of Removal of Organs Etc) (Scotland) Bill

21 December 2015

15/75

Louise Rennick

The Transplantation (Authorisation of Removal of Organs Etc) (Scotland) Bill is a Member's Bill which was introduced in the Scottish Parliament by Anne McTaggart MSP on 1 June 2015. The Bill provides for a move to a system of presumed consent for the removal of parts of a deceased adult's body (organs, in particular) for the purposes of transplantation in the absence of express authorisation.

This briefing sets out the Bill's main provisions and the response to these proposals from the Health and Sport Committee's call for written evidence.



# CONTENTS

<b>EXECUTIVE SUMMARY</b> .....	<b>3</b>
<b>INTRODUCTION</b> .....	<b>5</b>
<i>SCOTTISH LEGISLATION AND POLICY</i> .....	5
<i>UK Organ Donation Taskforce</i> .....	6
<b>STRUCTURES AND PROCESSES FOR ORGAN DONATION</b> .....	7
<i>UK Wide Practice</i> .....	7
<i>Current situation in Scotland</i> .....	8
<i>Consent systems</i> .....	9
<b>EVIDENCE FOR PRESUMED CONSENT</b> .....	<b>9</b>
<i>Organ Donation Taskforce Review</i> .....	9
<i>Other studies</i> .....	11
<i>Wales</i> .....	11
<i>Other countries</i> .....	11
<i>Spain and Belgium</i> .....	11
<i>Public Surveys in Scotland</i> .....	13
<b>PREVIOUS SCOTTISH PARLIAMENT ACTION</b> .....	<b>14</b>
<b>PREVIOUS CONSULTATION ON THE BILL</b> .....	<b>14</b>
<b>PROVISIONS OF THE BILL</b> .....	<b>14</b>
<b>HEALTH &amp; SPORT COMMITTEE CALL FOR EVIDENCE</b> .....	<b>15</b>
<b>SPECIFIC BILL PROPOSALS</b> .....	<b>16</b>
<i>Proxy</i> .....	16
<i>Response</i> .....	16
<i>Authorised Investigating Person (AIP)</i> .....	17
<i>Responses</i> .....	18
<i>Rule if order of acts unclear</i> .....	18
<i>Nearest relative</i> .....	19
<i>Publicity</i> .....	19
<i>Adults with Incapacity</i> .....	19
<i>Responses</i> .....	19
<i>Persons to whom the Bill applies</i> .....	20
<i>Responses</i> .....	20
<b>KEY THEMES</b> .....	<b>20</b>
<b>SCOTTISH GOVERNMENT RESPONSE TO THE BILL</b> .....	<b>23</b>
<b>FINANCIAL IMPLICATIONS</b> .....	<b>23</b>
<b>SCOTTISH GOVERNMENT'S RESPONSE TO THE FINANCIAL MEMORANDUM</b> .....	<b>24</b>
<b>SOURCES</b> .....	<b>26</b>
<b>ANNEXE: PROCESS UNDER 2006 ACT (AS AMENDED BY BILL) TO ESTABLISH WHETHER ORGANS MAY LAWFULLY BE REMOVED FOR TRANSPLANTATION</b> .....	<b>27</b>
<b>RELATED BRIEFINGS</b> .....	<b>28</b>



## EXECUTIVE SUMMARY

The Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill is a Member's Bill, introduced by Anne McTaggart MSP on 1 June 2015.

The Human Tissue (Scotland) Act 2006 is the current legislative framework for organ donation and transplantation in Scotland. This legislation provides for an opt-in system for organ donation where individuals must authorise the removal and use of their organs after death for the purposes of transplantation. In Scotland the current legislation applies to children from the age of 12.

There are different types of consent systems and the 2 main broad types are opt-in and opt-out with 'hard' and 'soft' versions. An opt-in system is where an individual expresses their choice to donate organs or tissue by joining the organ donor register or carrying an organ donor card. An opt-out system is where the individual is required to explicitly make it known while they are alive that they are not in favour of their organs being used for transplant when they die. The key difference between the two systems is that an opt-in system involves an individual expressly stating that a wish that their organs and tissue be used for transplant on their death. On the other hand, an opt-out system assumes that organs and tissue are available for transplant unless there is a specific instruction to the contrary. The 'soft' version of either opt-in or opt-out usually means that the family has a say in the final decision about organ donation at the time of a person's death.

The Bill provides for a move to a "soft opt-out" system which allows (in certain circumstances) for the removal of parts of a deceased adult's body (organs, in particular) for the purposes of transplantation in the absence of express authorisation.

Under the Bill, it will still be possible for people to opt-in to organ donation, but the Bill will also give adults resident in Scotland the options of appointing a proxy to make a decision about authorisation on their behalf, or to register in advance an objection to removal (i.e. to opt-out). The Bill then provides a mechanism that authorises the removal of parts of a deceased adult's body in certain situations where the adult did not register such an objection (i.e. did not opt-out) and where there is no appointed proxy to make a decision on their behalf.

The aim of the Bill is to increase the number of organs and tissue made available for transplantation in Scotland and hence to allow more transplants to be carried out, reducing waiting list and saving lives.

Scotland has increased the number of organ donations since the 2006 Act and the Organ Donation Taskforce report in 2008. Scotland has the highest proportion of people, (41%), registered on the Organ Donor Register when compared to the other countries of the UK. However there are still not enough donated organs to save people's lives in the UK.

In Scotland over the period 2008-2013 62% of donors were not on the register at the point of death.

The Organ Donation Taskforce<sup>1</sup> also undertook a review of opting-out systems in 2008 and did not advocate for the UK to move to an opt-out system at that time because they felt the risks outweighed the benefits. A number of countries have moved from an opt-in system to an opt-out system with varying degrees of success i.e. increased organ donor rates.

There were mixed responses to the Health and Sport Committee's call for evidence with some respondents supporting the Bill and other respondents not supporting the Bill. The main reason for supporting the Bill was because they agreed with an opt-out system. This was because they felt that this system would increase the rate of organ donations and were convinced by the evidence supporting opt-out systems. Some of the submissions who supported the Bill also believed that the introduction of an opt-out system would support both the deceased to have their wishes carried out and the families who were faced with these tough decisions. One submission felt that a move to an opt-out system which creates the default position could lead to a change in the philosophy within society where donation becomes seen as the norm. The submissions which did not support the Bill did so mainly because they did not agree with opt-out systems. They did not agree with opt-out systems because they were not convinced by the evidence that they increased organ donation.

Some of those who made submissions which agreed with the general aims of the Bill some of them had concerns with some of the provisions in the Bill. These were mainly around the proxy, authorised investigating persons and the role of the family.

---

<sup>1</sup> The Organ Donation Taskforce was established in 2006 by the Government to identify barriers to donation and to make recommendations for increasing organ donation and procurement within the existing legal framework.

## INTRODUCTION

The Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill is a Member's Bill. It was introduced in the Scottish Parliament by Anne McTaggart MSP on 1 June 2015. The [Bill](#) (as introduced) (Scottish Parliament 2015a) is accompanied by [Explanatory Notes](#), (Scottish Parliament 2015b) which includes a Financial Memorandum, and a [Policy Memorandum](#) (Scottish Parliament 2015c)

The Health and Sport Committee was designated lead committee for Stage 1 consideration of the Bill. The Committee issued a "call for written views", which closed on 12 October 2015.

The Bill provides for a move to a "soft opt-out" system which allows (in certain circumstances) for the removal of parts of a deceased adult's body (organs, in particular) for the purposes of transplantation in the absence of express authorisation. A diagram showing the different options and the process was provided in the Policy Memorandum (PM) and this has been replicated and shown in the Annex.

The current system in Scotland is an opt-in system where an individual expresses their choice to donate organs or tissue by joining the organ donor register or carrying an organ donor card. An opt-out system is where the individual is required to explicitly make it known while they are alive that they are not in favour of their organs being used for transplant when they die. The key difference between the two systems is that an opt-in system involves an individual expressly stating that a wish that their organs and tissue be used for transplant on their death. On the other hand, an opt-out system assumes that organs and tissue are available for transplant unless there is a specific instruction to the contrary.

The overall aim of the Bill is to increase the number of organs and tissue made available for transplantation in Scotland, and hence to allow more transplants to be carried out, reducing waiting lists and saving lives.

