



Proposed Organ and Tissue Donation (Scotland) Bill

“A proposal for a Bill to amend the law on human transplantation, including by authorising (in certain circumstances) the posthumous removal of organs and tissue from an adult who had not given express consent”

Consultation by

Anne McTaggart MSP

Glasgow Region

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FOREWORD

BACKGROUND

The existing opt-in system of organ donation in Scotland has been the subject of debate for a number of years. The United Kingdom has one of the lowest organ donation rates in Europe. In view of the significant difference between the number of people on the waiting list for transplant operations and the number of organs available, I believe that reform is essential.

I believe that most people in Scotland support a “soft opt-out system” of organ donation; a YouGov survey announced by the British Medical Association in 2007 indicated that 74% of respondents in Scotland supported a system of opt-out¹. A survey undertaken in early 2012 by the Scottish Government demonstrated that only 5% of the population oppose organ donation in principle, and yet less than 40% of us are registered as organ donors. I believe this serves as powerful evidence to propose reform of the current organ donation system.

Following initial consultation with representatives from the British Heart Foundation, the British Medical Association, the Royal College of Physicians, the Scottish Kidney Federation, the South East Scotland Kidney Patients Association and others, I have decided to take forward a Member’s Bill on this issue. I truly believe that the strong evidence in favour of reform will secure broad support for my proposal to adopt an opt-out system of organ donation in Scotland.

THE PROPOSED BILL

The aim of this bill is to introduce a “soft opt-out” system of posthumous organ donation in Scotland. With this reform we could truly tackle the shortage of organs available for transplant in Scotland. This would ultimately save lives.

Under an opt-out system (just as under the current opt-in system), individuals can decide to donate or not to donate. This proposal would not compromise the rights of an individual who objected to organ donation and wanted to make their views known. Those who did not wish to be organ donors would have the opportunity to make a clear declaration that they were opposed to the transplantation of their organs, and this decision could not be overturned after death.

ACKNOWLEDGEMENTS AND THANKS

There has been extensive research carried out in collecting, assessing and analysing the necessary information to compose this consultation.

I would like to thank Kidney Research UK and Caroline Wilson at The Evening Times for bringing this significantly important issue to the attention of the Scottish Parliament, through their work with the Public Petitions Committee. I would like to recognise the efforts of the team at the Scottish Parliament’s Non-Governmental Bills Unit, from whom I have received excellent advice and assistance in the development of this proposal. I would also like to extend my sincere gratitude to David McColgan, of the British Heart Foundation Scotland, for his hard work and dedication. The work of the British Medical Association, the Royal College of Physicians, the Scottish Kidney

¹<http://web.bma.org.uk/pressrel.nsf/wall/A2B95F1F0C609726802573780034838B?OpenDocument>

Federation, the South East Scotland Kidney Patients Association, the Scottish Youth Parliament and my staff team should also be recognised, and I thank these individuals and organisations for their unwavering commitment and support throughout this process.

Please take the time to give this document your full consideration and I look forward to your response.

A handwritten signature in black ink, reading "Anne McTaggart". The signature is written in a cursive style with a large initial 'A' and 'M'.

Anne McTaggart MSP

Glasgow Region

Executive Summary

This consultation seeks to canvass views on changing the system of organ and tissue donation registration from an opt-in system to a soft opt-out system in Scotland.

The basis of the proposed soft opt-out system would be that organs and tissues could be removed posthumously from an adult whom had not registered or expressed an objection during their lifetime. This is in contrast to the current opt-in system of organ and tissue donation whereby those wishing to become a donor are encouraged to register on the NHS Organ Donation Register.

The key features of the soft opt-out system proposed are:

1. All adults aged 16 or over who reside in Scotland would have the right to register an objection to some or all of their organs being used for transplantation after their deaths
2. The family of a deceased person will be consulted at the time of death to establish any objection of the deceased that had not been registered
3. Young persons under 16 years not covered by the opt-out system will continue to be able to opt in as potential donors
4. The proposal will only cover donation of organs and tissue for transplantation; uses for research or other purposes will not be covered

Each day 3 people in the UK die waiting for a transplant². Research shows organ donation rates increases by approximately 25-30% in countries where an opt-out system is introduced³. This Bill would help to increase the number of organs available for transplantation, thereby saving lives and improving quality of life for others.

² http://www.organdonation.nhs.uk/newsroom/statements_and_stances/

³ http://www.nber.org/papers/w10604.pdf?new_window=1

HOW THE CONSULTATION PROCESS WORKS

This consultation is being launched in connection with a draft proposal which I have lodged as the first stage in the process of introducing a Member's Bill in the Scottish Parliament. The process is governed by Chapter 9, Rule 9.14, of the Parliament's Standing Orders which can be found on the Parliament's website at:

<http://www.scottish.parliament.uk/parliamentarybusiness/17797.aspx>

A minimum 12 week consultation period is required, following which responses will be analysed. Thereafter, I would expect to lodge a final proposal in the Parliament along with a summary of the consultation responses. If that final proposal secures the support of at least 18 other MSPs from at least half of the political parties or groups represented in the Parliamentary Bureau, and the Scottish Government does not indicate that it intends to legislate in the area in question, I will then have the right to introduce a Member's Bill. A Member's Bill follows a 3-stage scrutiny process, during which it may be amended or rejected outright. If it is passed at the end of the process, it becomes an Act.

At this stage, therefore, there is no Bill, only a draft proposal for the legislation.

The purpose of this consultation is to provide a range of views on the subject matter of the proposed Bill, highlighting potential problems, identifying equalities issues, suggesting improvements, considering financial implications and, in general, assisting in ensuring that the resulting legislation is fit for purpose.

The consultation process is being supported by the Scottish Parliament's Non-Government Bills Unit (NGBU) and will therefore comply with the Unit's good practice criteria. NGBU will also analyse and provide an impartial summary of the responses received.

Details on how to respond to this consultation are provided at the end of the document.

