



Law Society  
of Scotland

# Consultation Response

Organ and Tissue Donation and Transplantation-  
A Consultation on increasing numbers of successful  
donations.

March 2017



## Introduction

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The Law Society of Scotland (the Society) is the professional body for over 11,000 Scottish solicitors. With our overarching objective of leading legal excellence, we strive to excel and to be a world-class professional body, understanding and serving the needs of our members and the public. We set and uphold standards to ensure the provision of excellent legal services and ensure the public can have confidence in Scotland's legal profession.

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 legal 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.

The Health and Medical Law Sub-committee of the Law Society of Scotland, welcomes the opportunity to consider and respond to the Scottish Government consultation: Organ and Tissue Donation and Transplantation - increasing numbers of successful donations.

We previously engaged with the Scottish Parliament during the parliamentary passage of the Transplantation (authorisation of removal of organs etc.) (Scotland) Bill submitting written evidence<sup>1</sup> and providing oral evidence<sup>2</sup> to the Scottish parliament's Health and Sport Committee.

## General comments

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While we generally support the promotion of good public health and health equality, we are not in position, nor would it be possible for us to comment on the policy aims of the consultation in its consideration on whether Scotland should move to a soft opt-out system for organ donation. However, if a soft opt-out system was to be implemented by legislation, this would reverse the law which is currently in place. Therefore, two general, but recurring themes underpin our responses.

First, proposals should be clear and transparent in their aims and objectives<sup>3</sup>. This would be the case not only for the Scottish general public but for those involved in health care practice.

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

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

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. We will say more on this in our response to subsequent questions.

We note that the Consultation comprises two chapters and advise that our focus is primarily on chapter 1 and the matters of law which pertain to it.

## Specific comments and question responses

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### Question 1 – what do you think of the principle of a soft opt out system for Scotland?

As we have set out in our general comments above, we are not in a position, nor would it be appropriate for us to comment on the principle of a sort opt-out system for organ donation in Scotland.

### Question 2 - are there any changes you would make to the current 'opt in' authorisation system, other than moving to opt out?

We note that other factors influence donation rates but there appear to be patterns of evidence which suggest that some countries who have an opt out policy do have higher donation rates than those countries which do not<sup>4</sup>. However it has been acknowledged in the consultation that this may not always be the case<sup>5</sup> and although opt-out systems have improved transplant figures in other countries, this would not necessarily translate from country to country because cultural differences and perceptions would also need to be considered.

The consultation refers to a survey which found that '*a great majority of Scottish people support organ donation*'<sup>6</sup> but such findings may not necessarily equate with public support for an opt-out system. Human nature and procrastination may also mean that, for some, accepting a default position may simply involve

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<sup>3</sup> The 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; Irving *et al*, (2014), 'What factors influence people's decisions to register for organ donation? The results of a nominal study group'. *Transplant International* 27 617-624

<sup>4</sup> Organ Donation Taskforce(2008). 'The potential impact of an opt out system for organ donation in the UK'. A report from the Organ Donation Taskforce. Supporting Information Annexes A-N, Dept. of Health, London.

<sup>5</sup> Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at pp10-13. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

<sup>6</sup> Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at p10. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

less effort. The question therefore is what benefits will legislating for an opt out system bring that could not be achieved by other means.

Increased awareness and education as noted in our general comments above, may improve willingness to donate organs and we are pleased to note the progress that has been made in relation to awareness-raising campaigns and that an educational resource pack is now being provided to all secondary schools in Scotland.<sup>7</sup>

As we have already noted, the consultation Document<sup>8</sup> notes that the merits of introducing an opt out model for procurement of organs remains unclear. It may be useful to maintain focus on progressing other proven strategies as public support is vital to ensure the success of any proposed legislative change.<sup>9</sup> Spain is frequently regarded a highly successful example in procuring a substantial increase in organ procurement.

Whilst Spain operates a system of presumed consent, it is regarded as promoting a more integrated approach, often referred to as the 'Spanish Model'.<sup>10</sup> Here legislation is complemented with other top level organisational measures including a multi-level transplant coordinator network and highly visible educational and awareness raising campaigns. This more comprehensive approach may be more attractive not only in terms of administration but also in relation to culture, and values.

