



SPICe Briefing

Pàipear-ullachaidh SPICe

The Human Tissue (Authorisation)(Scotland) Bill - Stage 3 Proceedings

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The Human Tissue (Authorisation) (Scotland) Bill sets out proposals to change the system for authorising organ and tissue donation in Scotland. Most notably, it proposes to introduce a system of 'deemed authorisation' (often known as presumed consent). This briefing summarises the proposals in the Bill, the findings and recommendations of the Health and Sport Committee at stage 1, amendments considered at stage 2 and amendments lodged at stage 3.



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Executive Summary

1. The Bill contains proposals to introduce a system of 'deemed authorisation' for organ and tissue donation for transplantation (often known as 'presumed consent').
2. The main aim of the Bill is to increase the organ donation rates and, as a consequence, the number of transplants carried out.
3. The current legislation operates on an opt-in basis. Relatives can authorise donation when someone has not recorded a decision.
4. The Bill would establish three options for expressing a wish on donation; opt-in, opt-out or do nothing. With the last option, the Bill would presume consent had been given and donation could go ahead.
5. Deemed authorisation would not apply to people under 16 years of age, those without capacity to understand deemed authorisation and those who have been resident in Scotland for less than 12 months.
6. Deemed authorisation would not apply to all organs and tissues but it is expected to apply to commonly donated organs and tissues.
7. The Bill would also clarify when certain medical procedures can be carried out before a person dies in order to help prepare someone for donation. The Bill calls this pre-death procedures.
8. The body of robust evidence in this area is relatively small, but country comparisons generally show an association between presumed consent and higher donation rates.
9. Key issues raised at stage 1 of the Bill included: the role of the state and the ownership of a person's body, whether the family's wishes should also be taken into account when deemed authorisation applies, whether there will be adequate opportunities to opt-out and confusion over the different options created by the Bill.
10. The Health and Sport Committee supported the general principles of the Bill but made a number of practical recommendations to the Scottish Government, including around the awareness raising campaign that will be required.
11. At stage 2, the main amendments agreed to included a duty for Ministers to carry out a public awareness raising campaign at least annually, a duty for Ministers to promote regular opportunities for people to make their donation wishes known, allowing people to verbally withdraw their decision recorded in the organ donor register and an obligation for Ministers to review and report on the operation of the Act.
12. Four amendments have been lodged at stage 3. These are concerned with refining three amendments agreed to at stage 2, namely, the frequency with which the public campaigns should be carried out, a duty to promote opportunities for people to opt-in and the requirement to review and report on the operation of the Act.

About the Bill

Aim of the Bill

The [Human Tissue \(Authorisation\)\(Scotland\) Bill](#) ¹ is a Scottish Government Bill which contains proposals to introduce a system of 'deemed authorisation' for organ and tissue donation for transplantation (often known as 'presumed consent').

What this means is that when someone dies but they have not made their wishes on donation known, their consent to donation would be presumed unless their next of kin provided information that this was against their wishes.

The main aim of the Bill is to increase the organ donation rates and, as a consequence, the number of transplants carried out.

What problem is the Bill trying to address?

The organ donation rate has generally been increasing over the last decade, as has the transplant rate. Consequently, the transplant waiting list has been decreasing. However, at any one time there are still over 500 people waiting for a transplant in Scotland and between 40-60 people will die each year while waiting.

The Bill is mainly concerned with increasing deceased donation rates. However, only a small number of people die in circumstances which allow them to be donors. In Scotland, there are about 400 potential donors each year but only around 100 of these people will actually become donors.

There are many reasons why someone may not become a donor but one reason is family refusal. The family refusal rate in Scotland is around 40% each year and results in the loss of around 100 potential donors.

Part of the logic of the Bill, is that by presuming consent, there will be fewer occasions when family authorisation is required and this may reduce the family refusal rate and thereby increase donations.

