TRANSPLANTATION (AUTHORISATION OF REMOVAL OF ORGANS ETC.) (SCOTLAND) BILL

POLICY MEMORANDUM

INTRODUCTION

1. This document relates to the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill introduced in the Scottish Parliament on 1 June 2015. It has been prepared by the Non-Government Bills Unit on behalf of Anne McTaggart MSP, the member who introduced the Bill, in accordance with Rule 9.3.3A of the Parliament’s Standing Orders. The contents are entirely the responsibility of the member and have not been endorsed by the Parliament. Explanatory Notes and other accompanying documents are published separately as SP Bill 72–EN.

POLICY OBJECTIVES OF THE BILL

2. The Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill ("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 “by operation of law” 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 able to make a decision on their behalf.

3. An adult for the purposes of the Bill is a person aged 16 years or over. The soft opt-out arrangements would normally only apply if the deceased person had been habitually resident in Scotland, as an adult, for a continuous period of at least 6 months prior to their death.

4. 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.
BACKGROUND

5. Organ donation has been the subject of debate in the Scottish Parliament many times over
the years. In 2008, the Parliament debated the Organ Donation Taskforce report.¹ The Organ
Donation Taskforce was set up by the UK Government in December 2006 with a remit to
identify barriers to organ donation and to recommend actions needed to increase organ donation
and procurement within the current legal framework.

6. The report made 14 recommendations for action which, if acted upon, could increase the
number of organs available for transplantation across the UK by 50% by 2013. The
recommendations focussed on improving the current legislative framework and establishing a
more effective and integrated UK-wide approach. The UK and Scottish Governments both
signed up to the report and its recommendations.

7. In 2008 the Organ Donation Taskforce also produced a report on its comparative review
of the implications on organ donation numbers of a move to an opt-out system and concluded
that an opt-out system should not be introduced in the UK at that time, but should be reviewed in
five years’ time in the light of success achieved in increasing donor numbers through
implementation of the 14 recommendations contained in its report Organs for Transplant.²

8. Anne McTaggart’s decision to lodge the proposal on which this Bill is based followed a
joint campaign by the Evening Times and Kidney Research UK who petitioned the Scottish
Parliament to urge the Scottish Government to move to an opt-out system in Scotland.³

9. While the member welcomes the recent improvements in the number of people
registering to donate, she believes that the available evidence supports her view that moving to
an opt-out system would increase the number of donor organs available for transplantation more
than any other method.

Current law and practice

10. 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 Tissue 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.

11. The 2006 Act sets out that—

Available at: http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf
² Organ Donation Taskforce (2008), The potential impact of an opt out system for organ donation in the UK.
³ 2012 SPICe briefing for the Public Petitions Committee on PE1453. Available at:
Parliamentary debate on the petition in May 2014. Available at:
Any adult (or child aged 12 and over) can authorise the posthumous removal and use of their organs or tissue for transplantation (or other purposes, such as research). (For a child under 12, only a parent or guardian can give authorisation.)

Authorisation to donate organs or tissue for transplantation generally takes precedence over authorisation for any other purpose.

In the absence of authorisation by the adult (or child aged 12 or over) to remove organs or tissue for transplantation, the nearest relative (or parent or guardian) can authorise their removal for that (or another) purpose, but not if the relative (or parent/guardian) has actual knowledge that the adult (or child) was unwilling for them to be so removed and used.

Authorisation from one of these sources is one of the essential pre-conditions for the lawful removal and use of organs or tissue from a deceased person, along with restrictions on who may carry out the removal, and a number of other requirements. (Separate provision is made for parts of the body to be removed in connection with the functions of the procurator fiscal, e.g. in connection with a post-mortem examination. The 2006 Act also covers donation by live donors – e.g. where a person donates one kidney to a relative on dialysis). The unlawful removal or use of organs and tissue is a criminal offence, carrying a maximum sentence (on indictment) of 3 years’ imprisonment, a fine (or both).