The rest of this briefing deals with the background to organ donation and the Bill's provisions. It sets out the key issues to emerge from the Health and Sport Committee's call for written evidence.

## SCOTTISH LEGISLATION AND POLICY

The Human Tissue (Scotland) Act 2006 provides the current legislative framework for organ donation and transplantation in Scotland. The equivalent legislation for the rest of the UK is the Human Tissues Act 2004. Both pieces of legislation generally provide an "opt-in" system for organ donation where individuals must authorise the removal and use of their organs after death for the purposes of transplantation. The legislation also sets out a range of provisions relating to other aspects of donation and transplantation. One of the differences between the Acts is that in England and Wales the Act allows for 'named representatives' and the Scottish Act does not. Named representatives are individuals who have been nominated to make decisions about consent on their behalf.

Express authorisation is needed under the 2006 Act before any organs may lawfully be removed for transplantation and this authorisation can be in the form of a discussion with relatives or in writing (e.g. by carrying a donor card), or by signing up to the NHS Organ Donor Register. The existence of authorisation is not always enough. Although there is no statutory requirement for a deceased person's relative to give consent, the practice is not to proceed with organ removal if the relatives object and this is generally respected even if the deceased person

was on the organ donor register or carrying a donor card. In Scotland over the period 2008-2013, some 62% of donors were not on the register at the point of death. Families are more likely to authorise donation when an individual has expressed their wish to donate.

Under the Human Tissue (Scotland) Act 2006 the nearest relative can authorise donation on behalf of a deceased person if that person has not expressed a wish to donate in life. In circumstances where wishes had not been made known family members can still authorise donation on behalf of the deceased.

In Scotland the current legislation applies to children from the age of 12.

The Human Tissue (Scotland) Act 2006 also places a legislative duty upon Scottish Ministers to promote and raise awareness of donation and transplantation.

Other legislation is also relevant to donation, in particular the Adults with Incapacity (Scotland) Act 2000. This Act sets out provisions in relation to individuals who have lost capacity for any reason. Such loss of capacity might relate to accidents or serious injuries that leave an individual in circumstances where further treatment, both family and clinicians agree, would be futile. Their death, following the withdrawal of life-sustaining treatment, is inevitable. However, until death has actually been pronounced, the provisions of the Adults with Incapacity (Scotland) Act 2000 apply. The provisions of the Human Tissue (Scotland) Act 2006, apply only after death.

## **UK Organ Donation Taskforce**

In 2006 the UK Organ Donation Taskforce was established with the task of identifying barriers to donation and making recommendations for increasing organ donation and procurement within the existing legal framework. The taskforce came up with [fourteen recommendations](#) in its 2008 report, which it believed could lead to a 50% increase in organ donation within five years. The 14 recommendations covered the three essential steps of:

1. Donor identification and referral
2. Donor coordination
3. Organ retrieval.

The taskforce identified five general areas that needed attention: legal and ethical issues, the role of the NHS, the organisation of coordination and organ retrieval, training, and public recognition and promotion of donation.

All four UK health administrations accepted the report. There were three main bodies, which were responsible for implementation: NHS Blood and Transplant, the Health Departments, and every acute hospital.

Following the Organ Donation Taskforce, a number of significant changes were made to improve the donation and transplantation infrastructure in Scotland, including:

- Establishment of a donation committee in each mainland NHS Board with links to the Island Boards
- Establishment of a Clinical Donation Champion (now referred to as Clinical Leads for Organ Donation) in each of the donating hospitals in Scotland; and
- Strengthening the network of donor transplant co-ordinators (now referred to as Specialist Nurses for Organ Donation) by appointing seven additional co-ordinators.



## STRUCTURES AND PROCESSES FOR ORGAN DONATION

Currently organs for transplantation can be made available in the following ways:

- Through deceased donation, (donation after death), specifically:
  - Donation after brain stem death (DBD), from individuals who generally have been pronounced dead in an Intensive Care Unit (ICU) using the neurological criteria known as 'brain stem death testing'
  - Donation after circulatory death, (DCD), from individuals who generally die in critical care and emergency medicine areas as a result of heart or circulatory failure and who are pronounced dead following observation of cessation of heart and respiratory activity.
- Through living donation, in the case of kidneys or liver.

Specialist Nurses for Organ Donation (SNODs) are usually senior nurses from a clinical background, usually in intensive care or emergency medicine. The role of the SNOD encompasses an on-call element to support the facilitation of organ donation in addition to a role within the hospital to which they are allocated. Part of the role of Specialist Nurse for Organ Donation (SNOD) is to check the individual's wishes (by checking the NHS Organ Donor Register) and to speak to the family. Even though the law in Scotland allows donation to proceed in the absence of family authorisation, in practice, donation would not currently proceed without this support. At all times Specialist Nurses for Organ Donation (SNODs) are devoted to the care and on-going support of the potential donor's family, often many years into the future. The SNOD also has a key role in discussing with Procurators Fiscal the potential for donation in circumstances where a criminal prosecution or police investigation into the cause of death may be necessary. There is a network of 18 whole time equivalent Specialist Nurses in Organ Donation, working in and across 24 Scottish hospitals and operationally managed by the UK wide NHS Blood & Transplant.

### UK Wide Practice

Organ donation and transplantation has always been delivered on a collaborative basis across the UK. This means that organs which become available in Scotland are made available to patients across the UK and vice versa. Organ donation and transplantation activity across the UK is co-ordinated by [NHS Blood and Transplant](#), (NHSBT), which is an English and Welsh Special Health Authority and operates in Scotland under a contractual arrangement with the Scottish Government.

Organ donation and transplantation also operates within a robust European and domestic regulatory framework. For Scotland, as with the rest of the UK, the [Human Tissue Authority](#) (HTA) is the regulatory body. The HTA was set-up in 2005 as a regulator for human tissue and organs by Parliament as an executive agency of the Department of Health.

The development of a new UK-wide strategy, "[Taking Organ Transplantation to 2020](#)", on organ donation and transplantation has been co-ordinated by NHSBT on behalf of the four UK Health Departments. This Strategy is the first document since the report of the UK Organ Donation Taskforce to set out the key areas where further activity is required across the UK as a whole. The Scottish Government has produced a strategy for organ donation and transplantation in Scotland and which is intended to complement, the UK Strategy document ('A Donation and Transplantation Plan for Scotland 2013-2020).

A Scottish Transplant Group (STG) was established in 2001 and meets quarterly. The Group includes representatives from donor families and transplant recipients. The STG provides advice to Scottish Ministers on all issues relating to organ donation, transplantation and tissue donation including implementation of the ODTF recommendations. The Scottish Transplant Group and donation and transplant services in Scotland work closely with the HTA to ensure services meet the necessary regulatory standards.

The Organ Donor Register now (since July 2015) allows people to register to opt-out as well as opt-in.

## **Current situation in Scotland**

The Scottish Government, in 2013, published its long-term strategy for organ donation, 'A Donation and Transplantation Plan for Scotland 2013-2020'. This strategy sets out 21 recommendations right across the pathway and to meet certain targets by 2020. One of the recommendations was as follows:

“[related to] the fact that significant improvements have been achieved over the last five years in relation to donation and transplantation rates in Scotland, the Scottish Government [...] to await evaluation of the move to 'opt-out' in Wales before making any decision about the introduction of opt-out in Scotland. (Recommendation 2)

Another recommendation is that the Scottish Government should continue to fund and deliver high-profile organ donation awareness raising campaigns.

The targets are as follows:

- Overall deceased donation rates to increase from 17.9 per million population in 2012/13 to 26 per million population
- Overall transplantation rates in Scotland from deceased donors to increase from 65.8 to 74 per million population
- Family authorisation rates in donation after circulatory death (DCD) to increase from around 50% to around 80%
- Family authorisation rates in donation after brainstem death (DCD) to increase from around 50% to around 80%.

This strategy stated that Scotland had achieved a 74% increase in donations over the last five-year period i.e. the five years up to 2013 and a 36% increase in transplants with deceased donor organs over the same period i.e. between 2007/8 – 2013. Scotland has the highest percentage of residents signed up to the NHS Organ Donor Register with 41% registered at the end of 2012/13 compared to the UK average of 31%.