Additional copies of this paper can be requested by contacting me at:

Anne McTaggart MSP, M1.11, The Scottish Parliament, Edinburgh, EH99 1SP

Tel: 0131 348 6211

Email: anne.mctaggart.msp@scottish.parliament.uk

An on-line copy is available on the Scottish Parliament's website under Parliamentary Business/Bills/Proposals for Members' Bills/Session 4 Proposals

<http://www.scottish.parliament.uk/parliamentarybusiness/Bills/12419.aspx>

Context to the proposal

Background

Organ transplantation has a major role in the management of organ failure. It is one of the most effective medical treatments that can save lives and greatly improve quality of life.

Transplantation can involve the kidneys, small bowel, liver, pancreas, heart, lungs, corneas and sclera (from the eyes), skin, bone, tendons and cartilage. Transplants may be needed because of primary organ disease, such as chronic inflammatory disease of the kidneys, or because of secondary effects of a disease – for example, people with diabetes needing kidney, islet cell and/or pancreas transplants, and people with cystic fibrosis needing lung transplants⁴.

There are three different sources of organ and tissue transplantation⁵:

- 1.) Transplantation following brain stem death - Most organ transplantation is from brain stem dead donors. The brain stem controls essential functions such as the ability to breath and regulation of blood pressure. Here the donor has been confirmed brain stem dead, although the heart may continue to beat for a short while afterwards and the circulation is supported by artificial ventilation until the donated organs have been removed.
- 2.) Transplantation following cardiac death - In the UK, almost all transplantation of this type is from people who have died in intensive care from severe brain injuries, but who are not quite brain stem dead. In these cases, the heart stops usually once life support has been removed, depriving the brain of oxygen and leading to death. The organs must be removed within a few minutes of the heart stopping to prevent them being damaged by a lack of oxygenated blood.
- 3.) Live donation - A live donation usually involves one family member donating an organ or tissue to another family member.

This proposal would cover donation only after death, not live donation. In 2013/14 there were a total of 343 deceased donor transplants in Scotland⁶.

There is a shortage of organs for transplant resulting in long waits for transplantation and a significant number of deaths among those awaiting transplantation, and among those not considered for transplantation because of organ scarcity. This is considered more fully under “Scale of the issue” below.

Current law regarding organ donation

The current legislative framework for organ donation and transplantation in Scotland is the Human Tissue (Scotland) Act 2006 (asp 4) (“the 2006 Act”)⁷.

⁴ <http://www.nice.org.uk/nicemedia/live/13628/57508/57508.pdf>

⁵ <http://www.nhs.uk/Conditions/Organ-donation/Pages/Introduction.aspx>

⁶ http://www.organdonation.nhs.uk/statistics/downloads/scotland_mar14.pdf

⁷ <http://www.legislation.gov.uk/asp/2006/4/contents>

Part 1 of the 2006 Act covers both deceased and living organ donation. The 2006 Act repealed and replaced the previous provisions of the Human Tissue Act 1961.

The main objective of the 2006 Act was to remove ambiguities that existed under the 1961 Act to ensure that an individual's wish, as to whether to donate their organs, was paramount.

The 2006 Act provides that:

- It is a criminal offence to remove any part of a person's body (before or after death) for transplantation without their authorisation or the authorisation of someone entitled to act on their behalf.
- Any adult or child aged 12 and over, who is able to make their own decisions, can authorise their organs or tissue to be used for transplantation after their death.
- An individual's decision is the most significant factor. The nearest relative does not have the right to overturn this decision after the person's death. However, where a person has not (so far as the nearest relative is aware) expressed a view against donation, the nearest relative may still authorise transplantation on behalf of the deceased.
- Children under the age of 12 cannot authorise transplantation themselves. For a child under the age of 12, only their parent or guardian can give authorisation.

There were, until recently, two key statutes governing organ donation and transplantation in the UK: The Human Tissue (Scotland) Act 2006 and The Human Tissue Act 2004 (c. 30) (covering England, Wales and Northern Ireland). Both pieces of legislation maintain the system of "opting in" for deceased organ donation, where an individual takes a positive decision, whilst alive, in favour of donating organs and tissue on the event of their death, for the purposes of transplantation.

However, on 10 September 2013 the Human Transplantation (Wales) Act 2013 received Royal Assent. The main provisions will come into effect 1 December 2015⁸ and will introduce a new "soft opt-out" system for Wales whereby organs and tissues may be removed unless the deceased objected during their lifetime. The family of the deceased will not normally have any right to object but will be consulted to establish whether the deceased was known to have any unregistered objections. Consent from a third party will only be required where the deceased did not opt out but either appointed a family member or a proxy to make the decision.

Organ donation in practice

An effective donation system is required so that people can have the right to decide whether they wish to donate or not. A move to a soft opt-out system would mean that consent is presumed to have been given by everyone to whom the system applies unless they registered or expressed an objection to becoming a donor. As this would be a substantial departure from the 2006 Act, legislation is required.

Organ donation is currently coordinated across the United Kingdom, with organs allocated throughout the UK on the basis of need. Therefore, organs from Scottish donors may be used right across the UK. Similarly, organs from donors in England, Wales and Northern Ireland may be used in Scotland. The only restriction on this basis would be the length of time an organ can reasonably travel, before it must be transplanted.

⁸ <http://wales.gov.uk/topics/health/nhswales/majorhealth/organ/?lang=en>

Selection and allocation policies are in place and are reviewed regularly in light of clinical developments and patient needs. Allocation schemes are developed to balance equity, utility, benefit and fairness. Many considerations are made including the need for blood and tissue type matching and the needs of the recipients.

NHS Blood and Transplant is a Special Health Authority in England and Wales but it has UK wide responsibilities to work with all of the UK Health Services, including NHS Scotland, in order to coordinate transplantation and the collection of data relating to donors and registering their wishes. As such the activities of NHS Blood and Transplant are directly accountable to health ministers in Scotland, Wales, Northern Ireland and England.