There are various ways in which people can give authorisation for the posthumous removal and use of their organs for transplantation (i.e. opt in to become an organ donor). These include:

- Joining the NHS Organ Donor Register. The NHS Organ Donor Register is the UK’s national, confidential list of people who are willing to become organ donors after their death. This list is maintained by NHS Blood and Transplant, a UK wide Special Health Authority who deal with the allocation of organs across the UK.
- Telling their closest relatives or friends.
- Carrying a donor card.
- Writing it in a letter or document, such as a will.

As noted above, express authorisation is needed under the 2006 Act before organs may lawfully be removed for transplantation. But the existence of authorisation is not always enough. Although there is no statutory requirement for a deceased person’s relatives 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.

Recent developments in other parts of the UK

The Organ Donation (Presumed Consent) Bill 2008-09 was a Private Member’s Bill introduced at Westminster by Mr Jeremy Browne MP to change to a soft opt-out system of organ donation. The Bill was debated at a second reading in the House of Commons on 19 June 2009 but ran out of time to be heard by a public bill committee before the end of the parliamentary session.
16. The National Assembly for Wales (NAW) passed the Human Transplantation (Wales) Act in 2013. This Act provides for the implementation of a soft opt-out system for organ and tissue donation in Wales and will come fully into force on 1 December 2015. NAW recently published its first yearly report on the implementation of this Act, covering September 2013 to October 2014. The Welsh Act provides for a move to a “soft” opt-out system where most adults will be “deemed” to have consented to the removal of their organs and tissues after death, for transplantation, unless they have expressed an objection. Deemed consent will not apply to children (aged under 18) or to “excepted adults” – i.e. adults who were not ordinarily resident in Wales for at least 12 months immediately before dying, or who lacked the capacity, for a significant period before dying, to understand the concept of deemed consent.

17. In Northern Ireland the process for organ donation and transplantation remains an opt-in system where express consent must be given for organ donation. In 2013 Mrs Jo-Anne Dobson MLA of the Northern Ireland Assembly consulted on a proposal for a Private Member’s Bill to change from an opt-in system to a “soft” opt-out system. There were 1,366 consultation responses received, 82% of which were supportive of the proposed change. The proposal and consultation results were discussed by the Health, Social Services and Public Safety Committee on 23 October 2013. It is understood that a Bill to give effect to this proposal is currently being drafted.

The case for change

Support for an opt-out system

18. In Scotland there are currently around 550 people waiting for an organ transplant and 41% of eligible people in Scotland have signed up to the organ donation register. Whilst this represents the highest sign-up rate in the UK, it is estimated that three people die every day in the UK whilst on the waiting list for a transplant.

19. The UK was ranked 13th in Europe in 2013 in terms of the number of deceased organ donation rates, at 21 donors per million population (pmp). This represents a significant increase from 2006 when the UK donation rate was 12.9 donors pmp. The increase is likely to be due in part to efforts made to improve the system of organ donation recommended by the Organ Donation Taskforce.

20. The 2006 figure showed that the UK lagged behind many of the European countries that have moved to an opt-out system. This includes Spain (35.5 donors pmp), France (23.2) and Italy (21.7). Whilst improvements in other aspects of the organ donation system in these countries, such as the introduction or better use of transplant co-ordinators, may account for some of these

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5 https://www.organdonationscotland.org/tell-me-more
6 https://www.organdonationscotland.org/tell-me-more
7 EC Journalistic Workshop on Organ donation and transplantation; recent facts and figures (2014). Available at: http://ec.europa.eu/health/blood_tissues_organs/docs/ev_20141126_factsfigures_en.pdf. In this context, a donor is a person from whom organs may lawfully be taken, not necessarily a person from whom organs are in fact taken.
increases, the member considers that the evidence supports her view that adopting an opt-out system significantly increases the number of donors.