**Question 3 – where someone has joined the Organ Donor Register (ODR) or indicated in another way that they wish to donate, what do you think should happen if the potential donor's family opposes the donation?**

We find this a very anomalous situation since, at present, there is no legislative requirement to ascertain the wishes of the family, but yet, through custom and practice, they will normally be consulted and have the potential to veto a decision made by the donor. In other words, there are key differences in what is provided by the legislation and what is done in practice.

An international study was undertaken relating to consent systems for deceased organ donation.<sup>11</sup> The study concluded that, where next of kin involvement was sought, their views have a larger and more

<sup>7</sup> Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at p7. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

<sup>8</sup> Ibid Fn 5

<sup>9</sup> Brazil implemented a system of presumed consent which was unsuccessful and resulted in the policy being reverted back to an opt in model. Csillag C. (1998) Brazil abolishes 'presumed consent' in organ donation. *Lancet* 1998 352:1367 .

<sup>10</sup> This term is favoured and supported by Spain's national transplantation organisation.

<sup>11</sup> 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

immediate effect than legislative changes.<sup>12</sup> 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.<sup>13</sup> 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'.<sup>14</sup>*

It would appear that whilst the views expressed by the potential donor are given priority, in the current and possibly future models of organ procurement, family members may be the ultimate arbiters of whether or not donation will proceed<sup>15</sup>. As was acknowledged by Dove *et al*, *'There is... significant space for manoeuvring around the letter of the law'*.<sup>16</sup> We make some further observations in relation to language used within the Human Tissue (Scotland) Act 2006 (the 2006 Act) under question 15 below and to the possible impact of two recent cases decided in the European Court of Human Rights. .

Research has shown that health care staff wish explicit guidance to be provided to both families and the health professionals on the consequences of a soft opt out scheme<sup>17</sup>. The consultation<sup>18</sup> makes it clear that families will be consulted and have a role, for example, in providing medical history. 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 possible donor of the importance of their decision.<sup>19</sup> Sharing best practice and looking to the experiences of other jurisdictions and international collaboration<sup>20</sup> may contribute towards the further enhancement of communication between the healthcare professional and the family.

It is suggested that further research is required in Scotland to investigate the relationship between family refusal and donation rates.

<sup>12</sup> 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

<sup>13</sup> 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

<sup>14</sup> 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

<sup>15</sup> Vincent A and Logan L. (2012) Consent for organ donation. *British Journal of Anaesthesia* 108 i80-i87 at p. i81.

<sup>16</sup> Dove, E.S. (2015) Elberte v. Latvia:Whose tissue is it anyway-Relational autonomy or the autonomy of relations? *Medical Law International* 15 2-3 77-96 at p.88

<sup>17</sup> The 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;

<sup>18</sup> Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at p13-15. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

<sup>19</sup> Ghorbani, F *et al* (2011) Causes of Family Refusal for Organ Donation. *Transplantation Proceedings* 43 405-406.

<sup>20</sup> For a comprehensive discussion on successful international collaboration please see- Mulvania, P. *et al* (2014) Successful International Collaboration Improves family Donation Conversations resulting in Increased Organ Donation. *Transplantation Proceedings* 2058-2065.

## Questions 4-6

Please see our earlier comments in relation to the role of the family and later observations in relation to definitions of consent and authorisation.

In relation to **Step 1** – concerning ‘high profile awareness raising campaigns’-<sup>21</sup> Our comments here focus upon the reach and effectiveness of any campaign. The 2006 Act incorporates a duty to promote information and awareness about organ donation<sup>22</sup> and we believe that this would provide some basis for any future guidance.