Individuals can opt in by putting their name on the NHS Organ Donor Register. The NHS Organ Donor Register is a UK-wide, confidential list of people who are willing to become donors after their death. The register doesn't have any statutory basis under the 2006 Act, and it is possible to consent in writing separately from the register, or consent verbally in the case of an adult. Joining the register counts as consent "in writing" under the 2006 Act. At the end of 2013/14, Scotland had 2,110,881 people signed up to the organ donation register, representing 40% of the total population⁹.

Currently a person can register:

- At the same time as applying for a driving license
- At the same time as applying for a Boots advantage card
- By completing a form that is available at a GP surgery, libraries, hospitals and pharmacies
- At the same time as applying for a European Health Insurance card (EHIC)
- Online at www.organdonation.nhs.uk
- By telephoning 0300 123 23 23

Opt-in or opt-out

The current organ donation system in use in Scotland (and in the rest of the UK) is commonly referred to as an opt-in system. Under this system, an individual's organs or tissue can be removed after their death only if they had expressed their consent in advance. In order to express consent in advance, it is not necessary to have signed the organ donation register; it can be done in another way (e.g. in a will, or by expressing a clear view orally to relatives). The current system is not a "pure" opt-in system, however, as it allows organs or tissue to be removed after death in some circumstances where the person has not opted in. Where a person is not on the register, their nearest relative (or other person qualified to act on their behalf) is consulted and, so long as they are not aware that the person had an objection to transplantation, may give consent on that person's behalf. Over the five year period 2008-2013, 62% of donations have come from donors who were not on the register at the time of their death¹⁰.

Families of those on the register are also notified at point of death and consulted on whether they know of any recent objection expressed by the deceased. Only such a change of mind by the deceased is legal grounds to prevent transplantation. However, in practice donation is dependent on the co-operation of the relatives, as they have to contribute information about the donor's

⁹ ibid

¹⁰ <http://www.scotland.gov.uk/Publications/2013/07/7461/4>

character, behaviour and travel history to ensure that any donation is safe. If relatives refuse to contribute such information, then any donation may place a potential transplant recipient at increased risk.

Under an opt-out system, every person is deemed to have given their consent to the posthumous removal of their organs or tissue unless they have specifically "opted out" by expressing their unwillingness to donate. The key difference between the two systems is that under an opt-in system organs and tissues normally cannot be removed after death except from people who expressly stated a wish to donate, while under an opt-out system organs and tissues normally can be removed after death, except from people who expressly objected.

There are two types of opt-out system:

- Hard opt-out systems - the removal of organs and tissues is permissible unless an individual recorded an objection in their lifetime. This applies even if the deceased was known not to want their organs or tissue removed, but had failed to record this, and regardless of the relatives' own views.
- Soft opt-out systems - the removal of organs and tissues is permissible unless an individual recorded an express objection in their lifetime or, at the time of death, their relatives confirm that they had an unrecorded objection. In some systems, the removal of organs and tissue is also only permissible if the relatives do not themselves object.

This proposal is for a soft opt-out system where family members are consulted only to establish whether the person was known to have an unregistered objection to donation – but not to seek their own consent to transplantation. This is to ensure the family of the deceased can raise any unregistered objections thus providing a vital safeguard to protect the interests of the person who had an objection but had not recorded it. See "Role of the family" for further details.

Scale of the issue

It is a fact that the supply of organs available for transplantation is outstripped by demand. At March 2014, 7,206 people in the UK were on the organ transplant waiting list, 595 of whom were in Scotland¹¹. However, this only includes those already on the list and is therefore probably an underestimate of the actual number. This waiting list figure is also rising by about 5% per year because of a number of factors, such as: increasing prevalence of renal and liver disease; growing ethnic diversity of the UK population (which makes it more difficult to match organs and tissue to patients); lower thresholds for transplantation and better clinical management of serious illnesses¹². Demand is also likely to be affected by the changing demographics of the UK and Scotland. Of particular note are an ageing population and an anticipated increase in the incidence of type 2 diabetes.

In terms of the availability of organs for donation, positive trends have been noted in recent years following action by the Scottish and UK Government based on the reforms recommended by the

¹¹ http://www.organdonation.nhs.uk/statistics/downloads/scotland_mar14.pdf

¹² <http://www.nice.org.uk/nicemedia/live/12952/50890/50890.pdf>

Organ Donation Taskforce in 2008¹³. This taskforce was established in December 2006 by the UK Government to identify barriers to organ donation, explore current issues that might have a bearing on donation rates and recommend action to be taken to increase organ donation within current legal frameworks. From 2009/10 to 2013/14 the proportion of the UK population on the Organ Donor Register has increased from 28% to 32% allowing the number of deceased donor transplants performed to also increase from 2,659 in 2009/10 to 3,514 in 2013/14, a 32% increase in total¹⁴.

These positive trends have meant the numbers of patients waiting on the transplant list has reduced by 12% from 7,974 in 2009/10 to 7,026 in 2013/14¹⁵.

The scarcity of available organs also means there are long waiting lists for transplants and this can result in deaths for some people if an organ is not found in time. The NHS Blood and Transplant service have estimated the following¹⁶:

1. The average waiting time for an adult kidney transplant is 1,110 days. Children, who are prioritised in the matching sequence, wait on average 277 days.
2. Adults wait an average of 184 days for a heart and 519 days for a lung. Children wait an average of 93 days for a heart.
3. Adults wait an average of 149 days for a liver transplant, while children wait an average of 86 days.
4. About 1,000 people die every year in the UK while waiting for an organ transplant or because they become too ill to survive an operation and are removed from the list.

Whilst the numbers of patients waiting for a transplant is currently falling as seen above this is a long way off the ultimate goal of reaching a position where there are no deaths as a result of organ scarcity.