21. A YouGov survey in 2007 indicated that 74% of respondents in Scotland supported a system of presumed consent for organ donation, whilst a Scottish Government survey undertaken in 2012 found that only 5% of the population opposed organ donation in principle. Despite recent surveys suggesting that there is widespread support for posthumous organ donation, this is not reflected in those registering to donate organs and/or tissue.

22. Historically, the number of donor organs available for transplantation has been outstripped by demand and this continues to be the case. It is estimated that the waiting list for donor organs is growing by around 5% per year, largely due to factors such as increases in renal and liver disease, better clinical management of serious illnesses, lower thresholds for transplantation and growing ethnic diversity within the population (making it more difficult to match organs and tissue to patients). Additionally, it is expected that an ageing population and an anticipated increase in the incidence of type 2 diabetes will further increase demand.

23. Organisations including the British Heart Foundation, the British Medical Association and the Royal College of Physicians in Edinburgh support the move to an opt-out system.

International comparisons

24. As mentioned above a number of European countries have adopted a form of presumed consent legislation for organ donation. Within the EU, the following countries surpassed the UK in 2011 for rates of deceased organ donations per million people: Austria, Belgium, Croatia, the Czech Republic, Finland, France, Ireland, Italy, Malta, Norway, Portugal and Spain. All of these countries, with the exception of Malta and Ireland, operate an opt-out system.

25. Research into the impact on organ donation rates of adopting opt-out systems has concluded that it has a positive effect on the number of organs donated. A joint study undertaken by Harvard University and the University of Chicago in 2005 found “that while differences in other determinants of organ donation explain much of the variation in donation rates, after controlling for those determinants presumed consent legislation has a positive and sizeable effect on organ donation rates”. The study also found that organ donation rates increase by approximately 25-30% in countries where an opt-out system is introduced.

26. In 2008, the University of York was commissioned by the Organ Donation Taskforce to carry out a systematic literature review with the aim of assessing the impact of opt-out legislation on organ donation rates in other countries. Results showed that Austria and Singapore both

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experienced an increase in donation rates of up to 25% after moving to a hard form of presumed consent.\(^{13}\)

27. In 2012, the Welsh Government carried out a further literature review of information assessing the impact of opt-out legislation on organ donation rates published since 2008.\(^{14}\) The main findings of this review were:

- International evidence suggests that an association exists between presumed consent legislation and increased organ donation rates;
- Recent surveys indicate that there is significant support for the introduction of an opt-out system for organ donation in Wales; and
- Experimental literature provides evidence for a mechanism through which presumed consent might increase organ donation, through the influence of the default position.

28. Whilst there are some countries operating an opt-out system that have lower donation rates than the UK, such as Sweden, the member considers that the international evidence clearly demonstrates a clear link between an opt-out system and higher donation rates.

29. Spain has been a particular success story with regards to increasing its rates of organ donation. In 2006 Spain had the highest organ donation rate in Europe at 35 donors per million population (pmp)\(^{15}\), and maintained that rate in 2013. In contrast, the UK had one of the lowest rates at 13 pmp in 2006.\(^{16}\) In the mid-to-late 1990s, before the Spanish authorities began to systematically address barriers to organ donation, Spain had a rate similar to that of the UK. Furthermore, where aspects of the Spanish approach were implemented in Italy and a number of South American countries, they all experienced an immediate rise in organ donation, with Tuscany doubling its donation rate within a year\(^ {17}\). The Organ Donation Taskforce’s view is that “it is entirely possible for the same to happen in the UK”.\(^{18}\)

30. Belgium provides another example of a country that introduced a soft opt-out system in 1986 and within three years saw donor rates double.\(^{19}\)

31. The member believes that, notwithstanding recent improvements, the UK’s continued comparatively low rate of organ donation and the growing need for the number of organ donations to increase present a strong case for moving to a new system of organ donation in Scotland. Given the clear evidence of the success of opt-out systems adopted by many countries a move to an opt-out system of organ donation offers the single most effective method of addressing the problem.