Current system of authorisation

The current legislation operates on an opt-in basis. Relatives can authorise donation when someone has not recorded a decision, but it does not contain any provisions which allow someone's relatives to overrule a recorded decision. However, in practice, organ retrieval does not proceed if the family object. Each year, around 10% of potential donors who have recorded a decision to donate will have this overturned by their relatives. Last year 69% of potential donors were not on the organ donor register.

How would the Bill change the current system?

The Bill would establish three options for expressing a wish on donation; opt-in, opt-out or do nothing. It is the last option where significant change is being proposed by the Bill as in these circumstances authorisation will be deemed and donation could go ahead. As with the current legislation, there would be no override for the family but they would be involved in ensuring the deceased person's wishes were known.

Deemed authorisation would not apply to people under 16 years of age, those without capacity to understand deemed authorisation and those who have been resident in Scotland for less than 12 months.

Deemed authorisation would not apply to all organs and tissues but it is expected to apply to commonly donated organs and tissues. Exceptions would be set out in regulations.

The Bill would amend existing legislation to allow greater flexibility in when donation could be authorised. This would allow authorisation to occur before death and enable preparations for non-heart beating donations.

The Bill would also clarify when certain medical procedures can be carried out before a person dies in order to help prepare someone for donation. The Bill calls this pre-death procedures. It proposes that some procedures may go ahead where authorisation for donation would be deemed.

Public opinion and key issues

Opinion polls tend to show the majority of people are in favour of presumed consent and opting-out. A survey carried out by the Health and Sport Committee found 68.8% in favour of a move to deemed authorisation.

Respondents to the Committee's survey contained differing opinions about the evidence around the effectiveness of presumed consent. The body of robust evidence in this area is relatively small, but country comparisons generally show an association between presumed consent and higher donation rates. Before and after studies have also shown an increase in donation rates, but these studies suffer from a number of methodological limitations.

Spain is used as an example of a country where opting-out has resulted in high donation rates. However, in practice, Spain effectively operates an opt-in system and its architects credit other factors for being instrumental in the higher than average rates.

The main objection of survey respondents who were opposed to the Bill related to the role of the state in assuming ownership of people's bodies and the idea that donation should be a gift. 22.5% of survey respondents said they would opt-out if the Bill became law.

Other key issues raised by respondents to the Committee's consultation included:

- whether the family's wishes should also be taken into account when deemed authorisation applies,
- whether deemed authorisation may increase family uncertainty about a person's wishes and lead to more refusals
- whether there will be adequate opportunities for people to opt-out
- confusion over the different options created by the Bill
- when pre-death procedures could take place.

For more detail on the Bill please see the [SPICe stage 1 briefing](#) ².

Stage 1 Consideration

The [Health and Sport Committee's Stage 1 report](#)³ supported the general principles of the Bill. However, it did also make a number of recommendations which are set out in the table below, along with the Scottish Government's response.

Recommendations from the Health and Sport Committee's Stage 1 Report and subsequent response from the Scottish Government