There are a number of reasons why people do not register as a donor. These include religious and cultural beliefs that oppose transplantation. However, in Scotland only 5% of the population oppose transplantation in principle¹⁷ and in fact over 90% of Scottish people support organ donation¹⁸. Nevertheless, only 40% of the population is on the organ donor register. A significant proportion of people in Scotland, therefore, would wish to donate their organs after death for the purpose of transplantation but (for whatever reason) have not registered as a donor.

International Comparisons

As well as the change made by Wales, Scotland can follow the example of a number of European countries that have implemented opt-out systems such as Spain, Belgium and Austria.

¹³ <http://www.nhsbt.nhs.uk/to2020/resources/OrgansfortransplantsTheOrganDonorTaskForce1streport.pdf>

¹⁴ http://www.organdonation.nhs.uk/statistics/downloads/united_kingdom_mar14.pdf

¹⁵ *ibid*

¹⁶ http://www.organdonation.nhs.uk/newsroom/fact_sheets/transplants_save_lives.asp

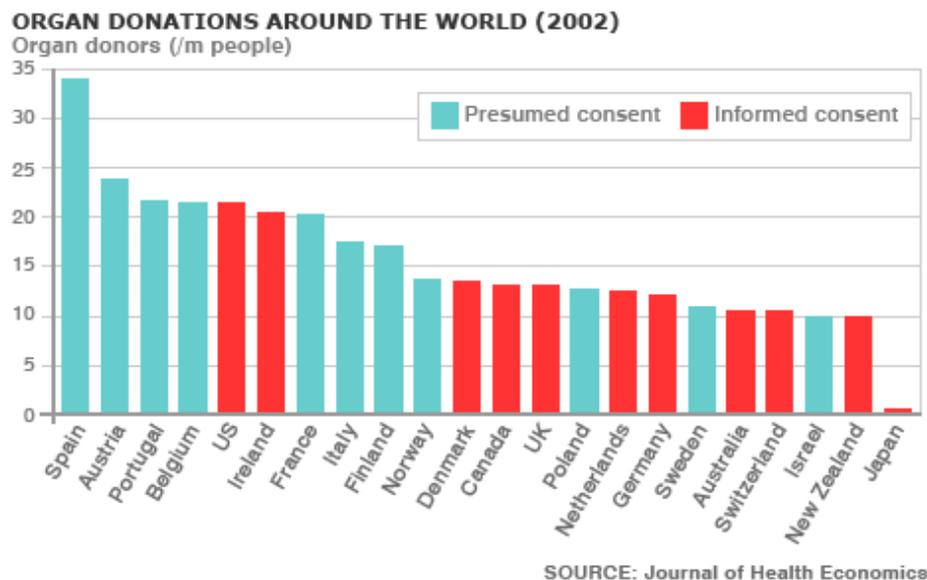
¹⁷ <http://www.scotland.gov.uk/Publications/2013/07/7461/2>

¹⁸ <http://bma.org.uk/working-for-change/improving-and-protecting-health/organ-donation/scotland>

The Organ Donation Taskforce in 2008 noted that the UK had one of the lowest organ donation rates in Europe with 13 donors per million of population (pmp). Spain in contrast had 35 pmp¹⁹.

In 2011 the following EU countries outperformed the UK in their rates of deceased donations per million people: Malta, the Czech Republic, Finland, Ireland, Spain, Austria, Croatia, Portugal, Belgium, France, Italy and Norway.²⁰ Of these only Malta and Ireland operate a system of opt-in rather than presumed consent or opt-out.

Whilst international comparisons does not show an entirely consistent picture - some countries where an opt-out system is in operation have lower donation rates than the UK, such as Sweden – overall it seems clear that opt-out systems are associated with higher donation rates. One study on the impact of presumed consent legislation on cadaveric organ donation concluded “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”²¹. Their cross country analysis is shown below. Further research by others shows organ donation rates increases by approximately 25-30% in countries where an opt-out system is introduced²².



As part of its evidence gathering, the Organ Donation Taskforce commissioned a systematic literature review from the University of York to assess the impact of opt out legislation on organ donation rates in other countries. There were five ‘before and after’ studies involving two countries in particular (Austria and Singapore, both of which have moved to a ‘hard’ form of presumed consent). These show an increase in donation rates of up to 25%²³.

¹⁹http://webarchive.nationalarchives.gov.uk/20130107105354/http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082120.pdf

²⁰http://ec.europa.eu/health/blood_tissues_organ/docs/ev_20121009_facts_figures.pdf

²¹A. Abadie & S. Gay, 2006, ‘The impact of presumed consent legislation on cadaveric organ donation: A cross-country study’, *Journal of Health Economics*, 25(4)

²²http://www.nber.org/papers/w10604.pdf?new_window=1

²³<http://www.odt.nhs.uk/pdf/the-potential-impact-of-an-opt-out-system-for-organ-donation-in-the-UK.pdf>

A note of caution should be made as the direction of causation is unclear. Namely, an opt-out system may have been implemented as a result of positive attitudes to donation already held by a population. Equally, donation systems are only one element of a package of measures that can be implemented to increase donation levels, others including public education, establishing specialist clinical advisers or increased funding for transplant programmes etc. Where countries have implemented change to an opt-out system, this is often as part of a wide range of measures undertaken. This makes it difficult to assess the exact contribution of presumed consent legislation alone.

The case for change

Many people may argue that we currently have a system for those that want to register, therefore, change is unnecessary. Or the current system could simply be improved by further public awareness campaigns. However, when 3 people on average die every day across the UK waiting for a transplant, and less than half of Scotland's population is registered on the NHS Organ Donor Register despite widespread support for donation, urgent change is clearly required. A soft opt-out system will help to increase the availability of organs and bring a cultural shift to ensuring donation becomes the norm in a more consistent and lasting manner than campaigning alone can achieve.

Objectives of the bill

The aim of the bill would be to introduce a soft opt-out system for adult organ and tissue donation, shifting the onus onto objecting to donation rather than registering to become a donor.