\(^{14}\) http://gov.wales/docs/caecd/research/121203optoutorgandonationsummaryen.pdf
\(^{15}\) Organ Donation Taskforce (2008), Organs for Transplant: A Report by the Organ Donation Taskforce, Page 20, paragraph 2.2. Available at: http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf
\(^{16}\) Ibid., Page 20, paragraph 2.2.
\(^{17}\) EC Journalistic Workshop on Organ donation and transplantation; recent facts and figures (26/11/14),
\(^{19}\) http://optingforlife.org/about-opt-out/
The Scottish Government’s position


33. The report commented that many people who support organ donation still have not signed up to the Organ Donor Register and that there is a wide variation of organ donation rates across Scotland. The report is a companion to the UK Strategy, *Taking Organ Donation to 2020*,21 and makes no reference to a move to an opt-out system; rather it states that the Scottish Government will continue to work closely with other parts of the UK and with NHS Blood and Transplant on implementing the 21 recommendations designed to improve the donation process as a whole.

DETAIL OF THE BILL

34. The Bill amends the Human Tissue (Scotland) Act 2006, but only to the extent necessary to achieve the move to a soft opt-out system. The Bill does not affect the existing position for children (under the age of 16), nor does it remove the existing provisions that allow an adult to give authorisation for the posthumous removal and use of his or her own organs (section 6), and that allow an adult’s nearest relative to give authorisation where the adult did not do so and where the nearest relative is not aware of any objection expressed by the adult (section 7). The Bill only applies to the removal and use of organs from deceased adults, and has no effect on the law so far as living donors are concerned.

35. The existing arrangements involving the NHS Blood and Transplant service will not be affected by the Bill, and Scotland will continue to share the UK-wide NHS Organ Donation Register and the services provided by NHSBT, such as the allocation of organs across the UK, management of data and information, and the training and management of specialist nurses and clinical leads.

36. The main process that would be followed under the 2006 Act, as amended by the Bill, in deciding whether organs or tissue may be lawfully removed from a deceased person, is illustrated in the flowchart that is annexed to this Memorandum.

A “soft” opt-out system

37. As noted above, the current system of organ donation in Scotland is an “opt-in system”, whereby a deceased person’s organs may be removed for transplant only if the person has expressly authorised such removal before his or her death (i.e. opted in), or if another person with a relevant relationship to the deceased (usually as a relative) has given express authorisation. The main purpose of the Bill is to reverse the presumption behind this system to one where organ removal may be authorised “by operation of law” – i.e. without the express authorisation of any such person – unless the deceased person expressed an objection to that removal before their death (i.e. opted out). The system created by the Bill is referred to as a

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“soft” opt-out system as it retains the right to opt in alongside the new option to opt out, and continues to require consultation with the deceased person’s relatives. (A “hard”, or pure, opt-out system would be one in which only an express objection by the deceased adult could prevent his or her organs being lawfully removed, in which there would no longer be any option to opt in, and in which there would be no role for the relatives.) It should be noted, however, that 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.

38. The Bill also allows an adult to appoint a proxy (or proxies) to make the decision, after the adult’s death, whether to authorise the removal of his or her organs for transplantation. Appointing a proxy is to be an additional positive 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). Authorisation “by operation of law” can only apply, therefore, where the adult chose none of these three options (or, if the choice was to appoint a proxy, where the proxy cannot be contacted or is unable or unwilling to reach a decision within a reasonable time).

39. The proxy provisions are explained further below.

Duties of Ministers

40. The Bill imposes some additional duties on the Scottish Ministers, and updates some existing duties. In particular, it requires 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. It is envisaged that this will be the existing Organ Donor Register, or another register that is available on an equivalent basis – so the obligation on Ministers is to approve such a register rather than necessarily create it. Ministers are also made responsible for ensuring that a publicity campaign is run throughout the period (of at least 6 months) between the “first appointed day” (by which the approved register must be up and running) and the “second appointed day” (when the new provision allowing organs and tissue to be removed from a deceased adult who had not opted out first comes into operation).

