



Law Society
of Scotland

Stage 1 Briefing

The Human Tissue (Authorisation) (Scotland) Bill

February 2019



Introduction

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We have a statutory duty to work in the public interest, a duty which we are strongly committed to achieving through our work to promote a strong, varied and effective solicitor profession working in the interests of the public and protecting and promoting the rule of law. We seek to influence the creation of a fairer and more just society through our active engagement with the Scottish and United Kingdom Governments, Parliaments, wider stakeholders and our membership.

We have previously engaged with the Scottish Parliament on a number of occasions in relation to proposals focused on organ donation. During the parliamentary passage of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill we submitted written evidence¹ and provided oral evidence² to the Scottish Parliament's Health and Sport Committee. In March 2017, we submitted a consultation response to the Scottish Government consultation: Organ and Tissue Donation and Transplantation - increasing numbers of successful donations.³ In relation to the present Bill, The Human Tissue (Authorisation) (Scotland) Bill, we submitted written evidence⁴ to the Health and Sport Committee and provided oral evidence before the committee on the 27 Nov 2018⁵ This briefing paper is consistent with the approach taken in our previous submissions and engagement.

If you would like to discuss this paper, or if you would like more information on the points that we have raised, please do not hesitate to contact us. Contact details can be found at the end of the paper.

¹ <http://www.lawscot.org.uk/media/604859/hea-transplantation-authorisation-of-removal-of-organs-etc-scotland-bill-final-12-10-15.pdf>

² <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=10247>

³ <https://www.lawscot.org.uk/media/9563/hea-organ-and-tissue-donation-and-transplantation-consultation-law-society-of-scotland-response.pdf>

⁴ <https://www.lawscot.org.uk/media/360960/03-09-18-hea-the-human-tissue-authorisation-scotland-bill-call-for-evidence-response.pdf>

⁵ <http://www.parliament.scot/parliamentarybusiness/report.aspx?r=11810&mode=pdf>

General comments

We welcome the publication of the Health and Sport Committee (the committee) Stage 1 report on the 1 Feb 2019.⁶ While we generally support the promotion of good public health and health equality, we are not in a position to comment on the policy aims of the Bill in its consideration of whether Scotland should move to a soft opt-out system for organ donation. However, before we comment on the provisions of the Bill, and the recommendations as set out in the stage 1 report, we do believe that it is important to highlight what we consider to be the underpinning themes to any legislation which implements a soft opt-out system, and themes that have consistently been the focus of our previous submissions.

First, proposals should be clear and transparent in their aims and objectives. This would be the case not only for the Scottish public but for those involved in health care practice. Second, we suggest that there should be advance publicity which is tailored to meet the needs of the diverse groups in our society, be timely and easily accessible. We also believe that targeted information should be available for someone considering organ donation which would promote reflection and discussion with their family and/or their healthcare professional. Also, there should be targeted information for families to ensure as much understanding and awareness of deemed authorisation as possible.

In summary, our comments on the Bill are:

- For clarity and the understanding of the public, we believe the short title should make mention of the term ‘transplantation’.
- The Bill refers to the term ‘authorisation’. We believe that this term does not necessarily have the same meaning as implied ‘consent’.
- Specific guidance should be published for families and health care staff on the consequences of a soft opt out scheme.
- The Bill should make reference to possible rights of individual family members under the European Convention on Human Rights.
- There should be more details on what types of procedures will fall into type A and type B for the purposes of Pre-death Procedures (PDPs).
- There must be a public awareness campaign leading up to the introduction of the Bill, with a lead in time of at least two years. This should be a targeted campaign aimed at minority groups, children, families and potential donors.

⁶ <https://sp-bpr-en-prod-cdnep.azureedge.net/published/HS/2019/2/1/Stage-1-Report-on-the-Human-Tissue--Authorisation---Scotland--Bill/HSS052019R2.pdf>

- There should be a duty for a review to take place to ascertain the impact of the Bill after a period of five years.
- There needs to be greater clarity on what will happen in relation to those who are currently registered as an organ/tissue donor.
- It is imperative that enough resources and the necessary infrastructure are provided so as to ensure that the policy intent is realised.