The table below provides some statistics around organ donation in Scotland which was taken from the NHS Blood and Transplantation [website](#).

Table 1

<b>Summary figures</b>	<b>2011/12</b>	<b>2014/15</b>
Total deceased donors	81	98
Living donors	57	81
Total donors	138	179
Total patients on waiting list	594	543
Deceased donor transplants	286	300
Living donor transplants	59	78
Total organ transplants	345	378

There is a wide variation in donation rates across the NHS in Scotland. For example in Ayrshire and Arran health board area the organ donation numbers was just under 10 whereas in Lothian it was over 20 (A Donation and Transplantation Plan for Scotland 2013-2020). Organs from a Scottish donor can be used for transplantation anywhere in the UK, and vice versa so there is not direct correlation between the number of organ donors in Scotland and the number of transplants in Scotland. Not all people die in circumstances that can allow for organ donation however the reality is in Scotland two thirds of eligible donations do not occur resulting in a missed opportunity to save a life.

## **Consent systems**

There are opt-in and opt-out systems for organ donation and transplantation. An opt-in system is where an individual expresses their choice to donate organs or tissue and an opt-out system is where the individual is required to explicitly make it known while they are alive that they are not in favour of their organs being used for transplant when they die. The key difference between the two systems is that an opt-in system involves an individual expressly stating that they wish that their organs and tissue be used for transplant on their death. On the other hand, an opt-out system assumes that organs and tissue are available for transplant unless there is a specific instruction to the contrary. The opt-in system is also known as an explicit or informed consent system and opt-out is also sometimes known as presumed consent.

There are different ways that opt-out and opt-in systems work in practice and these are broadly categorised as 'hard opt-out' and soft opt-out'. Soft opt-in and opt-out usually means the family has a say in the final decision about organ donation at the time of the person's death. Under opt-in this means that even if someone wished their organs to be donated on their death, if the family object, the family's wishes will be respected. Similarly, a soft opt-out system would involve consulting with the family to capture any unregistered objection, with scope not to proceed if this would cause severe distress to the family. Where hard opt-out or opt-in systems are in place, the declaration of the person when they were alive is final and there is no role for the family in the decision about organ donation at the time of the individual's death.

## **EVIDENCE FOR PRESUMED CONSENT**

### **Organ Donation Taskforce Review**

Despite the work of the Taskforce there remained considerable clinical and political interest in the UK in opting out. The UK Organ Donation Taskforce was asked to investigate the impact of

an opt-out system for organ donation in the UK and its recommendations were [published](#) in November 2008. Six working groups were established: practical, legal, ethical, clinical, cultural and communications. The taskforce commissioned research on the effect of presumed consent on organ donation rates (systematic review), a costing analysis was undertaken and a series of events held with the public, professional bodies, and with 17 faith and culture groups.

On balance the Taskforce concluded that moving to an opting-out system may deliver real benefits, for example it could increase organ donor numbers, but carries a significant risk of making the current situation worse.

The Taskforce found that when they spoke to the public, professional bodies and faith and culture groups many of the people who supported an opt-out system felt that having such a system would more accurately reflect majority wishes, allowing donation to become the default position. This they felt could increase organ donor rates. The systematic review, which is discussed in the next section of this briefing, found that countries with opting-out systems did have high organ donation rates. Some people thought that a system of opting-out would relieve families of the burden of making a decision in the absence of any indication as to the deceased's wishes.

The risks were around the fact that some of the people the Taskforce spoke to were concerned that a proportion who would not have wished to donate their organs, but never got round to registering an objection, could mistakenly be considered as willing donors under an opt-out system. This could lead to an undermining of the trust in the organ donation and transplantation system. The Taskforce felt that some people see organ donation as a gift and that the introduction of an opt-out system could lead to undermining this concept. In relation to the research undertaken by the Taskforce, it was found that some people were concerned with opt-out systems because they felt that it would give the 'state' too much control or ownership over people's organs and could remove their individual choice. The Taskforce felt that all of these factors could potentially reduce the number of people donating organs.

This quote explains why the Organ Donation Taskforce thought moving to an opt-out system in the UK was not appropriate at that time:

“After examining the evidence the Taskforce reached a clear consensus in recommending that an opt-out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the Government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs.”

However they did say that if donor numbers had not grown by 50% by 2013 then the question of opt-out should be revisited. In Scotland there was an increase of 74% of deceased organ donors between 2007/08 and 2012/13.

As part of the review of an opting-out system for the UK the Organ Donation Taskforce commissioned a systematic review from the University of York (Rithalia et al. 2009) to examine the impact of a system of presumed consent for organ donation on donation rates. They concluded that opt-out does increase organ donation, but is one of a number of factors

positively associated with increased donation rates. These included both factors affecting the total number of potential donors available (for example rates of motor accidents, the population's age distribution, and the country's definition of death), and factors affecting how many of those potential donors in fact went on to donate (for example the organisation and infrastructure of the transplant system, wealth and investment in health care and underlying public attitudes and awareness).

## **Other studies**

A study published in 2010 concluded that opt-out systems are associated with relatively higher rates of deceased donation, but also with relatively lower rates of living donation (Bird and Harris, 2010). This was also found in a recent study published in 2014 where they found that deceased donor rates were higher in opt-out countries; however the number of living donors was higher in opt-in than opt-out countries. This study investigated the difference between deceased and living organ donation rates in opt-in and opt-out consent systems across a 13 year period (Shepherd et al, 2014).

## **Wales**

In July 2013, the National Assembly for Wales passed the Human Transplantation (Wales) Act, which is due to come into force on 1 December 2015. The Act introduces a new "soft opt-out" system for organ donation for Wales which will allow organs and tissues to be removed unless the deceased objected during their lifetime. The family of the deceased person must be consulted to establish whether the deceased was known to have any unregistered objections. There are exceptions for certain "excepted adults", and there is provision allowing people to appoint a representative (proxy) to make decisions about consent on their behalf.

## **Other countries**

The UK, North America, Australasia and most of Asia (excluding Singapore which has a type of 'hard' opt out system) have explicit consent systems i.e. opt in systems in place. Many European countries have a form of opt out system. In practice the ways in which these systems – even the same types – functions differs between countries and even within regions.

Several countries, including Spain, Austria and Belgium, have presumed consent, whereby organs can be used for transplantation after death unless individuals have objected during their lifetime (an opt-out system). For example, in Spain the presumed consent law is "soft" in that doctors take active measures to ascertain that the next of kin do not object to organ recovery. In Austria the presumed consent law is relatively 'hard' in that organ recovery proceeds unless it is known that the deceased objected before death, and the views of relatives are not actively sought.