“Authorised investigating persons”

41. The Bill refers throughout to “authorised investigating persons” (or 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 is, 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.
Persons to whom the Bill applies

42. The provisions set out in the 2006 Act in relation to children aged 12 or over (sections 8 and 9) and children who die under the age of 12 (section 10) are not affected by this Bill. For them, express authorisation will continue to be required. The changes made by the Bill apply only to adults (defined as people who are aged 16 years and above).

43. For the reasons explained below, the new provision that allows authorisation “by operation of law” only applies, in practice, to people who were not only resident in Scotland at the time of their death, but had (by that time) been habitually resident here for a continuous 6-month period beginning after their 16th birthday and after the day the opt-out register first became available (and a publicity campaign about the new system had begun). Accordingly, the soft opt-out system will not apply to anyone who, for example, dies while on holiday in Scotland, nor will it apply – initially at least – to anyone who has only recently moved to Scotland from elsewhere in the UK (or overseas). However, in view of the fact that Wales has already legislated for a comparable soft opt-out system and that other parts of the UK may follow suit, provision is made in section 16 to allow the 2006 Act to be further amended (by regulations) so it can take a more joined-up approach to people in such circumstances. Such regulations could, in particular, allow the new soft opt-out system to be applied in future to someone who (at the time of their death) had recently moved to Scotland from another jurisdiction that had operated a similar opt-out system for at least as long as Scotland had.

Authorisation by operation of law

44. In terms of moving to a soft opt-out system, the key provision is new section 6B (inserted into the 2006 Act by section 6 of the Bill). This section only applies to an adult who was resident in Scotland at the time of death.

45. Authorisation under that section also requires that all of a number of separate pre-conditions are met, and it is the job of the authorised investigating person (or AIP) to investigate and reach a conclusion. If any one of the pre-conditions is not met, then there is no authorisation under section 6B, and the organ cannot be removed for the purpose of transplantation under that section.

46. The AIP’s first task is to check whether the deceased person had either opted in (e.g. by checking the organ donor register) or opted out (by registering an objection using the new register that Ministers must approve). Then the AIP must check for any proxy appointment and make reasonable efforts to contact that proxy (or any of them, if two or more were appointed). Where there is a proxy, and the proxy makes a decision (whether to authorise organ-removal or not), that decision is decisive and halts the section 6B process. But if there is no proxy, or no proxy can be contacted or can make a decision within a reasonable time, the AIP can move on to the final part of the process – which involves asking questions of the deceased person’s nearest relative.

47. The first question that must be asked of the nearest relative is whether the deceased person had a “reasonable opportunity” to opt out (i.e. object to the removal of the organ in question for transplantation). In this connection, a “rebuttable presumption” is created that anyone had a reasonable opportunity to opt out if they were habitually resident in Scotland (as an
adult) for any continuous period of six months beginning after the “first appointed day” – i.e. the
day by which an opt-out register must be available, and a publicity campaign drawing attention
to it must have begun. The idea here is that it can be reasonably inferred from the fact that the
adult did not (in fact) record an objection (to one of their organs being removed) that they had no
such objection, only if the adult was aware that they had the option of objecting, understood the
possible consequences of not exercising that option, and had a convenient and reliable means of
exercising that option if they chose to do so. In that context, six months is considered a sufficient
time for any adult who wishes to object to do so – but the presumption is rebuttable in case any
information comes to light that would lead the AIP to conclude that the adult (despite having
been habitually resident in Scotland for at least six months) did not have a reasonable
opportunity to object. This might, for example, be because they were not present in Scotland for
most of that time, or lacked capacity for a significant part of it.

48. The second question that the nearest relative must be asked is whether they are aware of
any (unregistered) objection that the adult had (to the removal of the organ in question for
transplantation). This is not about asking relatives to give authorisation themselves: the question
is about the deceased person’s own view (as understood by the relative), rather than about the
relative’s personal view. The AIP must decide whether this particular pre-condition has been met
taking into account any answer to the AIP’s question that is given by the nearest relative
(although the AIP may also take into account information from other sources).