	Committee Recommendation	Scottish Government Response
Increase in Donation Rates?	We recommend the Scottish Government take steps to monitor public attitudes after a period of time of perhaps five years after the Act comes into force.	The Scottish Government recognised the importance of monitoring public attitudes and confirmed it intends to do so. The response also indicated that as part of the long term evaluation, intermediate information will be produced after 5 years on issues such as public attitudes.
	We consider a longer period of time to evaluate the impact of the Act is required.	In response to the Committee, the Minister states the evaluation will be carried out over 10 years.
	We note the creation of the trauma centres across Scotland and we seek confirmation each has the capacity to support the aims of this Bill.	The response from the Minister highlights that the key aim of the trauma centres is to save lives so donation may not always be feasible. However, the Minister restates the Scottish Government's commitment to supporting boards to identify potential organ donors and provide the appropriate care.
	We further recommend the Scottish Government reviews the infrastructure across the country for organ donation.	The response stresses that this is an ongoing commitment as part of the plan for increasing donation and transplantation. The Minister does however commit to discussing with stakeholders whether there are any further initiatives which should be progressed to improve the infrastructure.
Rights of the family and their consent	We recommend a review of the authorisation process in Scotland to ensure each and every question is of clinical importance.	The response highlights that the medical and social history questionnaire is a matter for NHS Blood and Transplant and the Scottish National Blood Transfusion Service to decide and requires clinical expertise. It concludes that it would not be appropriate for the Scottish Government to influence this. However the Minister did commit to writing to both organisations to draw the Committee's recommendation to their attention.
	We also recommend investigating the use of an online medical system similar to Canada, which could be used to assist the authorisation process.	The Minister did not accept this response, asserting that although medical records are accessed as part of the assessment process, medical records will not contain all relevant information (e.g. travel and social history) and this is why the medical and social history questionnaire is necessary.
Pre-death Procedures	We recommend the [pre-death] procedures be reviewed in 5 years.	The Scottish Government response states the Scottish Government's intention to keep the procedures under review with key stakeholders and the Scottish Donation and Transplant Group.
Post-transplant Care	We recommend the support given to families is included in the evaluation of the Bill, five years from the date of implementation of the Act.	The Scottish Government accepted the Committee's recommendation.
Mental Health	We recommend the Scottish Government improves the services available for patients on the transplant waiting list, recipients of organ donation and families who have authorised the donation of an organ from a relative.	The response details that psychological support is the responsibility of National Services Scotland which is currently undertaking a review of psychological support for all national services, including organ transplantation. The Scottish Government also intends to look at post-transplant aftercare as part of its next organ donation strategy. It highlights that support for bereaved families is predominantly through generic bereavement services such as Cruse or services accessed via a GP.
Awareness Raising	We recommend reviewing [Wales'] methods of reaching new residents to the country, different demographics, various cultural backgrounds and ethnic minority groups to ensure the law is upheld and maintained with public awareness at the highest level.	The SG response accepts the Committee's recommendation and sets out that a review of the Welsh strategy will be undertaken while developing public information. They are also in contact with NHSBT who are developing campaign information for the proposed opt-out system in England

	Committee Recommendation	Scottish Government Response
	<p>We also recommend undertaking outreach sessions with minority groups in order to explain the implications of the Bill with regards to deemed authorisation (presumed consent).</p>	<p>The SG response accepts the Committee's recommendation and details that the SG will work with a range of organisations to ensure many methods of raising awareness are developed and that information provided meets the needs of different groups.</p>
	<p>We recommend a collaboration with the Anthony Nolan Trust and Fire and Rescue Service (SFRS), adding organ donation to their programme in secondary schools and colleges. An umbrella of information covering blood cancers, stem cell donation and organ donation could raise awareness but also utilise resources in Scotland. The secondary school and college curriculum should include equal information on the three options available; how to opt-in, how to opt-out and the meaning of deemed authorisation. This programme should begin 12 months prior to the implementation of the Act and be sustained to ensure universal coverage.</p> <p>We also recommend utilising social media platforms to engage with children before they reach the age of consent and continuing the campaign for future years to include application for a driving licence and entrance to University (UCAS).</p>	<p>The Scottish Government response acknowledged the importance of raising awareness among young people specifically. In light of this the SG details that it plans direct mailings to young people and is undertaking focus groups to identify the best form of communication with this group and inform the awareness raising campaign. The Scottish Government also intends to update its current organ and tissue donation teaching resource pack. The Scottish Government is also working in partnership with the Anthony Nolan Trust and the Scottish Fire and Rescue Service and will continue to do so but this will be supplementary to other methods aimed at young people.</p>

Stage 2 Consideration

The following table details the main amendments that were considered at stage 2. It details the purpose of each amendment, the subsequent decision and the key points that were made in the debate when an amendment was not agreed to.

The most notable amendments agreed to at stage 2 included:

- a duty for Ministers to carry out a public awareness raising campaign at least annually,
- a duty for Ministers to promote regular opportunities for people to make their donation wishes known,
- allowing people to verbally withdraw their decision recorded in the organ donor register, and
- an obligation for Ministers to review and report on the operation of the legislation.