## **Spain and Belgium**

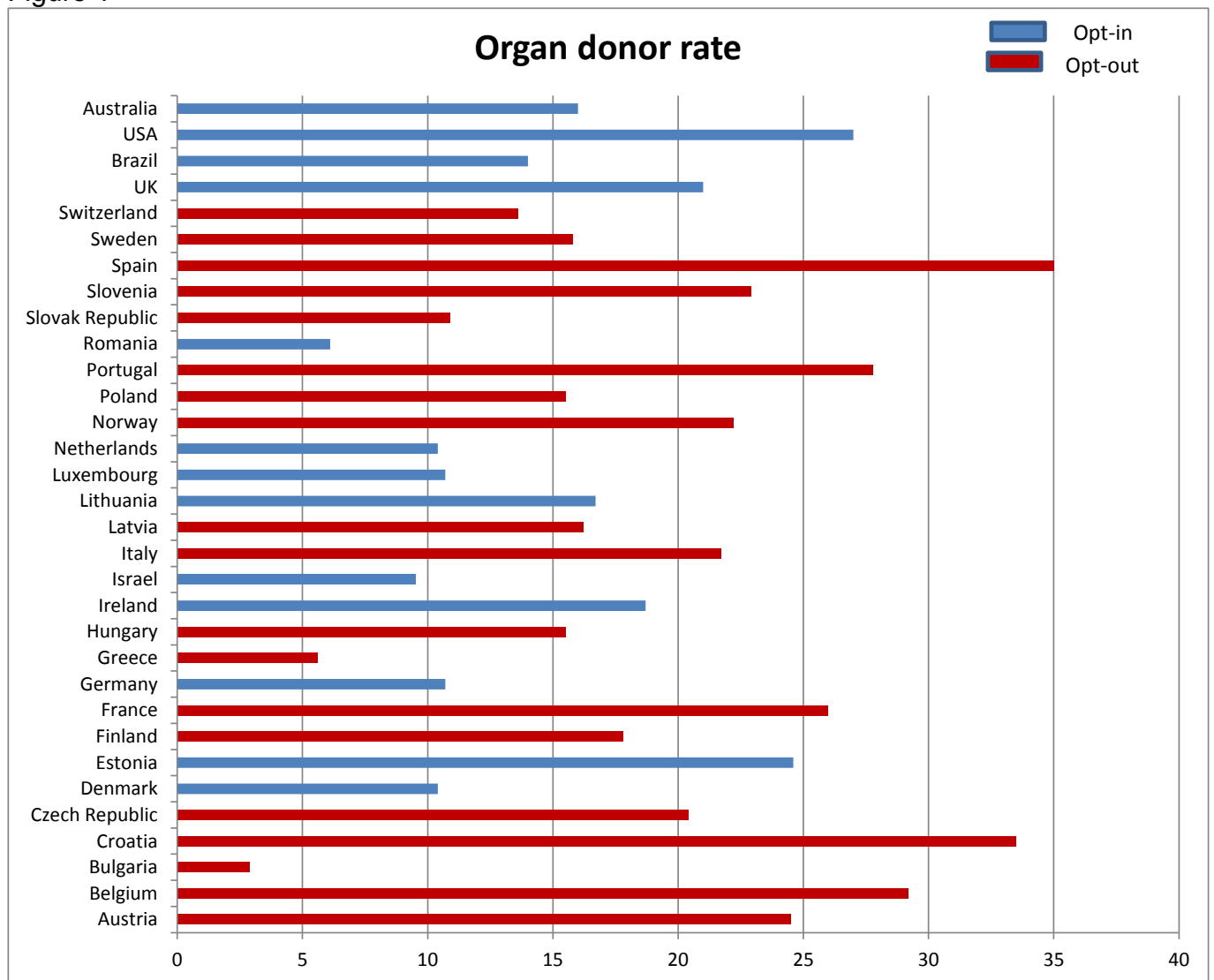
The two countries, which have been running successful, in terms of increasing organ donation, soft opt-out systems for the longest period are Belgium and Spain. Belgium is usually hailed as an example of where there is more robust evidence that the presumed consent legislation has worked. The Policy Memorandum (PM) to this Bill identified that Belgium introduced a soft opt-out system in 1986 and within three years saw donor rates double. Belgium currently has a rate of 29 donors per million people (pmp). The PM explains that in the 1990s Spain had a similar

donation rate to the UK but then started to address the barriers to donation and since 2006 has maintained a rate of 35 donors pmp. Spain introduced 'soft opt-out' legislation for organ donation in 1979 and now has the highest rate of donation from deceased donors, so is cited as a model for introducing such laws. However it is not clear whether Spain's high deceased organ donor rate can be attributed to its presumed consent laws. This is because improvements in donor rates followed other changes to the nationally organised organ donation system. Dr Matesanz, one of the transplant co-ordinators in Spain said "that many elements have to be right if an increase in organ donor rates is to occur" (Organ Donation Taskforce report on opt-out system).

Although the research has found an association between presumed consent and higher donation rates, not all countries that have presumed consent legislation have high organ donor rates. For example Sweden switched to presumed consent in 1996 but continues to have one of the lowest rates of organ donation in Europe. Brazil adopted a 'hard' presumed consent law in 1997, with opt out denoted by a note on an ID card or driving licence. The law had to be repealed in 1998, principally because of mistrust of government and accusations of body snatching. In France, which has a variation of presumed consent, there was an incident in 1992 in which corneas were taken from a 19-year-old road traffic accident victim whose parents had consented to only limited organ retrieval. This resulted in a great deal of negative press coverage of the medical profession, despite the clinicians having complied with the law, and damaged public trust in the organ donation system for some time.

The table below shows the different organ rates for different countries and whether they have opted-out or opted-in. The rate is shown as pmp. The rates were taken from a Journalist workshop on organ donation and transplantation and the IRODaT database ([IRODaT](#)).

Figure 1<sup>2</sup>



## Public Surveys in Scotland

In a 2014 British Heart Foundation (BHF) Scotland and British Medical Association Scotland commissioned a poll, which found that 94% of Scots said they support the principle of organ donation however only 41% of the population are registered as donors. In a 2015 commissioned poll by BHF Scotland 80% of Scots said they would want to donate their organ if they were to die in a situation that allowed them. However in 2014/15 only 28% of Scots did donate their organs. This highlights the gap between the wishes held compared to the proportion that go on to register as a donor. This is not helped by nearly a 50% family refusal rate.

<sup>2</sup> Figure 1 has been amended to reflect more up to date information on which countries have opt-in or opt-out systems. Please note that there are inconsistencies for Estonia, Israel, Lithuania, Luxembourg, Norway and Switzerland over whether they have an opt-out or opt-in system. The majority of information on which countries have opt-out or opt-in systems came from “An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study” Shepherd et al (2014).

A Scottish Government survey undertaken in 2012 found that only 5% of the population opposed organ donation in principle ('A Donation and Transplantation Plan for Scotland 2013-2020'). This shows the public support for an opt-out system of organ donation.

## PREVIOUS SCOTTISH PARLIAMENT ACTION

In November 2012 Motion (S4M-04418) was [debated](#) in the Scottish Parliament. This motion focused on a move to a system of presumed consent (opt-out) in Scotland. A petition was submitted to the Scottish Parliament's Public Petitions Committee in November 2012 by Caroline Wilson on behalf of the Evening Times & Kidney Research UK (Scotland). This petition called on the Scottish Parliament to urge the Scottish Government to introduce an opt-out system of organ donation in Scotland to help save more lives. The petition was [debated](#) in the Scottish Parliament on 1 May 2014. In March 2015 the Health and Sport Committee [considered](#) the petition to introduce an opt-out system of organ donation in Scotland. It was agreed to keep the petition open.

## PREVIOUS CONSULTATION ON THE BILL

The member's draft proposal was lodged on 26 June 2014, supported by a consultation that ran until 23 October 2014. A [summary of the responses](#) was prepared by the Non-Government Bills Unit and published (with the member's commentary) on 6 January 2015, alongside the [final proposal](#). In total, 559 responses were received: 529 from individuals and 30 from organisations. There was a clear division between individual and organisation views – with 80% of individuals supporting the principle of the proposal, in contrast to 30% of organisations.

A key theme from supporters was that moving to a soft opt-out system would increase the number of organ donations and thereby bridge the gap between the demand for organs and the current level of donation, while a recurring theme in opposition to the proposal (put forward from religious organisations and faith groups) was that it would undermine the principle of individual consent and the integrity of the individual.

The importance of a comprehensive education and public awareness campaign was highlighted as a key factor in achieving the aims of increasing donation rates and reducing organ transplantation waiting times and this point was highlighted both by respondents who were supportive and those opposed to the proposal.

## PROVISIONS OF THE BILL

The Policy Memorandum states that it was considered important to retain the existing right for people to opt-in (under section 6 of the 2006 Act), to allow those who support transplantation to express their wishes positively, and for a deceased person's nearest relative to give authorisation (under section 7). The Bill also retains a consultative role for relatives, even where authorisation by operation of law (under new section 6B) is being considered, in particular by allowing them to express on the deceased person's behalf any unregistered wishes of that person.

The Bill seeks to amend the Human Tissue (Scotland) Act 2006 although it also makes minor and consequential amendments to the Adults with Incapacity (Scotland) Act 2000.

The Bill requires Scottish Ministers to approve a register in which people resident in Scotland may record an objection to the removal of their organs or tissue for transplantation. The Bill would oblige Ministers to approve the register rather than necessarily creating it.

The Bill refers to “authorised investigating persons” (AIPs). These will be health professionals (appointed under regulations made by Ministers) whose role is to determine whether or not a deceased adult’s organs can lawfully be removed and used for transplantation.