Appointing a proxy

49. The Bill allows any adult to appoint a proxy to make decisions about authorisation (for
the removal of the adult’s organs for transplantation), on their behalf, after their death. Just as, at
present, an adult can authorise the removal of some organs but not all for transplantation, and
just as the new option to object may be applied only to some organs and not all, so a proxy may
be appointed only for some organs and not all. This allows an adult to make a range of choices,
differentiating among their various organs according to their personal views. (Without this
flexibility, a person’s reluctance to envisage the removal of just one organ could prompt them to
object wholesale, thus preventing others from becoming the recipients of the person’s other
organs even though that would have been quite consistent with the person’s wishes.) However,
an adult is not permitted to appoint different proxies for different organs (as this would create an
additional layer of administrative complexity, for no obvious benefit).

50. 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. Provision is also made to deal with various situations that
could arise when it has been necessary to contact more than one proxy in the list (either because
the first proxy could not be contacted or because, having been contacted, that first proxy could
not, or would not, make a decision quickly). The general aim is to allow the AIP to secure a
decisive answer to the question of authorisation as quickly as is consistent with giving the
individuals involved a reasonable time to make difficult decisions in potentially distressing
circumstances.
The nearest relative

51. As noted above, the new soft opt-out system created by the Bill (in new section 6B of the 2006 Act) requires active consultation with the deceased person’s nearest relative.

52. In this context, “nearest relative” is defined by reference to the existing definition of that term in section 50 of the 2006 Act. Under that definition, the nearest relative can be any of the following:

- the adult’s spouse or civil partner;
- living with the adult as husband or wife or in a relationship which had the characteristics of the relationship between civil partners and had been so living for a period of not less than 6 months (or if the adult was in hospital immediately before death had been so living for such period when the adult was admitted to hospital);
- the adult’s child;
- the adult’s parent;
- the adult’s brother or sister;
- the adult’s grandparent;
- the adult’s grandchild;
- the adult’s uncle or aunt;
- the adult’s cousin;
- the adult’s niece or nephew;
- a friend of longstanding of the adult.\(^{22}\)

53. Clearly, it would be unrealistic to expect the AIP to work through that entire list exhaustively to find at least one person to consult. Very often, there won’t be a problem if the deceased person’s close family are already at the bedside, but in other cases the AIP may have no way of knowing what relatives the deceased adult has (whether, for example, the deceased person has any living siblings or cousins), let alone who they are or how to contact them. Accordingly, 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.

54. Section 7 of the 2006 Act allows authorisation to be given by a nearest relative, where the deceased adult had not done so (under section 6). 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. In practice, it is expected that section 7 will be used less frequently once the new soft opt-out arrangements are in place, not least to avoid the emotional burden that asking relatives directly to authorise organ removal can often place on them. But it will remain as one of the means available to give authorisation, and there may still be cases where it is the most appropriate (e.g. where the deceased person’s family are keen to take some comfort from their loss by making a positive choice to donate).

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\(^{22}\) Section 50 includes other provisions qualifying this list in certain circumstances – for example to allow for step-children etc., and to discount relatives under the age of 16.
55. The main function of the 2006 Act, as amended by the Bill, is to establish (as quickly as reasonably possible) whether it would be lawful to remove part of a deceased person’s body for the purpose of transplantation. The AIP’s role, in particular, is to state a conclusion on that question under new section 6B, taking into account information provided by the deceased person’s nearest relative. But it is important to note that having lawful authority to remove an organ, for example, does not mean it will be removed. The person responsible for the removal must still decide that the organ is suitable for transplantation, and that there is a suitable recipient available. In addition, it is already established practice not to remove organs or tissue if doing so is likely to cause significant distress to the family of the deceased, even if the necessary authorisation for removal exists. (As a result, organs are sometimes not removed even from people whose names are on the Organ Donor Register, or who were carrying a donor card when they died.) Nothing in the Bill changes this, and it is likely to remain the case, even under the soft opt-out system that it creates, that family distress will be taken into account before any final decisions are made.