These are discussed further below.

Overview of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill

The Bill before the Scottish Parliament has the effect of reversing the current law in relation to organ donation. Organ donation and transplantation is currently underpinned by the provisions of the Human Tissue (Scotland) Act 2006 (the 2006 Act).⁷ The 2006 Act provides that for organs or tissue to be donated, the donor themselves must provide authorisation. Alternatively, the nearest relative may provide authorisation at the point of, or after, the death of the person from whom the organs or tissue are to be donated from. Therefore, the current position is that organ and tissue donation operates on a 'opt-in' basis. This is the opposite to the effects of the Bill, which proposes a 'soft' opt-out – or 'deemed authorisation'.

It is not proposed to repeal the 2006 Act. The current Bill, in seeking to achieve its policy intent, makes significant amendments to the 2006 Act which shall remain in force.

The policy intent of the Bill is to increase the availability of organs and tissue for transplantation, and therefore reduce the number of those awaiting a transplant and the associated deaths which occur each year whilst awaiting the availability of suitable organs. To this aim, the Bill seeks to introduce a system where three options are provided;

1. Opt-in – where a potential donor may expressly record their authorisation for donation,
2. Opt-out – where a potential donor may expressly 'remove' authorisation, or
3. Deemed authorisation – this would be, under the provisions of the Bill, the default option if the donor did not expressly state their wishes, in effect the donor does nothing to record their wishes.

The third option 'deemed authorisation' would only apply to those over the age of 16 years, with the capacity to understand the effects and meaning of deemed authorisation and who are resident in Scotland for over 12 months. In relation to those under the age of 16, authorisation would be sought from those with parental rights and responsibilities. Children aged 12 and over, as is the current position, would be able to opt-out or opt-in, but deemed authorisation would not apply where the child is under 16. Where a child

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

over the age of 12 has chosen to expressly opt-in or opt-out, then these express wishes cannot be overridden.

The Bill does not set out the nature or types of the organs or tissue to which the provision of the Bill will apply. However, those organs to which it does not apply will be set out in regulations. We recommend that a draft of these regulations excluding excepted body parts should be made available to MSPs before Stage 3 of the Bill. Setting these out in regulations will allow for the type of organs to be donated to be controlled and amended to reflect medical needs, research and advancements.

Summary of the provisions of the Bill

The Bill is set out in four parts;

Part 1

Provides a brief overview of the 2006 Act and the structure of the current Bill.

Part 2,

Sections 2 – 3 set out the duties of the Scottish Ministers, amending those as set out within the 2006 Act to support the amended provisions. This includes the duty to promote information and awareness of the new provisions, how transplantation may be authorised and how this can be deemed. In addition, it provides for the creation of a register to record those who expressly opt-in and opt-out. The register is not a public register, but a duty is placed to release information from the register to specified persons. These include, for example, the Health Board and the donors nearest relative or, in the case of a child, those having parental rights and responsibilities.

Part 3

Sections 4 – 11 relate to authorisation of, or on behalf of, an adult and provides that an adult may expressly record their wishes (opt-in or opt-out) in the relevant register and the adult retains the right to withdraw their express wishes. Where no express wishes have been recorded, section 7 provides that authorisation for donation is to be deemed (except in cases where the adult lacks capacity or has not been resident in Scotland for 12 months or the organ in question is an 'excepted body part'. Section 8 provides for authorisation to be given by a nearest relative where the potential donor has been resident for a period of less than 12 months and has not expressly made known their wishes. Section 9 provides for authorisation by the nearest relative where the potential donor lacked capacity to understand the nature and consequence of deemed authorisation and where no express wishes have been recorded. Section 10 provides for authorisation where the organ is an 'excepted body part'. The nearest relative may authorise removal if the potential donor did not expressly opt out and the nearest relative has no actual knowledge of

the donors most recent view. Section 11 provides provision allowing the nearest relative to authorise organs for purposes other than transplantation.