Stage 2 amendments by topic and the subsequent outcome

	Amendment	Outcome
Information and awareness about authorisation of transplantation and about pre-death procedures	Amendment 4 in the name of Jeremy Balfour MSP sought to require the Scottish Government to send information to people about opting-out at least every 2 years.	Withdrawn - During the debate on the amendment, Members expressed concern that the amendment potentially limits the methods that can be used to raise awareness. Members also stated a preference for yearly campaigns.
	Amendment 56 in the name of Lewis MacDonald MSP - sought to ensure that the duty to promote information and awareness is continuous and that ministers should promote awareness at least on an annual basis.	Agreed to - given the crossover of the amendment with other provisions in the Bill, the Minister and the Member agreed to refine the text of the amendment and bring it back at stage 3. This has been taken forward in amendments 1 and 2 at stage 3.
Excepted body parts	Amendment 5 (together with amendments 6, 9 to 17 and 19 to 23) in the name of Jeremy Balfour MSP - sought to ensure that donated tissue is not used to create reproductive cells and human embryos. The amendments also sought to remove the distinction between 'excepted' and 'non-excepted' body parts, arguing that we should be encouraging people to use all parts of the body for transplantation.	Withdrawn - the Minister highlighted that the intention is that deemed authorisation would only apply to organs and tissues commonly transplanted (non-excepted body parts). These organs and tissues will be set out in regulations subject to the affirmative procedure. The distinction is intended to provide a protection by limiting what can be taken under deemed authorisation. The Minister also highlighted that the procurement, storage and use of gametes, or reproductive cells, are dealt with separately under the Human Fertilisation and Embryology Act 1990 and require a Human Fertilisation and Embryology Authority licence.
Establishment and maintenance of register	Amendment 57 in the name of David Stewart MSP sought to give Ministers a duty to promote regular opportunities for people to make their wishes known.	Agreed to by division (5 for, 4 against) - During the debate the Minister contended that the existing duties upon Ministers could be used to meet the aim of the amendment.
	Amendments 24 to 33 in the name of the Minister, Joe Fitzpatrick MSP sought to reflect more accurately whom information from the register needs to be shared with and to clarify that information that is disclosed must be about a particular potential donor. The amendments also refine the purposes for which information can be shared.	Agreed to.
Express authorisation by adults	Amendment 34 (grouped with 36,40 and 42) in the name of the Minister, Joe Fitzpatrick MSP, sought to enable a person to verbally withdraw their decision as recorded in the register. At the moment people can make their decision known verbally but have to withdraw it in writing.	Agreed to.
Standard of evidence	Amendment 35 (together with 37,38,39, 41 and 43) in the name of the Minister, Joe Fitzpatrick MSP, aimed to change the evidential test of whether someone was unwilling to donate. The Bill as introduced would allow someone to provide information that donation was against the deceased's wishes and therefore prevent deemed authorisation going ahead. The initial test in the Bill was that this information should 'convince a reasonable person'. The amendment proposed to change this to the information should 'lead a reasonable person to conclude'. These amendments were lodged after discussion with Mike Rumbles MSP who expressed concerns about the use of the word 'convince' and wished the test to be	Agreed to.