## HEALTH & SPORT COMMITTEE CALL FOR EVIDENCE

During September and October 2015, the Parliament’s Health and Sport Committee issued a [call for written evidence](#) on the Bill and received 32 responses. All of the responses submitted were from organisations; however the Health and Sport Committee also commissioned a survey to ask the public their views on the Bill. A paper summarising the results of the responses to the survey has been produced with the majority of respondents supporting the Bill. Most of the submissions were from health related organisations including groups representing health professionals and health clinicians, health boards, research and health charities such as the British Heart Foundation Scotland. Although there were a few others from organisations such as the Scottish Government, religious and faith groups, the Law Society and groups concerned with ethics and children’s rights (Scottish Youth Parliament).

Table 1 shows a breakdown of the responses to the question ‘Do you support the Bill?’ Not all of the submissions answered the questions with a direct ‘yes’ or ‘no’ and for these submissions a judgement had to be made by SPICe on the basis of the comments provided

Table 1: Breakdown of opinion among respondents to the Health and Sport Committee’s Call for Evidence

Table 2

<b>Response Category</b>	<b>Number (%)</b>
Generally supports aim of Bill	9 (28%)
Supportive, but with reservations	5 (16%)
Unsupportive	10 (31%)
Unclear or undecided	8 (25%)

Just under fifty percent (44%) were generally supportive of the Bill however some of the submissions, 16%, supported the Bill at ‘face value’, i.e. agreed with the aims of the Bill, but did not support all the aspects of the Bill for example the appointment of proxies. They supported the Bill because, in the main, they agreed with a ‘soft’ opt out approach because in some cases they thought that the Bill would increase the number of organ donors.

A number of submissions (31%) did not agree with the Bill. The majority of these submissions were from faith/religious groups or ethics groups or organisations involved in transplants on a day to day basis. Some of the submissions, which did not support the Bill, did so because they did not agree with opting-out even though they agree with organ donation and transplantation, and/or preferred to stay with the current system. These submissions also felt that the Bill would not achieve its aim of increasing the number of organ donors.



## SPECIFIC BILL PROPOSALS

The following section considers the specific provisions of the Bill, together with responses from submissions.

### **Proxy**

The Bill allows any adult to appoint a proxy (or proxies) to make decisions about authorisation (for the removal of the adult's organs for transplantation), on their behalf, after their death. The appointment of a proxy is an additional choice for an adult, as an alternative to either opting in (e.g. by joining the organ donor register) or opting out (by recording an objection). The proxy is not an essential feature of a soft opt-out system but the proxy provision has been included according to the PM to this Bill to extend the range of choices available to people who wish to ensure that their wishes are complied with after their death

A proxy may be appointed only for some organs and not all. However, an adult is not permitted to appoint different proxies for different organs. The PM states that this would create an additional layer of administrative complexity, for no obvious benefit.

To maximise the chances that a proxy will be available to make a decision when required, the Bill allows each adult to appoint up to three proxies, who must be listed in priority order. The AIP is then required to contact them in that order and to give each proxy so contacted a reasonable time to make a decision.

To be valid, the Bill proposes that proxy details can be included within the organ donation register or can pre-exist in writing, signed by the deceased, and should contain accurate contact information.

The Bill and Policy Memorandum make clear that the intention is for the existence of a proxy to be determined, and their authorisation sought, before the views of the next of kin are sought.

In the Explanatory Notes to the Bill it states that

“it is not necessary for the proxy to consent to or be aware of their appointment”

### *Response*

A number of submissions supported proxies in principle in that it made sense for a person to appoint someone to make decisions after their death (e.g. Scottish Youth Parliament, Aberdeenshire Health and Social Care Partnership, Scottish Ambulance Service). However some submissions (Royal College of Physicians of Edinburgh, Scottish Intensive Care Society) including organisations that supported the aims of the Bill, could not see how the system of proxies would work. One example was how would the proxy and next of kin be involved at the time of death and decide about donation? There were concerns that it could cause disagreement and conflict between proxies and family members, which could lead to distress to the families, the proxies and to clinical staff.

It was also felt that there is a lack of clarity in the Bill and supporting documentation as to whether the next of kin would have the final say on donation i.e. override what the proxy says. For some organisations it appears that the Bill gives decision-making priority to a proxy over the next of kin, but others felt that this is not entirely clear (e.g. Scottish Government). Some

submissions were concerned that the legislation could put clinicians in a position of removing organs, with the permission of a proxy, but against the wishes of some family members. It was felt that this could undermine the confidence and trust in medical teams when the trust between families, proxies and clinicians is crucial to the organ donation system (Christian Medical Fellowship).

It was also claimed that it could lead to legal challenges under Article 8 of the European Convention of Human Rights, for example by the family members of a deceased person whose organs are removed for transplantation under the Bill, i.e. proxy makes the decision, contrary to the family's wishes (Scottish Government, Scottish Council on Human Bioethics).

Some submissions thought that proxies could overly complicate the transplantation system and slow it down (e.g. Scottish Government, NHS Lanarkshire, Revival), and that the ability to appoint three proxies could complicate matters further. There is the potential to give conflicting opinions was also highlighted as possibly confusing matters and being time consuming. The Scottish Government, in its submission, did not feel that the Policy Memorandum was clear about who a proxy could be. The Law Society of Scotland, NHS Greater Glasgow and Clyde and Scottish Council of Jewish Communities had concerns over it not being necessary for the proxy to consent or to be aware of their appointment. Also the current Organ Donor Register allows for a person to nominate up to two representatives so if this Bill was passed the register and the systems would have to be changed to allow for three proxies (NHS Blood and Transplant). NHS Blood and Transplant thought that this could be costly and difficult to change.

## **Authorised Investigating Person (AIP)**

The Bill proposes to create “authorised investigating persons” (AIPs). These will be health professionals (appointed under regulations made by Ministers) whose role is to determine whether or not a deceased adult's organs can lawfully be removed and used for transplantation.

The AIP's role will be, firstly, to check whether the person's wishes (to opt in, opt out or appoint a proxy) were formally registered, and to contact, or attempt to contact, any proxies that had been appointed to obtain a decision (authorising or refusing authorisation for the removal of organs). Where there is no proxy, or the proxy or proxies are unable or unwilling to make a decision within a “reasonable time”, it is for the AIP to consult the nearest relative to determine whether they are aware of any objection to the removal of organs that the deceased person had expressed (but not registered), or of anything that might lead to the conclusion that the deceased person did not have a reasonable opportunity to object. The Bill only requires the AIP to take account of the views of any relative that he or she can consult using “best endeavours” within a “reasonable time”.

Authorisation requires that all of a number of separate preconditions are met, (these are documented in section 6 of the Bill), and it is the job of the AIP to investigate and reach a conclusion. If any one of the pre-conditions is not met, then there is no authorisation and the organ cannot be removed for the purpose of transplantation under that section. If any applicable information comes to light that indicates the deceased did not have a reasonable opportunity to opt out, then the bill would allow the AIP to stop a donation from proceeding.

The Bill states that the role of ‘Authorised Investigating Person’ as integral to the efficient working of the new system.

## *Responses*

Some submissions (e.g. Royal College of General Practitioner Scotland, Aberdeenshire Health and Social Care Partnership, PBC Foundation) agreed with AIPs, but a few of these felt that the proposed awareness campaign in the Bill should provide safety nets if decisions are made in this way based on the wishes of the deceased person. Some submissions felt that the purpose of the AIP, i.e. their role, and what they would do and how they would operate was not clear (e.g. Scottish Government, NHS Blood and Transplant, UK Donation Ethics Committee). It was felt to be not clear who would take on this role or from what profession because it seemed to have a legal responsibility attached to it and because they thought that health professionals, including SNODs, would not be equipped to take on this role without adequate additional training and their current role did not lend itself to the role. The Scottish Government was unclear if it was an investigative or authorising role. For example SNODs largely undertake the role of ‘investigator’ rather than that of ‘authoriser’, but if they took on the role of AIP then it is likely that they would also have to be an ‘authoriser’ and therefore determining the ‘lawfulness’ of donation. NHS Blood and Transplant felt that hospital clinicians and nurses are unlikely to be comfortable performing the AIP role if there is a risk that it may bring them into conflict with families.

