

**British Transplantation Society (BTS)**

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Dear Ms McTaggart

**Consultation on the Proposed Organ and Tissue Donation (Scotland) Bill: written response from the British Transplantation Society Ethics Committee**

Thank you for inviting us to respond to your proposal. I am responding as Chairperson of, and on behalf of, the British Transplantation Society Ethics Committee. Our response focuses on ethical issues set out in the proposal, including in places reference to practical issues that we consider may have bearing on these. Where we consider relevant we have made reference to the Human Transplantation (Wales) Act 2013, which as you know is due to come in to force on 01 December 2015.

There are several questions that the BTS Ethics Committee has not discussed in detail, and which we therefore do not address in this written response.

**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.**

The BTS Ethics Committee considers that your proposal is well thought-out and provides a cogent argument for a soft ‘opt-out’ system of deceased organ donation for transplantation in Scotland. We see no fundamental ethical objection to such a soft ‘opt-out’ system. However, we would like to highlight several concerns related to the practicalities of the scheme over time. In our view such a system must (a) be able to ensure individual consent (or authorisation) is valid over time; (b) be responsive to professional concerns and the impact opting-out may have on the relationship between healthcare professionals and donor families. We are particularly concerned about this impact as new techniques aimed at optimising and increasing successful donations emerge and become an integral part of the organ donation (especially DCD) process. Many of these techniques (for example normothermic regional perfusion) are ethically challenging. We consider that it is important for healthcare professionals involved in organ donation to be able to continue to have the confidence to explore them with donor families within an appropriate framework; (c) have robust

provisions in place to safeguard the interests of adults lacking capacity. Your proposal rightly identifies the need to protect such individuals. However, in our view it is not straightforwardly the case that all those who lack mental capacity should automatically be excluded from the system upon the basis that they could not have capacity to opt-out as your proposal suggests. The Welsh Act for example stresses that 'every effort should be made to facilitate those lacking capacity to understand the new law and to make a decision in the light of it'.<sup>1</sup> More detail on how decisions related to donation in this context would in fact work in practice would be useful, in order that donor families and professionals feel supported.

**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?**

The opt-out laws are probably the best known of the various mechanisms which attempt to achieve increases in donation. They have been adopted in many countries, notably in Western Europe,<sup>2</sup> in contrast to the English-speaking countries,<sup>3</sup> which mostly require express consent. Under such laws, all mentally capable adults are presumed to consent to donation of their organs after death unless evidence of objection is produced. Opt-out laws, although differing as regards methods of recording dissent, the status of children, non-nationals, persons with mental incapacity etc. can be classified as either 'hard laws', which do not allow any influence to the deceased's relatives, or 'soft laws',<sup>4</sup> which do. However there is no overall uniformity, so that varying degrees of hardness and softness are usually present.

In our view assessments of the effects of opt-out laws on donation rates are hampered by differences in cultural attitudes, economic conditions, availability of intensive care units, numbers of transplant co-ordinators, degree of governmental support and other factors, whose influence may be important but uncharted. Therefore, whether it is essential to change the law (from an opt-in to a soft opt-out system) in order to achieve the intended benefits (increased transplant rates and reduced waiting lists) is open to question.

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<sup>1</sup> Human Transplantation (Wales) Bill Explanatory Memorandum 3 December 2012, 'Communicating with the Public' <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%20Transp>

<sup>2</sup> Including Austria, Belgium, Croatia, Cyprus, Finland, France, Greece, Luxembourg, Italy, Norway, Portugal, Slovenia, Spain and Sweden. Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Poland, Slovak Republic and Turkey also have opt-out laws. (2012) Council of Europe 'International [Figures on Donation and Transplantation – 2011](#)' *Newsletter Transplant Vol. 17 No. 1, September 2012*. Editor. Rafael Matesanz.

<sup>3</sup> Including Australia, Canada, Ireland (no actual statute but follows guidance), New Zealand, UK and USA. Other opt-in countries include Argentina, Denmark, Germany, Lithuania and Switzerland (some cantons have presumed consent).