Commencement

56. The Bill provides for a staged commencement process. Some provisions come into force on the day after Royal Assent – including provisions imposing duties on Ministers (to approve an opt-out register, and to organise a publicity campaign), and provisions allowing regulations to be made (e.g. to define who qualifies as an authorised investigating person). The main provisions of the Bill come into force on a day appointed by Ministers. By this day (the “first appointed day”) an opt-out register approved by Ministers must be available for people to use, and the publicity campaign must have begun. There is then a second appointed day – which must be at least six months after the first – which is when authorisation by operation of law (under the new section 6B) may first apply. This ensures that no AIP can apply the test of whether a deceased adult had a reasonable opportunity to opt out until the adult could have been resident in Scotland for a six-month period since the first appointed day.

CONSULTATION

57. 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.23

58. In total, 559 responses were received: 529 from individuals and 30 from organisations. There was a clear division between individual and organisation views – 80% of individuals supported the principle of the proposal, in contrast to only 36% of organisations.

59. 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.

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23 The proposal, consultation document and consultation summary are available at: http://www.scottish.parliament.uk/parliamentarybusiness/Bills/78936.aspx
ALTERNATIVE APPROACHES

60. Alternative approaches suggested in the consultation responses included keeping the current system or waiting until there has been some post-legislative scrutiny of the Welsh Bill.

61. The member considers that if the current opt-in system is retained in Scotland while awaiting any findings in relation to the Welsh legislation, it could be 2022 before any legislation is introduced in Scotland. It is the member’s position that there could be as many as 7,500 deaths across the UK due to lack of organ availability over this period, despite the efforts of the Scottish Government and its partners to raise awareness and increase the number of people on the Organ Donor Register. The member also considers that there is sufficient evidence of the positive benefits of moving to an opt-out system from other countries that have had such a system in place for years, without the need to wait for evidence of its effectiveness in Wales.

62. The member therefore considers that despite best efforts, the pace of change is too slow, and the time is now right to reform the organ donation system. This should be supported by further high profile awareness raising campaigns and education alongside suitable coordination, resourcing and support for specialist healthcare professionals.

63. Another alternative would have been to provide for a “hard opt-out” system. This would have allowed organs or tissue to be removed from any deceased person, with the sole exception of a person who had recorded an objection. This would have been simpler, but risked unnecessarily distressing relatives who would have had no involvement in discussions about transplantation. In particular, 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.

64. The Bill also includes provision for authorisation by proxy (under new section 6A). This is not an essential feature of a soft opt-out system, but has been included in order to extend the range of choices available to people who wish to ensure that their wishes are complied with after their death. For some people who do not have a definite view either way on organ donation, it will still be important to retain some control over who makes the decisions after their death (for example if their relatives are unlikely to be able to agree among themselves).

EFFECTS ON EQUAL OPPORTUNITIES, HUMAN RIGHTS, ISLAND COMMUNITIES, LOCAL GOVERNMENT, SUSTAINABLE DEVELOPMENT ETC.

Equal opportunities

65. The Bill will give legislative backing to measures that the Scottish Government already has in place, such as its recent awareness raising campaigns and the Donation and Transplantation Plan. In particular, there is potential for an increase in donations from within the black and minority ethnic (BME) population, with individuals from within those communities who are at greater risk of conditions that might lead to requiring transplantation (for example, diabetes or heart disease), benefitting from any increase in donations.
66. The Bill will not impact on the rights of those with moral, ethical, faith or cultural objections – these groups will be able to opt out and their relatives will retain the right to make the final decision after a family member’s death. There is also sufficient time in the process to ensure that members of the public are aware of these rights.