Sections 12-17 set out the provisions in relation to authorisation by or on behalf of a child. Children, those under the age of 16, are exempted from deemed authorisation for the purposes of the Bill. Where a child is under the age of 16 years, authorisation would be sought from the person with parental rights and responsibilities or the nearest relative. Where a child is over the age of 12 years, they retain the current right to opt-in. The Bill's provisions also confer the right to opt-out. Where a child over the age of 12 has chosen to record their wishes, then this cannot be overridden by the wishes of the person holding parental rights and responsibilities.

Sections 18 – 21 set out general provision relating to authorisation, such as the steps necessary for a person who is visually impaired or unable to write to opt-out of deemed consent and the removal of body parts for the purposes of quality assurance.

Sections 22 sets out the provision relating to PDPs, and provides the authorisation process under which the procedures may be carried out. There are two separate procedures, Type A procedure and Type B procedure. The Bill does not expressly state the nature of either type of procedure, but leaves this to be set out in regulations. It is expected that Type A will include routine testing, for example blood/urine etc. This type of procedure could be carried out under deemed authorisation. Type B procedures are expected to be more invasive tests. These will not be carried out under deemed authorisation.

Section 23 places a duty on the health care worker to take steps to ascertain the wishes of the potential donor, which includes inquiring if there was an express wish of authorisation or opt-out. Where there is no express wish, then the health care worker must inquire if the adult is a non-resident or is an adult who is incapable of understanding the nature and consequence of deemed authorisation.

Part 4

Sections 24 – 29 set out provisions relating to consequential amendments to the 2006 Act which result due to the main provisions of the Bill.

Summary of comments

Short title of the Bill

The title of the Bill does not clearly reflect its purpose, which is to effect a radical change to the legal basis on which organs can be used for transplantation. Such a change has the potential to affect the whole population and so it is particularly important to be as transparent as possible to draw the public's attention to the proposed changes.

We recognise that the Bill is designed to make amendments to the Human Tissue (Scotland) Act 2006 and the words "Human Tissue" are bound to appear in the title to make the link with that Act, but we think that it is unhelpful not to include a reference to transplantation in the short title. We note that the long title refers to transplantation, but do not feel that this is a sufficient signal to the general public of the real nature of the Bill's provisions.

Use of the term 'authorisation'

In general discussion over different approaches to procuring organs and tissues, the focus tends to be upon two legislative regimes: 'informed consent', where an explicit declaration makes the person a potential organ donor (as currently operates in Scotland) and 'presumed or deemed consent', which is the model which is now in operation in Wales, in which an explicit declaration is required for not being a potential donor.⁸ The England and Wales Human Tissue Act 2004 uses the word 'consent' but its Scottish counterpart the Human Tissue (Scotland) Act 2006 instead uses the word 'authorisation'.

Whilst the Human Tissue Authority's Code of Practice on Consent (para 19) regards these as expressions of the same principle, we are not convinced that this is the case. Authorisation is about giving permission - it does not mean the same as presumed, deemed or implied consent. Some commentators reconcile this by saying that, for the purposes of organ donation, authorisation is "used to differentiate the process from

⁸ Of course, views can be diverse. See for example, Fabre, J (2014) Presumed consent for organ donation clinically unnecessary and corrupting influence in medicine and politics. *Clinical Medicine* . 14 6 567-571. Cf Ugar, Z.B. (2014) Does presumed consent save lives? Evidence from Europe. Available from: https://zbugur.files.wordpress.com/2012/11/presumed-consent_job-market-paper.pdf [Accessed March 2017]

what may be understood by ‘usual’ consent”.⁹ But it has been recognised that the validity of authorisation does not depend on information being given or received.¹⁰ We suggest that for consent to be valid, the disclosing and importantly, understanding, of information is required before a decision is made.¹¹

We recognise that the use of the term authorisation is being used in this proposed Bill since it flows from the 2006 Act.