Key advantages on a soft opt-out system would be to:

1.) Increase supply of available organs

The shortage of organs for transplantation causes unnecessary loss of life and suffering both for those on the list and their relatives. Around 7,000 people are on the UK waiting list at any one time²⁴. The more potential donors there are in the population, the more likely it is that each person on the waiting list can be found a suitable donor within a reasonable time. Moving to a soft opt-out system is probably the single most effective thing we could do to close the gap between supply and demand.

2.) Reduce the number of people dying while waiting on the transplant list

With an increase in the availability of organs the potential for making a suitable match for transplantation is greatly increased. In 2012/13 over 1,300 people in the UK died whilst on the waiting list or became too sick to receive a transplant²⁵. A change in the system would help to save at least some of these lives.

3.) Promote the identification and fulfilment of the wishes of a potential donor

Those who oppose donation will be able to easily opt out and for those who do not opt out, it would be presumed they have considered the options and given consent. There are concerns a soft opt-out system would imply individuals have lost control over their bodies and power lies with the state or health officials. However, it is hoped that a soft opt-out system will in fact encourage more people to make decisions about donation during their lifetime. It has been shown that where views on donation are known, families are more likely to make a decision conforming to that view. The Potential Donor Audit in 2011/12 has shown when a patient is known to have expressed a wish to donate, for example they were registered on the Organ Donor Register, carried a donor card or expressed a wish to donate verbally or in writing, the potential donors after brain death consent/authorisation rate was 93% compared to 48% when a patient hadn't expressed a wish to donate²⁶.

²⁴ http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf

²⁵ *ibid*

²⁶ http://www.odt.nhs.uk/pdf/pda_report_1112.pdf

4.) Reduce pressure on the family

The death of a close relative or friend is a very trying and difficult time and any change in the system should ensure no additional worry is created. Families at time of death will be consulted, not to make a decision about donation but about their understanding of the deceased person's wishes. In this way there is less pressure being placed on the family.

5.) Bringing a cultural shift around organ donation

By shifting the onus onto the donor to record an objection rather than a desire to donate it is hoped that donation will become a more normalised position. Organ donation would become the default option when someone dies. Such cultural shifts have been seen following the mandatory introduction of seatbelt wearing and restrictions on smoking in public. In addition it is hoped that such a system would help to foster open and frank discussions regarding donation and encourages people to make known to their families their wishes regarding donation.

Why now

I welcome the recent increases made in organ donation and am very proud Scotland has the highest proportional level of donors registered in the UK, currently 40% of the population whilst the UK average is 32%. During a recent five-year period (2007/8 – 2012/13), Scotland achieved a 74% increase in deceased organ donations, as well as a 36% increase in transplants with deceased donor organs²⁷. However, further improvements are still needed. Despite major national campaigns and a national strategy, over half of the population is not registered. Indeed, from 2012/2013 to 2013/2014 the percentage of the Scottish population registered as a donor even fell 1%²⁸. Further effort is required to raise and importantly maintain donation levels and I believe this can most effectively be done by introducing an 'opt-out' system.

The Scottish Government approach is to wait until results from the Welsh system are available before consideration of moving to an opt-out system would be made. In a Parliamentary debate on organ donation Michael Matheson (the Minister for Public Health) said "we remain unconvinced that we should make any move to introduce an opt-out system. I will ensure that we keep the issue under review and learn from what happens in Wales."²⁹ However, given the Welsh system will not be implemented until December 2015 and additional time will be required for results to be obtained and assessed, the delay in waiting is simply too costly. 38 people in Scotland alone died as a result of a lack of available organs in 2013/14³⁰ and we cannot afford to wait any further. In addition by taking action now and following the Welsh lead, additional pressure will be placed on the rest of UK to consider a similar path.

²⁷ <http://www.scotland.gov.uk/Resource/0042/00427357.pdf>

²⁸ http://www.organdonation.nhs.uk/statistics/downloads/scotland_mar14.pdf

²⁹ <http://www.scottish.parliament.uk/parliamentarybusiness/28862.aspx?r=9137>

³⁰ <http://news.scotland.gov.uk/News/Donor-and-transplant-rates-soar-b58.aspx>

Proponents

The soft opt-out system is favoured and supported by British Heart Foundation Scotland, British Medical Association Scotland, the Royal College of Surgeons, Cystic Fibrosis Trust, Scottish Kidney Federation, National Kidney Federation, Kidney Research UK and Scotland Patients Association.

The Evening Times has been running a campaign supporting an opt-out system since 2011. It has gathered much support from the public and various organisations and now has over 20,000 signatories³¹.

Moving to soft opt-out

A secure database would be established prior to the introduction of any new system to record opt-out objections. This system would also allow objection to some or all organs and tissues. In this way people can retain the right to decide which organs they wish to donate. Where a person objects to some organs or tissues being donated, their consent will be presumed for others.

There would be an interval of at least 6 months between the new opt-out register going “live”, i.e. recording objections, and the actual move to an opt-out system. This is in order to allow every adult at least 6 months to opt out before it would be legal to remove their organs on the basis of their presumed consent.

A national publicity campaign lasting at least 6 months would run either throughout this transition period or in an earlier period prior to the actual registration changeover.

Those under 16 years old residing in Scotland will not be covered by the soft opt-out system. However, young persons over 12 years can currently register to opt-in to become a potential donor so long as consent is made in writing. To ensure young persons from 12-15 years can retain this right the current system of opt-in will still be applicable to them.

When a person reaches 16 years old or has resided for a minimum period of 1 year in Scotland they will be covered by the new system.

³¹ <http://www.eveningtimes.co.uk/campaigns/opt-for-life/msps-back-our-fight-for-opt-out-transplant-system-161936n.24113826>

Details of the proposal

The soft opt-out system would still provide individuals with the choice to donate or not.

How to object

It is critical that an opportunity to object to donation is created and protected. It must be as easy as possible for someone to object, safe in the knowledge that their views will be upheld and respected.

Measures will be taken to ensure the objection can be made confidentially and easily. The methods of objection will be by the same methods that are currently available to register and at no cost to the objector. This objection would last indefinitely unless an individual requests to remove this objection from the opt-out register.