Some submissions (e.g. NHS Forth Valley, NHS Fife) also thought that the provisions of AIPs would be unworkable and add more bureaucracy, which would increase the time the process takes and complicate it further. For example the Scottish Government felt there would be a real risk that introducing the additional authorisation checks set out in the Bill will result in slowing down the process. A few submissions wondered how many AIPS would be required because they would be needed day and night and that would add to the costs of the donor and transplantation system. The Scottish Government, Church and Society Council of the Church of Scotland and the Law Society of Scotland all highlighted that there was nothing in the proposed Bill about preventing a legal challenge against the decision made by an AIP.

It was also pointed out that there was no detail provided on a “reasonable time” for AIPs to contact subsequent proxies or to take a decision to proceed with the retrieval of organs. They believed this could be open to interpretation by AIPs and legal challenge, for example from families, which may have a detrimental effect on donation overall because it could undermine the trust in the transplantation system.

### **Rule if order of acts unclear**

Section 7 of the Bill “Rule if order of acts unclear”, which means if it is uncertain which system of authorisation i.e. opting-in or appointment of a proxy or registering an objection (i.e. opting-out) was the last thing an individual did in response to organ donation, then the adult is to be treated as having done none of them. This would mean that they had presumed consent for their organs to be removed.

## *Responses*

This implies that donation through authorisation by law would be allowed implying that the objection would always be ignored (NHS Greater Glasgow and Clyde and NHS National Services Scotland). They felt that proceeding with donation under such circumstances may lead to public outcry.

## **Nearest relative**

The Bill does not allow relatives to block the removal of organs by reference to their own views or preferences about organ donation; they are consulted only to help establish whether the deceased person had expressed any objection, having had a reasonable opportunity to do so.

### *Responses*

There were mixed responses to this provision with some submissions thinking it diminished the role of the nearest relative because they only had to be “consulted”.

Section 7 of the 2006 Act allows authorisation to be given by a nearest relative, where the deceased adult had not done so. The Bill does not repeal this provision, although it is amended to ensure it cannot be exercised while the question of proxy authorisation is under active consideration.

### *Responses*

This raised concerns with some of the respondents about clarity of whose final decision it was – the proxy, or the nearest relative.

## **Publicity**

Scottish Ministers are responsible for ensuring that a publicity campaign is run throughout the period (of at least 6 months).

### *Responses*

A number of submissions felt that a one-off publicity campaign of six months was too short and that it should be longer and on-going (e.g. Scottish Government, NHS Blood and Transplant, Free Church of Scotland).

## **Adults with Incapacity**

Section 16 of the Adults with Incapacity (Scotland) Act 2000 allows a person to grant a power of attorney relating to his personal welfare (i.e. a “welfare power of attorney”) that may be exercised at such time as the granter lacks the capacity to make the decisions for himself or herself. It imposes various restrictions on what a welfare attorney may do and this currently includes preventing the attorney giving authorisation for the removal or use of organs. This Bill prevents a welfare attorney from either appointing (or withdrawing the appointment of) a proxy, or objecting to the removal of the adult’s organs.

### *Responses*

NHS Greater Glasgow and Clyde and NHS National Services of Scotland felt that it seemed that the Bill, in the case of Adults with Incapacity, would prevent a welfare attorney from either appointing a proxy or objecting to the removal of the adult’s organs. The Scottish Government was concerned that adults with incapacity could end up being “locked-in” to organ donation as neither they, nor someone acting on their behalf under the provisions of the 2000 Act, would be able to appoint a proxy, or be able to register an objection to the removal of organs. In other

words it could make it difficult for adults with incapacity, and their next of kin/guardians, to opt-out of the provisions relating to the authorisation of the removal of organs by operation of law.

## **Persons to whom the Bill applies**

The Bill would apply to people who at the time of their death had been habitually resident here for a continuous 6-month period beginning after their 16<sup>th</sup> birthday and after the day the opt-out register first became available.

### *Responses*

The Law Society of Scotland felt that the period was too short and should be 12 months instead of the 6 months. This was also alluded to by the Scottish Government and the Scottish Council of Jewish Communities who had concerns over the six month residency having additional implications for international students and foreign contractors.

The changes made by the Bill only apply to adults (defined as people who are aged 16 years and above). The Law Society of Scotland thought that the age limit should be set at 18 years of age. This is because they felt that at the age of 18 the person is more likely to have an understanding and can make fully considered and informed choice. Also they felt it would be more consistent if Scotland adopted the same age criteria as Wales, i.e. 18 years of age. The Scottish Government had concerns that the 'authorisation' only applies to adults over the age of 16 because the current legislation allows children aged over 12 to opt-in i.e. the Organ Donor Register allows children over 12 to opt-in and opt-out. This means that the proposed Bill risks removing a right that a child already has.

## **KEY THEMES**

The following is a summary of the general themes that emerged about the Bill from the Committee's call for evidence. This is not intended to be an exhaustive account of all of the points raised and for more detail of the submissions please see the Health and Sport Committee's [webpage](#).

### *General support of Bill*

BMA Scotland, Nuffield Council on Bioethics, and the British Heart Foundation Scotland believe that the introduction of an opt-out system will support both the deceased to have their wishes carried out and the families who are faced with these tough decisions. BMA Scotland believes that a move to an opt-out system which creates the default position could lead to a change in the philosophy within society where donation becomes seen as the norm.

### *Not supporting the Bill*

The main issues were around the ethics, practicalities of the Bill, in particular proxies and authorised investigating persons (AIPs), and the diminished role of the family, which they felt could undermine the trust within the donor and transplantation system. For example CARE for Scotland, in their submission, were

“concerned that the Bill does not explicitly set out a right of objection for families on the face of statute.”

### *Families/Next of Kin*

The Scottish Government, NHS Greater Glasgow & Clyde and NHS National Services Scotland highlighted, in their submissions, the importance of the next of kin in providing the necessary medical, social and behavioural history of the potential donor to ensure the safety of the donated organs/tissue for intended recipients. They felt that this Bill would remove the need to gain authorisation from the next of kin and proceeding with donation in the absence of next of kin support is likely to lead to a decline in the safety of retrieved organs/tissue.

A few submissions felt that the Bill is not clear on the family involvement and the relationship between them and proxies, and AIPs, which could create conflict between families, proxies and AIPs. This could lead to potentially damaging trust in the UK's organ donation system.

### *Presumed Consent*

A number of submissions felt that the concept of presumed consent is a misnomer because in practice it is not consent at all (e.g. Church and Society Council of the Church of Scotland, CARE for Scotland, Christian Medical Fellowship).

“Silence does not amount to consent.” (Christian Medical Fellowship).

They thought that it is likely that under a presumed consent system that organs will be removed from individuals who would not have consented to their removal. For example they felt that not all persons who fail to opt out will have wished to give consent for retrieval and transplantation of their organs in the event of death. There could be various reasons for this, for example just not getting round to it or not knowing about the system. This was felt to be of particular concern for vulnerable groups such as those with limited capacity as well as hard-to-reach groups. A few submissions felt that it would be extremely difficult to ensure that everyone, especially those belonging to some minority or disadvantaged groups, was aware of the legislation and understood the consent process, knew their options and could easily opt out. For all these reasons a number of submissions felt that introducing presumed consent would be unethical and potentially could be distressing to families. It was also claimed that it could also potentially lead to legal challenges by families over decisions made by medical staff and specialists based on proxy or ‘authorised investigating person’ decisions.

### *Human Rights*

Some submissions went further to suggest that if a deceased person was not aware of the system of consent/authorisation and the possible destiny of his/her body or its parts (transplantation, research etc.) and the use of its parts did go ahead without the individual having given his/her informed consent, there may be grounds for taking the case to the European Court of Human Rights. This is because the European Convention on Human Rights and Biomedicine requires informed consent to take place before any intervention is envisaged (e.g. Scottish Government, Scottish Council for Human Bioethics).

### *Donation as a gift*

There was a feeling amongst some submissions that donations should be seen as an altruistic gift and not be taken by force or by default (CARE for Scotland, Christian Medical Fellowship, Church and Society Council of the Church of Scotland, Scottish Council on Human Bioethics). A couple of these submissions went further to note that some opponents of any form of opt-out scheme felt:

“that the state (acting through health professionals and the health care system) would be intervening to ‘take’ organs rather than facilitating their being ‘given’ there is at least a risk that some degree of trust in the system would be lost.”