	Amendment	Outcome
	compatible with the wording of the Human Tissue (Scotland) Act 2006.	
	Amendments 58-61 in the name of Gordon Lindhurst MSP sought to change the test to overturn deemed authorisation from one which would require evidence that the deceased was unwilling to donate, to one which would only allow donation to go ahead if the nearest relative provided evidence that they were willing to donate.	Withdrawn - during the debate, the Minister argued that this would undermine the principle of an opt-out system because there is no assumption of willingness; instead, willingness must be demonstrated by the nearest relative.
Deemed authorisation for transplantation as respects adults	Amendments 7 and 8 in the name of Jeremy Balfour - sought to extend the period of time in which deemed authorisation would not apply to people who had moved to Scotland. The Bill as introduced sets the period at 12 months. These amendments proposed extending that to either 2 or 3 years.	Withdrawn - during the debate the Minister assured the Member that the Scottish Government is looking at what has been undertaken in Wales, where various channels are used for awareness raising among new residents, including new GP registrations, universities, estate agents and major employers. This would supplement the broader on-going awareness-raising campaign.
Removal of part of body of deceased person: further requirements	Amendments 44-49 in the name of the Minister, Joe Fitzpatrick MSP to make it clear that the body parts of a deceased person may be removed by a person who is not a registered medical practitioner but is authorised to do so under a general authorisation made in accordance with regulations.	Agreed to.
Pre-death procedures relating to transplantation	Amendments 50 and 51 in the name of the Minister, Joe Fitzpatrick MSP, sought to amend the Bill to allow pre-death procedures to also be described in accordance with how they are carried out.	Agreed to.
	Amendment 18 in the name of Jeremy Balfour MSP sought to amend the Bill to insert a requirement that pre-death procedures should not shorten the life expectancy of the individual.	Disagreed to (For 0, Against 9) - during the debate the Minister argued that there is already a requirement not to harm patients and that the Bill requires that these procedures should not be carried out if they are likely to cause more than minimal discomfort.
Duty to inquire	Amendments 52 to 54 in the name of the Minister, Joe Fitzpatrick MSP, sought to change the definition of health worker to reflect a broader range of professions who may be involved in the authorisation process.	Agreed to.
Review and operation of the Act	Amendment 62 in the name of Lewis MacDonald MSP, sought to place an obligation on ministers to research and report on the impact of the provisions in order to determine the efficacy of the legislation. It imposes a duty to undertake a review and report back to Parliament. The review period would be 5 years after the Bill achieves Royal assent.	Agreed to - the Minister also committed to working with the Member prior to stage 3 in order to refine the amendment so the review period begins with the day the system is introduced rather than when the Bill achieves Royal assent. This is being taken forward in amendments 3 and 4 at stage 3.
Commencement	Amendment 55 in the name of the Minister, Joe Fitzpatrick MSP, sought to ensure certain sections of the Bill are not commenced on the day after Royal assent. The intention is that the provisions will be commenced via commencement regulations. This would allow time for an awareness raising campaign for at least 12 months.	Agreed to.
	Amendment 63 in the name of Lewis MacDonald sought to amend the bill to provide for a two-year information and awareness period before the commencement of the provisions in the bill	Withdrawn - in the debate the Minister committed to an awareness raising period of at least 12 months and argued that awareness was already at a higher level due to exposure to the debate in Wales and the rest of the UK.

	Amendment	Outcome
Short Title	Amendment 64 in the name of Lewis MacDonald MSP, sought to change the short title of the Bill to include the word transplantation and improve the clarity and raise awareness of the Bill's purpose.	Withdrawn - in the debate, the Minister explained that they had considered adding a reference to transplantation in the short title however, such a reference was not added because it was felt that it would potentially mislead the public to think that the bill was about transplantation only. The short title reflects the fact that the bill is also about authorisation of donation for other purposes, not only transplantation.

Stage 3 Amendments

There are four amendments lodged in advance of stage 3. These are taking forward commitments made by the Minister at stage 2.

Amendments 1 and 2

Amendment 1 inserts a revised version of the amendment made by Lewis MacDonald MSP which stipulated that awareness raising campaigns should be carried out at least annually. It also incorporates the duty for Ministers to promote regular opportunities for people to opt-in, which was added by David Stewart MSP at stage 2. Consequentially, amendment 2 removes David Stewart's original amendment.

Amendments 3 and 4

Amendment 4 removes the amendment made by Lewis MacDonald MSP at stage 2 which would require Ministers to review and report on the functioning of the Act. Amendment 3 inserts a revised version of the original amendment, with the wording changed to detail that the review period will commence from the day the system becomes operational as opposed to when the Bill receives Royal Assent.

Bibliography

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