It may also 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 2 years.<sup>23</sup>

As the consultation recognises<sup>24</sup>, most professional organisations favour an extensive and high profile public campaign<sup>25</sup> and we agree that the robust provision of information is important to ensure that any decision made is fully informed. The information should be provided via a variety of mechanisms explaining the legislative changes and what opting out means in practice. A recent Australian study<sup>26</sup>, indicated that whilst public support for organ donation was ‘fairly consistent’, the reasons for support varied depending on age group. It is acknowledged that other studies have produced different results<sup>27</sup>. Diverse communication strategies may therefore be required to effectively inform different age groups and differing views. It should also be made clear that a change of mind is possible with a simple process in place to accommodate this.

## Question 8 – Under what age do you think children should only be donors with explicit authorisation?

We believe that children and young persons should only be opted-in with their consent. We note that the Human Transplantation (Wales) Act 2013, has adopted the approach of the Human Tissue Act 2004, which sets out the definition of ‘appropriate consent’ in relation to activities regarding the body of a deceased

<sup>21</sup> As set out in step 1 of 3 steps articulated in p.14. Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at p10. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

<sup>22</sup> Human Tissue (Sc) Act 2006, S1

<sup>23</sup> The Welsh Government, Taking organ transplantation to 2020. Available from : <http://gov.wales/topics/health/nhswales/organ/transplantation/?lang=en>

<sup>24</sup> As set out in step 1 of 3 steps articulated in p.14. Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- arch 2017] at p14 Step 1. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)

<sup>25</sup> See, for example, Reilly H., ‘BMA Scotland submission in support of Petition PE1453’, British Medical Association, Scotland . available from <http://bma.org.uk/organdopnation>. [Accessed 22 august 2014]

<sup>26</sup> Irving *et al*, (2014), ‘What factors influence people’s decisions to register for organ donation? The results of a nominal study group’. *Transplant International* **27** 617-624 at p. 622.

<sup>27</sup> Cronin, A,J Harris J,(2010) ‘Authorisation, altruism and compulsion in the organ donation debate’. *Journal of Medical Ethics* **36** 627-631.

child. For the purposes of section 2 of the 2013 Act, a child is any person under the age of 18 years, and parental / guardian consent is required below that age.

Consent to organ donation in Scotland is currently covered under the Human Tissue (Scotland) Act 2006. Section 8 of the 2006 Act provides that a child over the age of 12 can consent to organ donation without parental consent and if written consent is given by that child, this cannot then be vetoed by family members or those with parental responsibility. We agree that the proposed age limit of 16 years old for automatic opt-in is appropriate and we further agree that the current age limit for express consent to organ donation, as set out in the 2006 Act is appropriate.

However, in relation to consent of the child between the ages of 12-16 years, we do suggest that there should be safeguards in place to ensure a child aged between 12 and 16, and who provides written consent in accordance with 5 Section 8 of the 2006 Act, fully understands the nature of the authorisation and the nature of organ donation.

We note that Section 8 (5) of the 2006 Act requires any person who signs on behalf of a child aged 12 or over to certify that the child understands the effect of the authorisation, but there are no comparable requirements where a child signs the written consent him or herself.

We would also suggest that below the age of 16, consideration should be given to the views of family members or those with parental responsibility to take into account cultural and religious beliefs. For many potential donors, religious beliefs and cultural environment will be an important factor to be taken into consideration. Although a child of 12 may have an understanding of the general beliefs of his or her culture and faith, these may not include a full understanding of that faith's or culture's views and beliefs regarding organ donation.

#### **Question 14 – what do you think about allowing people to appoint one or more authorised representatives to make decisions for them?**

In line with the approach taken in many other areas of law, we believe that an individual should be able to appoint a proxy. We note that in the consultation<sup>28</sup> this has been utilised on very few occasions in England and Wales but, given the nature and importance of the decision that is being made, it is one more option to facilitate the procurement process.

<sup>28</sup> Scottish Government. Organ and Tissue Donation and Transplantation. A consultation on increasing numbers of successful donations. [Accessed Jan- March 2017] at p24. Available from: [https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting\\_documents/00511160.pdf](https://consult.scotland.gov.uk/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf)



We note the possible challenges in being able to trace the proxy and that it is preferable that families have had a discussion on whether the individual may or may not wish to donate their organs. However, many families have not, with research showing that it is only about 50% of individuals who have had such a discussion<sup>29</sup>. Some individuals may not want to place such a responsibility upon their family and if it were permissible for a proxy to be appointed, consideration would then need to be given as to whether or not the family could then override the proxy's decision.