### *Organ Donor Register*

Some submissions, who did not support the Bill, felt that resources should be put into improving the current organ donor and transplantation infrastructure and system and further promotion of the Organ Donor Register. A few submissions (e.g. Scottish Government, NHS National Services Scotland) asked if the Bill was still required because the Organ Donation Register now (since July 2015) allows for people to register to opt-out as well as opt-in. However the Bill also allows for presumed consent, which means that if a person has not opted-in or opted-out or appointed a proxy then this means that they have consented to their organs being donated.

### *Research evidence*

Many submissions cited the international research on whether opt-out legislation increases organ donation and discussed what part the opt-out legislation plays in the increase in organ donation. There were mixed views between submissions because some submissions (e.g. BMA Scotland, Royal College of Physicians of Edinburgh, Aberdeenshire Health and Social Care Partnership, British Heart Foundation) felt that the international evidence showed or convinced them that opt-out schemes did increase organ donation (or contributed to an increase in organ donation) whereas others felt that the evidence did not show this or they were not convinced by the evidence (e.g. Scottish Government, Scottish Council of Jewish Communities, Free Church of Scotland, NHS Highland). The most often quoted evidence included the systematic review (Rithalia et al. 2009) and the success of the ‘soft opt-out’ legislation in Spain. Some of the submissions who were not convinced by the evidence state that Spain does not have a full ‘soft opt-out’ system. They mean that in Spain there is no register for people to use to express their wish to opt-out and they always ask the family. They also claimed that in Spain the legislation was not the main reason for its increase in donation numbers, but was due to improvements in its donation and transplantation system. The Scottish Government, in their response, stress that the organ donor rate in the UK is now at 21pmp, which is roughly comparable with most of these countries.

### *Wales*

A number of submissions suggested it would be a good idea to wait to see what happens with the ‘soft’ opt-out legislation in Wales before moving to an opt-out system in Scotland (Scottish Council for Human Bioethics, NHS Greater Glasgow and Clyde, UK Donation Ethics). This is in terms of whether the system works and whether it increases organ donation rates. This was very much the view taken by the Scottish Government not only in its written submission in its call for evidence, but also in their latest strategy for organ donation and transplantation.

### *End of life care*

A few submissions (e.g. Royal College of Nursing Scotland) felt that organ and tissue donation should be integrated into the culture of best practice in end of life care and this would impact on donation rates.



### *Simplicity*

BMA Scotland, NHS Fife and PBC Foundation felt the Bill needs to be extremely simple, for example a simple opt in/opt out system. The proposed Bill has several ways or choices of consenting or not consenting to organ donation e.g. opting-in, opting-out or appointing a proxy.

### *Language*

A few submissions felt the language was moving away from 'donation' to the 'removing' of organs, which they felt should be changed. The Law Society of Scotland highlighted that the principle of consent is not referenced in relation to the aims of the Bill and they see authorisation as being about giving permission, which does not mean the same as presumed or implied consent.

## **SCOTTISH GOVERNMENT RESPONSE TO THE BILL**

The Scottish Government submitted a written response to the Health and Sport Committee's Call for Evidence. The Scottish Government commends the aim of the Bill, but states that it is not in a position to support it. It cites three main reasons for not supporting it and these are as follows:

- It is not convinced that the Bill would lead to an increase in the number of organs and tissues being made available for transplant
- It has significant concerns about specific measures set out in the Bill and its Policy Memorandum, in particular proxies, authorised investigating persons and legal implications.
- It has concerns that the financial cost to Scottish Ministers and the NHS have not been fully reflected.

Another major concern that the Scottish Government had was the extent to which the measures contained within the draft Bill had been tested with the experts working in the field of organ donation.

It also had concerns that the Bill or accompanying documents does not state or estimate the number of additional donors the Bill would be expected to lead to. This means it is not only difficult to clarify costs, but it also provides no certainty on whether the Bill has achieved its aims.

The Scottish Government submitted a separate written [response](#) to the Scottish Parliament Finance Committee who issued a Call for Evidence on the Financial Memorandum of the Bill and a summary of this is provided below.

## **FINANCIAL IMPLICATIONS**

The financial memorandum outlines that the two main areas of cost for the Scottish Ministers are the set-up and implementation costs of an opt-out system, and the costs of the publicity campaign (of at least six months duration) that the Scottish Government is required to inform the public about the changes being made by the Bill.

The Financial Memorandum contained in the Explanatory Notes for this proposed Bill stated that:

“the estimated overall cost of £7.5 million over 10 years for the Wales Act seemed a reasonable overall estimate for this Bill as well.”

A UK Parliament briefing note on Organ Donation and Transplants indicates that the transplant programme delivers an annual cost saving of £316 million to the NHS, according to NHS Blood and Transplant.

The Bill could have direct cost implications for local authorities with regards to the provision of social care, such as care and support in the home, for those awaiting a donor transplant. Any reduction in the number of people on the waiting list for transplant operations may reduce demand on the local authorities' social budgets. It is not possible to quantify the financial benefits to local authorities,

The Financial Memorandum stated that there will be staff and IT costs associated with setting up and maintaining the opt-out register and increasing awareness amongst medical staff of the new system and training them to implement it. There will also be costs associated with an increase in the number of transplant operations. However these financial costs could be offset by the long-term savings of a reduction in the burden of the health service through reduced dialysis provision and associated long-term care costs.

## **SCOTTISH GOVERNMENT'S RESPONSE TO THE FINANCIAL MEMORANDUM**

The Scottish Government felt that the Bill's Financial Memorandum significantly underestimates the potential costs of the legislation to Scottish Ministers.

The Scottish Government felt that the organ donation campaign would be £3.3 million over either one or two years rather than the £2.8 million suggested in the Financial Memorandum.

They suggested that the implementation of the Bill and therefore the cost to the Scottish Ministers would be £22.2 million over 10 years and recurring costs of around £2 million each year thereafter rather than the £7.5 million over 10 years as suggested in the Financial Memorandum. (The Scottish Government however interpreted the figure as £6.1 million rather than the £7.5 million stated). The reason for the increase in costs, from £6.1/£7.5 million to £22.2 million, is to accommodate a team of AIPs, (not mentioned in the Financial Memorandum) and the delivery of an on-going publicity campaign rather than the proposed 6 month campaign suggested in the Policy Memorandum and Financial Memorandum.

It was felt by the Scottish Government that the identified cost for the advertising, in the Financial Memorandum, taken over one year would be almost half the Scottish Government's total (not just health related) marketing budget. They indicated that additional funding would have to be identified for costs above the existing baseline.

The overall implied position in the Bill appears to be that the financial benefits generated from any additional transplants will offset any and all extra costs to NHS Boards over time, and therefore all costs can be accommodated from within existing Board budgets. The Scottish

Government felt that this was a very generalised assumption and would need detailed discussion with NHS Boards.

The Scottish Government and a few other submissions highlighted that the Bill and the accompanying documents do not state the number of additional donors which the Bill would achieve. This makes it difficult to calculate the cost savings versus the costs of implementing the Bill.

The Scottish Government, in their submission, felt it is impossible to accurately assess the costs of the proposed measures from the information contained within the Financial Memorandum. The Scottish Government feel that any long term costs/savings analysis to NHS Scotland and NHS Boards are difficult to calculate until the impact of the legislation i.e. the number of additional donors and transplants is understood.