Under the Bill, it would not be permitted to remove organs or tissue posthumously from anyone who was, at the time of death, over 16 years old and a resident of Scotland, without first checking the new opt-out register. If the individual had expressed an objection on the new opt-out register, the organ or tissue in question could not be removed.

The system will be robust enough for individuals to change their minds i.e. to withdraw an objection. The system will also allow a person to object to just some of their organs or tissue being removed after death. Currently a potential donor has the right to pick which organs or tissue they would like to donate; the new system should give equivalent flexibility.

Who is included and excluded

Age threshold

The system will apply to all persons over 16 years old who live in Scotland and have had an opportunity to make an objection. 16 is considered an appropriate age since young persons beneath this age may not fully understand the nature and purpose of donation. 16 is also the age in Scotland that an individual can consent to their own medical, surgical and dental treatment. The Welsh opt-out system applies at 18 years old, however, it is felt those aged 16-18 should be able to make a decision that concerns their own bodies. If they make decisions concerning their medical treatment donation should not be treated differently.

Those under 16 but above 12 years old will retain their right to authorise transplantation (including by registering on the NHS Organ Donor Register). Currently under the 2006 Act where the donor is a child 12 or over, consent must be written (this would include an online form). An adult may give verbal consent, but the medical staff need to be satisfied that there is an adequate record of this. If a child over 12 has registered then family have no legal right to veto this. A child under 12 cannot consent, although someone with parental responsibility other than a local authority can consent for them after death.

Residency

Only those people who had been resident in Scotland for a reasonable period by the time of their death, and die in Scotland, will be covered by the soft opt-out system. A minimum period of 1 year residency is required before they are part of the new system in order to give them time to consider

and understand the system in operation. The basis of residency will be made on the main domiciled address of an individual, not place of work or second home.

It will not apply if a Scottish person dies outside Scotland. Tourists and other visitors will not be covered.

Whilst Wales has implemented a system of opt-out this is only applicable to Welsh citizens that die in Wales, therefore, should a Scottish resident die in Wales or a Welsh resident die in Scotland presumed consent does not apply.

Mental capacity

Those who lack mental capacity would also be excluded from the system as it is felt they may lack the ability to understand the information and issues surrounding donation. The Adults with Incapacity (Scotland) Act 2000 (“the 2000 Act”)³² provides a definition of incapacity at section 1 and sets out provisions which relate to individuals who have lost capacity for any reason.

Where my proposal will impact is on those individuals who by reason of incapacity are not able to register an objection. In order to safeguard this group of people I propose that anyone who would be defined as an adult with incapacity on the basis of the 2000 Act definition could not have capacity to opt-out and therefore should not be automatically opted-in.

Role of the family

Currently families can and do often prevent transplantation. Whilst there is no statutory basis for family consent to be required for transplantation to occur where a person has registered as a donor or made an expressed wish, in practise the cooperation of relatives is required for gathering medical history etc, and should it be considered significant distress would be caused to the family transplantation does not occur. For example, NHS Greater Glasgow and Clyde estimates that in up to 15% of cases, the opportunity to remove organs or tissues from people who were on the organ donor register is lost because their families refuse consent³³. In fact families refuse consent in around 43% of cases where donation would be possible³⁴. This refusal rate has not changed since 2008 and the UK has one of the highest refusal rates in the Western world. Spain in contrast has a refusal rate of less than 20%³⁵. Under an opt-out system cooperation from relatives is still required and whilst there is no certainty that a change in the system would alter these refusal rates it would increase the proportion of registered donors and thus the impact of these rates would be minimised.

Reasons behind family refusal may include a poor understanding of the process, cultural and religious objections or medical mistrust. For others they are simply uncertain of the deceased’s wishes as many people fail to make known to their family their views on organ donation. Where the deceased’s wishes are unknown the family refusal rate rises further to 57%³⁶.

³² <http://www.legislation.gov.uk/asp/2000/4/contents>

³³ http://www.nhsggc.org.uk/content/default.asp?page=s1240_38

³⁴ http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf

³⁵ <http://www.parliament.uk/business/publications/research/briefing-papers/POST-PN-441/organ-donation-and-transplants>

³⁶ *ibid*

Under the proposed soft opt-out system some of this uncertainty will be removed as the onus is moved from the family to consider donation to the potential donor. Under the present system, uncertainty will arise where there is no entry in the Organ Donor Register, and this could either mean the person was opposed to donation, or that they had no objection, but just had not registered. The family must make a decision based on what they think the deceased person's attitude to donation was. Under the Bill, the presumption will be that the deceased had no objection to donation – since, if they had, they would have registered that objection during their lifetime, and this would have been a straightforward thing for them to do. There will remain a degree of uncertainty when there is no entry in the opt-out register but those who strongly opposed transplantation are likely to have registered an objection, so the family may feel more confident in not objecting and may have less uncertainty to deal with.

Whilst the role of the family will be reduced, as there will be fewer cases in which they will be asked for consent, they will retain some role in the process, acting as a vital safeguard. At the time of death, family members will be consulted to understand if there were aware of any recent objections by the deceased that had not been registered.

It is important to stress that the family is to be consulted not on their own personal views to allow donation or not, but rather on their knowledge of the deceased person's wishes. Their role is to confirm, not choose. This ensures the donor's wishes are protected as fully as possible, and the family will not be able to override the known wishes of the deceased. However, to ensure the most up-to-date views of the deceased are known, the family will be consulted.

There is a risk the family may make a false statement about their knowledge of the deceased person's wishes in order to give expression to their own view. However, to preserve some role for the family and create this critical safeguard, this is a risk that must be taken (and it is a risk that already exists under the current system). It is hoped that family members would respect the wishes of those closest to them regardless of their own personal views.