In their discussion paper of 2016, the UK Donation Ethics Committee suggested that ‘authorisation’ brought with it an expectation that if someone expressed wishes about what should happen to their bodies after death, there is “an expectation that these wishes would be respected”.¹² If this interpretation was accepted, such expectation would need to be balanced against any conflicting views of the family or whether proceeding with donation would cause them distress.

Finally, a brief comment on the application of such terminology to the family. Whilst their role is addressed in more detail below, the use of consent and authorisation should also be viewed from their perspective. As early as 2003, it was acknowledged that whilst families may be prepared to permit the removal of organs and tissue, “They do not wish to or do not feel able to participate in a process akin to giving fully informed consent to medical treatment in life”.¹³ What this does highlight is the importance of a potential donor, where possible, taking steps to ensure that their wishes are known.

Educating the public and raising awareness

We believe that raising public awareness is crucial and therefore it is paramount that there should be advance publicity which is tailored to meet the needs of the diverse groups in our society, timely and easily accessible. We also suggest that targeted information should be available for someone considering organ donation which would promote reflection and discussion with their family and/or their healthcare professional. We have noted previously that when legislation has been introduced, it seems to be more effective if accompanied by prominent education and public awareness campaigns. Therefore, we are

⁹ Vincent A and Logan L. (2012) Consent for organ donation. *British Journal of Anaesthesia* **108** i80-i87 at p. i80.

¹⁰ Academy of Medical Royal Colleges (UK Donation Ethics Committee) (2016) Involving the Family in Deceased Organ donation. At p.22. Available from: <http://www.aomrc.org.uk/publications/reports-guidance/ukdec-reports-and-guidance/involving-family-deceased-organ-donation-discussion-paper/> [Accessed March 2017]

¹¹ For further discussion please see- Iltis, A.S. (2015) Organ Donation, Brain Death and the Family: Valid Informed Consent. *Journal of Law, Medicine and Ethics*. 369-382 at p. 369.

¹² Academy of Medical Royal Colleges (UK Donation Ethics Committee) (2016) Involving the Family in Deceased Organ donation. At p.22. Available from: <http://www.aomrc.org.uk/publications/reports-guidance/ukdec-reports-and-guidance/involving-family-deceased-organ-donation-discussion-paper/> [Accessed March 2017]

¹³ Brazier, M (2003) Organ retention and return: problems of consent. *Journal of Medical Ethics* 2003 **29** 30-33 at p. 30.

supportive of the recommendations of the Health and Sport committee (at page 30 of the Report) that a high profile public information campaign is undertaken including outreach sessions to be held with minority groups and awareness raised with children through the appropriate methods.

However, we suggest that any information campaign should be over a prolonged period and commence sooner than the 12 months which the committee has recommended. It may be useful to consider the approach taken in Wales. The campaign to raise awareness of the Human Transplantation (Wales) Act 2013 had a lead in time of two years.¹⁴ We also suggest that following introduction, the information campaign should continue until such time as it can be demonstrated that the public have become familiar with the new process. As noted in evidence to the committee (para 151 of the Stage 1 report) it is important that public awareness campaign continues to be 'drip-fed' long term.

Rights of the family

As recognised in the Stage 1 Report (para 99) the role of the family will be a fundamental element in the success of the policy intent behind the Bill. Currently the wishes of the family are ascertained. This has developed through custom and practice, rather than through legislation. In practice the wishes of the family have the potential to veto any decision by the donor.