We note the importance of ascertaining the medical circumstances of a potential donor and again, we believe that targeted publicity and media campaigns may help highlight the importance of advance discussion to communicate wishes and preferences.

**Question 15- Do you have any other comments which you think should be taken into account in relation to any Scottish opt out system?**

We would like to put forward the following additional comments for further consideration.

**Consent/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.<sup>30</sup> The English Human Tissue Act 2004, uses the word 'consent' but its Scottish counterpart the Human Tissue (Scotland) Act 2006 instead uses the word 'authorisation'.<sup>31</sup>

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. We note that the terminology used in the consultation refers to 'authorisation' and assume that this would be the terminology used in any future legislative proposals.

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 what may be understood by 'usual' consent*'.<sup>32</sup> But it has been recognised that the validity of authorisation does not depend on information being given or

<sup>29</sup> Vincent A and Logan L. (2012) Consent for organ donation. *British Journal of Anaesthesia* **108** i80-i87 at p. i81.

<sup>30</sup> 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](https://zbugur.files.wordpress.com/2012/11/presumed-consent_job-market-paper.pdf) [Accessed March 2017]

<sup>31</sup> 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.

<sup>32</sup> Vincent A and Logan L. (2012) Consent for organ donation. *British Journal of Anaesthesia* **108** i80-i87 at p. i80.



received.<sup>33</sup> We suggest that for consent to be valid, the disclosing and importantly, understanding of information, is required before a decision is made<sup>34</sup>.

In their discussion paper of 2016, the UK Donation Ethics Committee suggested that ‘authorisation’ brought with it an expectation that if an individual expressed wishes about what should happen to their bodies after death, there is ‘an expectation that these wishes would be respected.’<sup>35</sup> If this interpretation was accepted, such expectation would need to be balanced against any conflicting views of the family or if proceeding with donation would cause them distress. A full discussion on the concept of consent and autonomy within the context of organ and tissue procurement after death is outwith the scope of this submission but a valuable discussion can be found in a recent paper which considers, amongst other things, the notion of ‘relational’ autonomy.<sup>36</sup>

This leads us on to a final observation. Given what we have said already about the role of the family, we note that the consultation makes no reference to possible rights of individual family members under the European Convention on Human Rights. Two cases are highly relevant here - *Petrova v Latvia*<sup>37</sup> in 2014 and *Elberte v Latvia*<sup>38</sup> in 2015, and we suggest that any future proposals are considered in the light of the outcome of these cases. We refer to a comprehensive submission which was made in response to this consultation which considers these cases in detail and their impact on current legislative provision in Scotland and any possible future provisions.<sup>39</sup>

**Process:** Any database or process adopted should be effective, up to date and accessible. Issues pertaining to the status of the patient, including residence have already been considered above, but it would also be desirable, given that organs are to be made available throughout the United Kingdom and to accommodate any potential cross border networks.

<sup>33</sup> 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]

<sup>34</sup> 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.

<sup>35</sup> 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]

<sup>36</sup> Dove, E.S. (2015) *Elberte v. Latvia*:Whose tissue is it anyway-Relational autonomy or the autonomy of relations? *Medical Law International* **15** 2-3 77-96

<sup>37</sup> Application no.4605/05 [2014] ECHR 805

<sup>38</sup> Application no. 62143/08 [2015] ECHR 1

<sup>39</sup> 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](https://www.academia.edu/31856953/Scottish_Government_consultation_response_In_accordance_with_law_Is_Scottish_organ_donation_law_ECHR_compatible) [Accessed March 14 2017]

Any process should also provide an option should an individual choose to exercise a preference over which organs should or should not be removed.

***Advancement of medical science:*** We note that through the advancement of medical research and technology, the scope of transplantation of both organ and other body parts is rapidly evolving. We suggest that any proposed Bill has enabling provisions to take into account those advances.

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