While reference has been made in this consultation to “the family”, in practice the decision would be made by the deceased person's “closest relative”: i.e. their

- a) spouse, civil partner or cohabitee;
- b) parent or child;
- c) brother or sister;
- d) grandparent or grandchild;
- e) child of a brother or sister;
- f) stepfather or stepmother;
- g) half brother or half sister;
- h) friend of long standing

This suggested list is based on the Human Transplantation (Wales) Bill definition of “qualifying relationship” (section 19)³⁷. The list is set out in a strict order of priority, i.e. consent would be sought from the top of the list and only if there was no one further up the list who was contactable, or willing and able to decide, would consent be sought from those further down the list.

³⁷ <http://www.senedd.assemblywales.org/documents/s18966/Bill,%20as%20passed.pdf>

One area of consideration I seek consultation upon is establishing the right to appoint a proxy. A proxy could be appointed during the lifetime of an individual to make the final decision, to allow transplantation or not, on their behalf at the time of their death. The position as a named proxy would then take precedence over consulting relatives.

Other safeguards

Clear safeguards are required to ensure no one is unfairly treated by an opt-out system. Therefore, we have included restrictions concerning age, residency and mental capacity as well as consultation with the family. Other safeguards include, firstly, not allowing organs or tissue to be removed from a deceased person whose identity is not known. This is to ensure that any possible objection that person may have had is protected and the system will err on the side of caution.

Secondly, the opt-out register will have sufficient security built into the system to ensure the list is kept up-to-date, backed-up, subject to appropriate access controls and confidential.

Public campaign

To ensure the public can make an informed decision regarding organ donation a substantial public awareness campaign would need to occur across Scotland prior to the introduction of the new system and lasting for at least 6 months. During this time information would be provided to the public in a variety of forms so everyone is aware of the change in system, the options available to them and how to opt-out of donation if they so wish.

The national publicity campaign would run either throughout the 6 month period between the new opt-out register going “live” and the actual move to an opt-out system or for an earlier period.

The campaign would also help to dispel some of the common misconceptions that surround donation - for example, concerning age or sexual orientation – as referred to below.

Equality issues

According to the NHS Choice - organ donation website, ‘there is a particular need for more people of African, African-Caribbean and south Asian ethnicities to join the Organ Donor Register’³⁸. This is because donation rates among these ethnic groups are relatively low. Black people are three times more likely to develop kidney failure than the general population, and the need for donated organs in Asian communities is three to four times higher than in the general population.

It is important to highlight that being an older person or having some disabilities do not prevent individuals from being organ donors. There is no age limit to becoming a donor. A person's physical condition, not age, is the deciding factor. Specialist healthcare professionals decide in each case which organs and tissue are suitable. Organs and tissue from people in their 70s and 80s are transplanted successfully. Notwithstanding this, an important feature of my proposal is safeguarding those individuals who are not able to object to being a donor. In these circumstances, presumed consent will not apply to those who do not have the capacity to register an objection.

³⁸ <http://www.nhs.uk/conditions/Organ-donation/Pages/Introduction.aspx>

It is noteworthy that when the consultation exercise was undertaken on the Welsh legislation it was found that there was confusion amongst members of the gay community as to whether or not gay men could be organ donors because of the restrictions in relation to blood donation. The current situation is that there are no restrictions on gay men becoming organ donors³⁹.

It is useful to highlight now that, should my proposal be successful, any public information campaign to publicise the change to the donor system would have to be provided in different languages (including BSL) and other formats (such as Braille) to engage with Scotland's multi-cultural society and to also make the change accessible to those who have disabilities and those with learning difficulties.

Financial implications

The overall objective of my proposal is to move from an opt-in system of organ donation to a soft-opt out system and this will necessarily incur significant outlay.

Capital expenditure would be required on the development and establishment of a secure database, plus running costs, the cost of initial inputting of data and the ongoing training of a wide range of healthcare professionals. Costs to set up and maintain the infrastructure in Wales have been estimated at £8m over 10 years.

As well as the cost of initial outlay, costs and benefits relate to the treatment of donor recipients. Long-term net savings can be made by moving to a soft opt-out system. The entire transplant programme across the UK delivers an annual cost saving of £316m to the NHS according to NHS Blood and Transplant (NHSBT)⁴⁰.

In Wales they have estimated that if an increase in donation rates of 25-30%, that research has found to be associated with the introduction of opt-out systems, occurred there would be approximately 15 additional donors. Just one additional donor a year would create sufficient benefits for an opt-out system to break even⁴¹. The Welsh Government has also performed a number of projections for the costs and benefits associated with additional transplants. They have shown that an analysis of the costs and benefits for heart transplants, based on the cost of organ retrieval and transplantation and the benefits of quality of life improvements and reduction in the cost of medical management could be highly cost effective. It is estimated that over a ten year period – the median survival time for transplanted patients – there would be a net benefit of £2.4 million per transplant⁴².

Having a successful transplant often allows patients to return to work and reduces the number of hospital visits. For example the average annual cost of dialysis for a patient with kidney failure is £30,800 but a successful kidney transplant operation costs £17,000 and £5,000 thereafter⁴³. The

³⁹ <http://wales.gov.uk/docs/dhss/consultation/090508organdonationen.pdf>

⁴⁰ http://www.nhsbt.nhs.uk/to2020/resources/nhsbt_organ_donor_strategy_long.pdf

⁴¹ [http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20\(Wales\)%20Bill%20-%20Explanatory%20Memorandum](http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20(Wales)%20Bill%20-%20Explanatory%20Memorandum)

⁴² *ibid*

⁴³ http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp

NHSBT predicts that for every year a kidney transplant remains functional, the NHS saves £24,100 per patient⁴⁴.

Given just one donor can save or improve the lives of up to nine people the potential number of transplants and associated savings can be far greater than the number of donors.