## SOURCES

Bird, S.M. and Harris, J. Time to move to presumed consent for organ donation. *BMJ* 2010; 340:2188

Fabre, J., Murphy, P. and Matesanz, R. Presumed consent is unnecessary. *BMJ* 2010; 341: 922  
Rudge, C.J. and Buggins, E. How to Increase Organ Donation: Does Opting Out Have a Role? *Transplantation* 2012; 93(2): 141-144

Organ Donation Taskforce *Organs for transplants: a report from the Organ Donation Taskforce* (2008). Available at:

<http://www.bts.org.uk/Documents/Publications/Organs%20for%20transplants%20-%20The%20Organ%20Donor%20Task%20Force%201st%20report.pdf>

Organ Donation Taskforce *The potential impact of an opt out system for organ donation in the UK: an independent report* (2008). Available at:

<http://www.nhsbt.nhs.uk/to2020/resources/ThepotentialimpactofanoptoutsystemfororgandonationintheUK.pdf>

Rithalia, A., McDaid, C., Suekarran, S. et al. *Impact of presumed consent for organ donation on donation rates: A systematic review*. *BMJ* 2009: 338: a3162

Rudge, C. J. and Buggins, E. How to Increase Organ Donation: Does Opting Out Have a role? *Transplantation* 2012 93(2):141-144

Scottish Parliament (2014a) *Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill – Draft proposal*. Available at

[http://www.scottish.parliament.uk/S4\\_MembersBills/Organ\\_Donation\\_Consultation\\_Document.pdf](http://www.scottish.parliament.uk/S4_MembersBills/Organ_Donation_Consultation_Document.pdf)

Scottish Parliament (2014b) *Transplantation (Authorisation of Removal of Organs Etc.) (Scotland) Bill – Summary of consultation responses*. Available at:

<https://annemctaggartmsp.files.wordpress.com/2014/10/consultation-summary-final.pdf>

Scottish Parliament (2015a) *Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill [as introduced]*. Edinburgh, Scottish Parliament. Available at:

[http://www.scottish.parliament.uk/S4\\_Bills/\(1\)Transplantation%20\(Authorisation%20of%20Removal%20of%20Organs%20etc.\)%20\(Scotland\)%20Bill/b72s4-introd.pdf](http://www.scottish.parliament.uk/S4_Bills/(1)Transplantation%20(Authorisation%20of%20Removal%20of%20Organs%20etc.)%20(Scotland)%20Bill/b72s4-introd.pdf)

Scottish Parliament (2015b) *Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill – Explanatory Notes*. Edinburgh, Scottish Parliament. Available at:

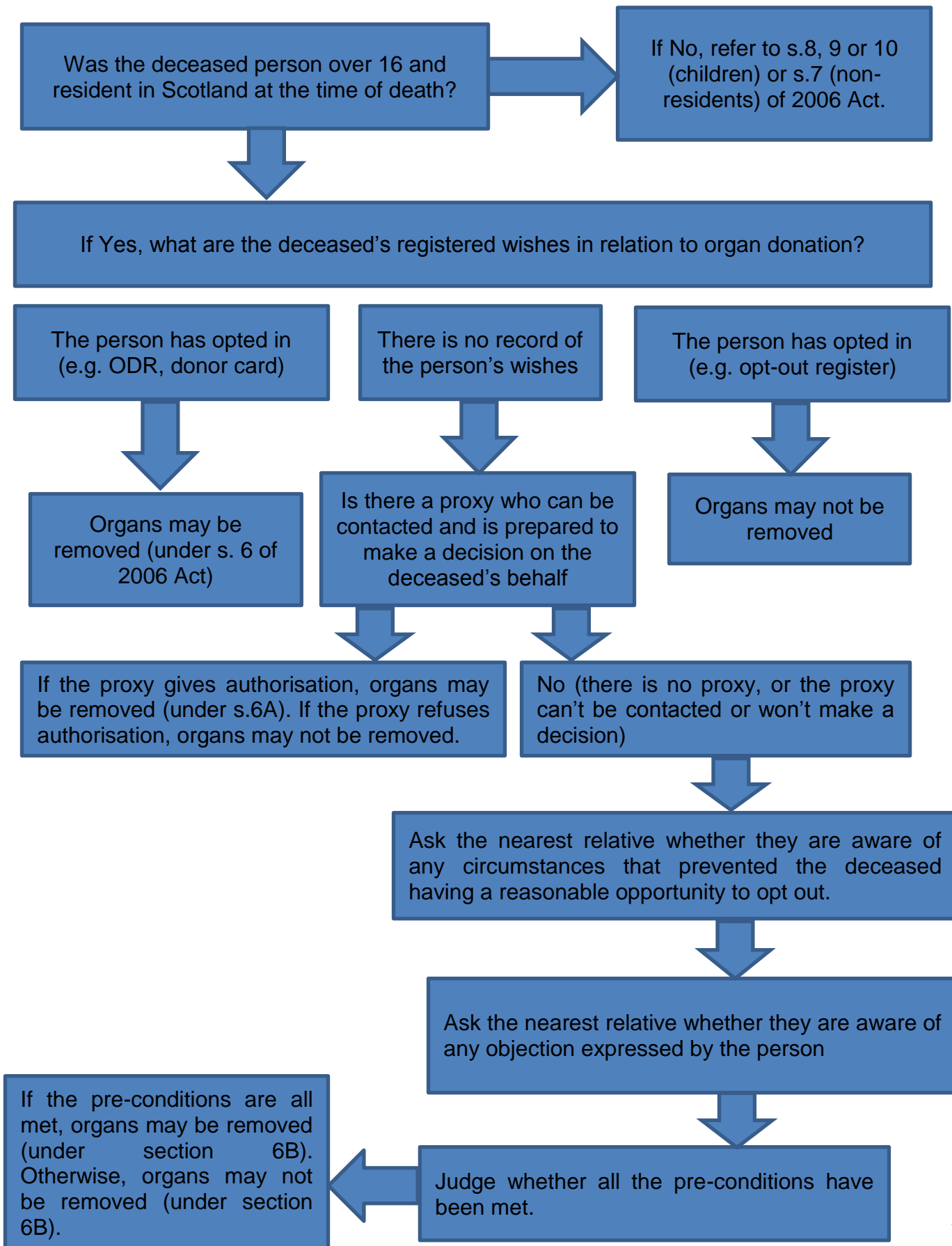
[http://www.scottish.parliament.uk/S4\\_Bills/\(1\)Transplantation%20\(Authorisation%20of%20Removal%20of%20Organs%20etc.\)%20\(Scotland\)%20Bill/b72s4-introd-en.pdf](http://www.scottish.parliament.uk/S4_Bills/(1)Transplantation%20(Authorisation%20of%20Removal%20of%20Organs%20etc.)%20(Scotland)%20Bill/b72s4-introd-en.pdf)

Scottish Parliament (2015c) *Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill – Policy Memorandum*. Edinburgh, Scottish Parliament. Available at:

[http://www.scottish.parliament.uk/S4\\_Bills/\(1\)Transplantation%20\(Authorisation%20of%20Removal%20of%20Organs%20etc.\)%20\(Scotland\)%20Bill/b72s4-introd-pm.pdf](http://www.scottish.parliament.uk/S4_Bills/(1)Transplantation%20(Authorisation%20of%20Removal%20of%20Organs%20etc.)%20(Scotland)%20Bill/b72s4-introd-pm.pdf)

Shepherd, L. O'Carroll, R.E. and Ferguson, E. An international comparison of deceased and living organ donation/transplant rates in opt-in and opt-out systems: a panel study. *BMC Medicine* 2014; 12: 131

# ANNEXE: PROCESS UNDER 2006 ACT (AS AMENDED BY BILL) TO ESTABLISH WHETHER ORGANS MAY LAWFULLY BE REMOVED FOR TRANSPLANTATION



## RELATED BRIEFINGS

[PB12-1453 Petition Briefing – Opt for Life](#)

[SB 08-13 Organ Donation](#)

[SB 05-44 Human Tissue \(Scotland\) Bill: Organ Donation and Transplantation](#)

Scottish Parliament Information Centre (SPICe) Briefings are compiled for the benefit of the Members of the Parliament and their personal staff. Authors are available to discuss the contents of these papers with MSPs and their staff who should contact Louise Rennick on extension 85392 or email [louise.rennick@scottish.parliament.uk](mailto:louise.rennick@scottish.parliament.uk). Members of the public or external organisations may comment on this briefing by emailing us at [SPICe@scottish.parliament.uk](mailto:SPICe@scottish.parliament.uk). However, researchers are unable to enter into personal discussion in relation to SPICe Briefing Papers. If you have any general questions about the work of the Parliament you can email the Parliament's Public Information Service at [sp.info@scottish.parliament.uk](mailto:sp.info@scottish.parliament.uk).

Every effort is made to ensure that the information contained in SPICe briefings is correct at the time of publication. Readers should be aware however that briefings are not necessarily updated or otherwise amended to reflect subsequent changes.

Published by the Scottish Parliament Information Centre (SPICe), The Scottish Parliament, Edinburgh, EH 99 1SP

[www.scottish.parliament.uk](http://www.scottish.parliament.uk)