An international study was undertaken relating to consent systems for deceased organ donation.¹⁵ The study concluded that where next of kin involvement was sought, their views have a larger and more immediate effect than legislative changes.¹⁶ This was regardless of the type of organ donation model that was adopted and whether the views of the potential donor were expressed or unknown.¹⁷ The study notes that: *"Nineteen out of the 25 nations [interviewed] with presumed consent provide a method for individuals to express a wish to be a donor. However, health professionals in only 4 of these nations responded that they do not override a deceased's wish because of a family's objection."*¹⁸

We note that the Bill's provisions do not place a duty to ascertain the wishes of the family, but to ascertain if the family *know of the wishes* of the potential donor. In reality the family may be forceful in their

¹⁴ The Welsh Government, Taking organ transplantation to 2020. Available from : <http://gov.wales/topics/health/nhswales/organ/transplantation/?lang=en>
¹⁵ Rosenblum, A.M *et al.* (2012) The authority of next-of- kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. *Nephrol Dial Transplant* 2012 27: 2533-2546
¹⁶ Rosenblum, A.M *et al.* (2012)The authority of next-of- kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. *Nephrol Dial Transplant* 2012 27: 2543
¹⁷ Rosenblum, A.M *et al.* (2012)The authority of next-of- kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. *Nephrol Dial Transplant* 2012 27: 2533-2546 at p. 2533
¹⁸ Rosenblum, A.M *et al.* (2012)The authority of next-of- kin in explicit and presumed consent systems for deceased organ donation: an analysis of 54 nations. *Nephrol Dial Transplant* 2012 27: 2533-2546 at p. 2533

objections and it will be responsibility of the Specialist Nurses-Organ Donation (SNODS) to ascertain the final wishes of the deceased in such cases and to proceed with deemed consent. However, in practical terms, we agree with the findings of the committee that it would be difficult for donation to proceed against the wishes of the family. Therefore, it is crucial that guidance is provided to both the SNODS/health care workers and families.

Research has shown that health care staff wish explicit guidance to be provided to both families and health professionals on the consequences of a soft opt-out scheme¹⁹. The Bill makes it clear that families will be consulted and have a role, for example, in providing medical history. Having proper communication skills is essential. Awareness of the family's emotional needs, and being able to skilfully navigate discussions on difficult issues such as brain stem death or bodily integrity may advance a greater understanding from the family of a potential donor of the importance of their decision²⁰ and we agree with the committee's recommendations (at para 116 of the Stage 1 report) that a review of the authorisation process in Scotland be undertaken to ensure every question asked is of clinical importance. We also agree with the recommendation that the use of an online medical system be investigated to determine if this would be beneficial.

Human Rights

We note that the Bill makes no reference to possible rights of individual family members under the European Convention on Human Rights, and the Stage 1 Report does not consider this.

Two cases are highly relevant here - *Petrova v Latvia* in 2014 where it was argued that a lack of clarity in Latvian law about whether there was an obligation to inform or gain consent from close relatives prior to removing tissue or organs was a violation of Article 8²¹ and *Elberte v Latvia* in 2015.²²

Mrs Elberte's husband died in a car accident. During forensic medical examination, it was noted that he had no stamp on his passport which would have indicated an objection to use of his tissues and organs. Under a state approved agreement, these were subsequently used by a pharmaceutical company for use in bio implants. Since the tissue had to be used within 24 hours there was only reliance on the passport to

¹⁹The need for clarity and transparency is a recurring theme in many studies to date. See, for example, Welsh Government, (2013) 'Soft opt-out system of organ donation: researching the views of Specialist Nurses and Clinical Leads. *Research Summary* 46/2013 at pp3-4;

²⁰Ghorbani, F et al (2011) Causes of Family Refusal for Organ Donation. *Transplantation Proceedings* 43 405-406.

²¹ Application no. 4605/05 [2014] ECHR 805

²² Application no. 62143/08 [2015] ECHR 1

ascertain the wishes of the deceased and no attempt was made to contact relatives. Mrs Elberte was only made aware of the circumstances around this donation some two years later following a criminal investigation. The question was whether there was an obligation to inform the deceased's relatives and ascertain their wishes. The court found a violation of Mrs Elbert's right to privacy under Article 8. They also found that she had suffered degrading treatment under Article 3 due to the removal of her husband's tissues.²³ Given what we noted above about relational autonomy it was interesting to note that this case was not decided on the basis of family life protections under Article 8 but the focus instead on a private life.²⁴

We suggest that the proposed Bill is considered in the light of the outcome of these cases²⁵.