**Human rights**

67. While some respondents to the member’s consultation raised concerns in relation to people’s freedom of choice, the Bill does not contravene people’s rights under the European Convention on Human Rights. A number of ECHR Contracting States already operate an opt-out system, and the member considers that the Bill will improve the quality of life of adults who will benefit from transplant operations.

**Island communities**

68. It is important that everybody in Scotland has the opportunity to donate their organs or tissues after death, if that is their wish. This was identified in the Donation and Transplantation Plan, with particular regard to those living in island or remote communities, observing that these communities may lack the access to specialist intensive care facilities which are required to enable organ donation to take place.

69. The Plan considered that “donation should be a core activity for all parts of the NHS” and accordingly recommended that “the Scottish Government and the Scottish Transplant Group should look at options to ensure that individuals who live in remote parts of Scotland are able to donate if they wish to do so. Consideration should be given to transportation arrangements to enable potential donors to be moved to hospitals which can facilitate donation if necessary and appropriate”.

**Local government**

70. The Bill will encourage a coherent, coordinated approach to managing the organ donation register, involving potential donors, their families or proxies, health boards and specialist healthcare professionals. There is no direct impact on local authorities.

**Sustainable development**

71. The UK Shared Framework for Sustainable Development\(^{24}\) was adopted by the Scottish Government in 2005. Commitment to the Framework was reaffirmed in the recent draft Scottish Planning Policy.\(^{25}\) The Framework includes the principles: “*Ensuring a Strong, Healthy and Just Society – meeting the diverse needs of all people in existing and future communities, promoting well-being, social cohesion and creating equal opportunity for all*” and “*Using Sound Science Responsibly*”.


72. The Bill has the potential to contribute towards these principles by increasing the number of organs that are available for donation, not just within the BME population but more widely, and through continuous improvement and investment in coordination and resources for the healthcare professionals.

73. The Scottish Government’s National Performance Framework, “Scotland Performs”\(^\text{26}\), measures and reports on progress in creating a more successful country, with opportunities for all to flourish through increasing sustainable economic growth.

74. This Bill will assist with that progress, by contributing towards some of the targets, objectives, indicators and outcomes set out in the National Performance Framework, in particular by tackling inequalities in Scottish society (e.g. increasing registration within the BME population), to help to reduce premature mortality, and increasing healthy life expectancy.

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\(^{26}\) Scottish Government. National Performance Framework, Scotland Performs. Available at: http://www.scotland.gov.uk/About/Performance/scotPerforms
This document relates to the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (SP Bill 72) as introduced in the Scottish Parliament on 1 June 2015

Annexe

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

Was the deceased person over 16 and resident in Scotland at the time of death?  
If Yes, what are the deceased’s registered wishes in relation to organ donation?  
If No, refer to s.8, 9 or 10 (children) or s.7 (non-residents) of 2006 Act.

The person has opted in (e.g. ODR, donor card)  
There is no record of the person’s wishes  
The person has opted out (e.g. opt-out register)

Organs may be removed (under s.6 of 2006 Act)  
Is there a proxy who can be contacted and is prepared to make a decision on the deceased’s behalf?  
Organs may not be removed

If the proxy gives authorisation, organs may be removed (under s.6A). If the proxy refuses authorisation, organs may not be removed.

No (there is no proxy, or the proxy can’t be contacted or won’t make a decision)

Ask the nearest relative whether they are aware of any circumstances that prevented the deceased having a reasonable opportunity to opt out.

Ask the nearest relative whether they are aware of any objection expressed by the person.

If the pre-conditions are all met, organs may be removed (under section 6B). Otherwise, organs may not be removed (under section 6B).

Judge whether all the pre-conditions have been met.
This document relates to the Transplantation (Authorisation of Removal of Organs etc.) (Scotland) Bill (SP Bill 72) as introduced in the Scottish Parliament on 1 June 2015

TRANSPLANTATION (AUTHORISATION OF REMOVAL OF ORGANS ETC.) (SCOTLAND) BILL

POLICY MEMORANDUM