⁴⁴ *ibid*

Your Input

Consultation questions

1. The overarching purpose of my proposal is to move from the current opt-in system to a soft opt-out system of organ donation. Do you support this move? Please indicate “yes/no/undecided” and explain the reasons for your response.
2. How essential is it to change the law (from an opt-in to a soft opt-out system) in order to achieve the intended benefits (increased transplant rates, reduced waiting lists)? Are there other (non-legislative) measures that could achieve similar outcomes without the need for legislation?
3. I believe the role of the family should be limited to being consulted on whether they are aware of any (unregistered) objection by the deceased rather than asking for their consent. Do you agree? Please indicate “yes/no/undecided” and explain the reasons for your response.
4. Do you think an individual should be able to appoint a proxy to make the final decision regarding transplantation on their behalf? Please indicate “yes/no/undecided” and explain the reasons for your response.
5. My proposal is that only adults should be automatically opted-in to be a donor. Younger persons would have to register to be a donor, by themselves or with parental consent as they currently do. This approach is I believe the best way to safeguard children and young people. Do you agree? Please indicate “yes/no/undecided” and explain the reasons for your response.
6. Do you agree the age limit for an adult should be set at 16 years old? Please indicate “yes/no/undecided” and explain the reasons for your response. If you answered no, what would you consider a more appropriate age?
7. Do you agree the soft opt-out system should apply to people who have been resident in Scotland for a minimum period of 1 year prior to their death? Please indicate “yes/no/undecided” and explain the reasons for your response.
8. If you answered no to the above how long, if any, should this period of residency last before they become subject to the soft opt-out system? Would this residency need to be for a continuous period?
9. Do you think 6 months is a long enough period to run a campaign prior to change over?
10. What is your assessment of the likely financial implications (if any) of the proposed Bill to you or your organisation? What (if any) other significant financial implications are likely to arise?

11. Is the proposed Bill likely to have any substantial positive or negative implications for equality? If it is likely to have a substantial negative implication, how might this be minimised or avoided?

12. Do you have any other comments on or suggestions relevant to the proposal?

How to respond

You are invited to respond to this consultation by answering the questions in the consultation and by adding any other comments that you consider appropriate.

Responses should be submitted by 5pm 25 September 2014 and sent to:

Anne McTaggart MSP,

M1.11,

Scottish Parliament,

Edinburgh, EH99 1SP.

Tel: 0131 348 6211

E-mail: anne.mctaggart.msp@scottish.parliament.uk

Please indicate whether you are a private individual or an organisation.

Respondents are also encouraged to begin their submission with short paragraph outlining briefly who they are, and who they represent (which may include, for example, an explanation of how the view expressed was consulted on with their members).

To help inform debate on the matters covered by this consultation and in the interests of openness, please be aware that the normal practice is to make responses public – by posting them on my website www.annemctaggart.co.uk. I am also obliged to provide copies of all responses to the Scottish Parliament's Information Centre (SPICe), which may then make them available to MSPs or staff on request.

Therefore, if you wish your response, or any part of it, to be treated as **anonymous**, please state this clearly along with the reasons for this. If I accept the reasons, I will publish it as “anonymous response”, and only the anonymised version will be provided to SPICe. If I do not accept the reasons, I will let you know and give you the option of withdrawing it or submitting it on the normal attributable basis. If your response is accepted as anonymous, it is your responsibility to ensure that the content of does not allow you to be identified.

If you wish your response, or any part of it, to be treated as **confidential**, please state this clearly and give reasons. If I accept the reasons, I will not publish it (or publish only the non-confidential parts). However, I would still be obliged to provide a full copy of the response to the Parliament's Non-Government Bills Unit, and a redacted copy to SPICe when lodging my final proposal. As the Parliament is subject to the Freedom of Information (Scotland) Act (FOISA), it is possible that requests may be made to see your response (or the confidential parts of it) and the Parliament may be legally obliged to release that information. Further details of the FOISA are provided below.

NGBU may be responsible for summarising and analysing the results of this consultation and will normally aim to reflect the general content of any confidential response in that summary, but in such a way as to preserve the confidentiality involved. You should also note that members of the committee which considers the proposal and subsequent Bill may have access to the full text of your response even if it has not been published in full.

There are a few situations where not all responses will be published. This may be for practical reasons: for example, where the number of submissions we receive does not make this possible or where a large number of submissions are in very similar terms. In the latter case, only a list of the names of people and one response who have submitted such responses would normally be published.

In addition, there may be a few situations where I may not choose to publish your evidence or have to edit it before publication for legal reasons. This will include any submission which contains defamatory statements or material. If I think your response potentially contains such material, usually, this will be returned to you with an invitation to substantiate the comments or remove them. In these circumstances, if the response is returned to me and it still contains material which I consider may be defamatory, it may not be considered and it may have to be destroyed.

Data Protection Act 1998

As an MSP, I must comply with the requirements of the Data Protection Act 1998 which places certain obligations on me when I process personal data. Normally I will publish all the information you provide (including your name) in line with Parliamentary practice unless you indicate otherwise. However, I will not publish your signature or personal contact information (including, for example, your home telephone number and home address details, or any other information which could identify you and be defined as personal data).

I may also edit any information which I think could identify any third parties unless that person has provided consent for me to publish it. If you specifically wish me to publish information involving third parties you must obtain their consent first and this should be included in writing with your submission.

If you consider that your response may raise any other issues concerning the Data Protection Act and wish to discuss this further, please contact me before you submit your response.

Further information about the Data Protection Act can be found at: www.ico.gov.uk.

Freedom of Information (Scotland) Act 2002

As indicated above, once your response is received by NGBU or is placed in the Scottish Parliament Information Centre (SPICe) or is made available to committees, it is considered to be held by the Parliament and is subject to the requirements of the Freedom of Information (Scotland) Act 2002 (FOI(S)A). So if the information you send me is requested by third parties the Parliament is obliged to consider the request and provide the information unless the information falls within one of the exemptions set out in the Act, even if I have agreed to treat all or part of the information in confidence or to publish it anonymously. I cannot therefore guarantee that any other information you send me will not be made public should it be requested under FOI.

Further information about Freedom of Information can be found at:

www.itspublicknowledge.info.