Pre-death procedures

Section 22 of the Bill relates to pre-death procedures (PDPs). The Bill distinguishes between two types of PDPs, type A and type B procedures. Type A are described as 'routine' procedures and are procedures to which deemed consent would be attached. The second type are type B procedures "*which could be carried out, including the administration of some forms of medication, but they may not be of a type where people would assume that they are consenting to them by simply authorising donation*" As described by the committee type B "*are anticipated to be less routine including....more invasive tests*".²⁶ As also noted by the committee, families have expressed their 'discomfort' on invasive tests, the ones that may fall under type B.

Type A procedures will be prescribed by Scottish Ministers in secondary legislation, after consultation, to allow the list to fully reflect current practice. Type B procedures will also be set out in secondary legislation after consultation alongside information on how they may be authorised, and safeguards over and above those which will apply to type A procedures.

²³ Neethu R (2016) *ELBERTE v LATVIA*: The To be or not to be question of Consent . *Medical Law Review*, Volume 25, 3, 1 August 2017, Pages 484–493

²⁴ Dove ES (2015) *Elberte v Latvia*: a curious case of tissue, relatives and the 'right to private life' The Motley Coat Blog of the Mason Institute. Available from: <http://masoninstitute.blogspot.com/2015/02/elberte-v-latvia-curious-case-of-tissue.html> [Accessed August 25 2018]

²⁵ Tickell A. (2017) 'In accordance with the law: Is Scottish organ donation law ECHR compatible? Available from: https://www.academia.edu/31856953/Scottish_Government_consultation_response_In_accordance_with_law_Is_Scottish_organ_donation_law_ECHR_compatible [Accessed August 14 2018]

²⁶ Stage 1 Report on the Human Tissue (Authorisation)(Scotland) Bill para 120

We believe it would be helpful and informative, from the donor's perspective, that of the family and the health care professionals, for greater detail to be included on the face of the Bill as to what types of procedures type A and, in particular, type B will include and involve. As the Bill currently stands, this is very vague in relation to PDPs. If type A and type B procedures are to be set out in regulations then we recommend that the draft regulations, setting out the nature of type A and type B, be provided to MSPs before Stage 3 of the Bill.

We recommend that the draft recommendations, setting out the nature of type A and type B, be provided to MSPs before Stage 3 of the Bill.

We do however support the committee recommendation (at page 26 of the Report) that the procedures are reviewed after 5 years.

Review clause

So as to determine whether or not the policy intent has been realised, we suggest that there should be a duty to undertake a review and report back to the Scottish Parliament. We note that an impact evaluation of the Human Transplantation (Wales) Act 2013 was published in December 2017. The evaluation was undertaken within a relatively short period of the Act coming into force in December 2015, therefore benefits were not evidenced, and the evaluation found there had been little increase. However, in the 12 months following publication of the evaluation, there had been a marked increase. Therefore, we suggest that any review should be timed to allow for education and awareness to be developed and further suggest that this should be five years after the Bill comes into force. We also agree with the committee's recommendation that the review includes the support given to families following donation, as referred to above.

Existing consent

The Bill proposes a new model for organ and tissue donation, which is centred around the registration of the wishes of the potential donor. As we understand, two new registers will be created, an 'opt-in' register and 'opt-out' register. However, the Bill is not clear on what will happen to those individuals where there is existing and express consent, for example where a person has actively registered with the NHS Organ

Donor Register. Will there be a transition period where both the opt-in register and the current NHS Organ donation register operate side by side, which will require health workers to carry out checks on each?

Resource

It is crucial that the necessary resource and funding is provided to ensure an infrastructure which supports and develops the policy intent of the Bill and which has the capacity to manage resultant increases in organ and tissue donation. In this respect, we agree with the recommendation of the committee (at page 17 of the Report) that the Scottish Government reviews the infrastructure across Scotland for organ donation.



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