<sup>4</sup> A. Rithalia, C., McDavid, S., Suekarran, L. Myers and A. Sowden A. 'Impact of Presumed Consent for Organ Donation on Donation Rates: a Systematic Review' (2009) Br Med J 338 3162. Austria's law is 'hard' in that donation proceeds unless it is known that the deceased objected before death, and the views of relatives are not actively sought. Spain's law is 'soft', since doctors take active measures to ascertain that the next of kin do not object to organ recovery.

Evidence collated by the Welsh Government Social Research unit showed that, in general, opt-out systems have higher donation, and lower refusal, rates than express consent (opt-in) systems.<sup>5</sup> In contrast the UK Organ Donation Taskforce report ‘The Potential Impact of an Opt Out System for Organ Donation in the UK.’ published in 2008 recommended that opting out should not be introduced in the UK ‘at the present time’, since it had the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the government, and to ‘impact negatively on organ donation numbers’.<sup>6</sup> This report recognised support, amounting to about 60 per cent of the public, for an opt-out law in the UK and considered that it might deliver real benefits, but considered that it would distract attention from essential improvements to the donation mechanisms and the need to increase public awareness and understanding. It would also be costly and difficult to put in place. According to the report, it was not clear that implementing an opt-out system would lead to sufficient increases in deceased organ donations to justify the significant investment needed to put a new system in place.<sup>7</sup> However, the Taskforce advised that, if implementation of its recommendations set out in its earlier report failed to produce a 50 per cent increase in donor numbers by 2013, the question of an opt-out law should be revisited.<sup>8</sup> In April 2013, NHS Blood and Transplant (NHSBT)<sup>9</sup> announced that the target of a 50 per cent increase in deceased donors had been met, with 1212 donors in 2012-13 as compared to 809 in 2007-08.<sup>10</sup> One way forward for Scotland therefore could be to assess the impact of the change in law to a soft opt-out system of deceased organ donation in Wales before implementing legal change.

**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.**

We consider that this view is similar to that set out in the new Welsh Act. Section 4(4) of that Act sets out the circumstances in which a relative of the deceased, or friend of long standing, may object to the deeming of consent on the grounds that they knew of the deceased’s objection to donation. An important restriction however is that they are not allowed to object for their own personal reasons, but only because of what they know of the deceased’s state of mind prior to death. This is made clear by the requirement that, to justify an objection, the information provided ‘should lead a reasonable person to conclude that the person objecting did indeed know the most recent views of

<sup>5</sup> [Welsh Government Social Research, ‘Opt-out Systems of Organ Donation: International Evidence Review’ figure 1 \(Number 44/2012 57 2012\) at http://www.cymru.gov.uk.](http://www.cymru.gov.uk)

<sup>6</sup> [Organ Donation Taskforce, ‘The Potential Impact of an Opt-out System for Organ Donation in the UK: A Report from the Organ Donation Taskforce’ \(2008\) at http://www.nhsbt.nhs.uk/to2020/resources/ThepotentialimpactofanoptoutsystemfororgandonationintheUK.pdf](http://www.nhsbt.nhs.uk/to2020/resources/ThepotentialimpactofanoptoutsystemfororgandonationintheUK.pdf) Organ Donation Taskforce. *The potential impact of an opt-out system for organ donation in the UK: A report from the Organ Donation Taskforce.* At: <http://www.nhsbt.nhs.uk/to2020/resources/ThepotentialimpactofanoptoutsystemfororgandonationintheUK.pdf>. Accessed 28 January 2014.

<sup>7</sup> *Supra*, note 31: Organ Donation Taskforce Report at 15.2.

<sup>8</sup> Organ Donation Taskforce, ‘Organs for Transplants: a Report from the Organ Donation Taskforce’ (London: Department of Health, 2008) at [http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_082](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_082)

<sup>9</sup> NHSBT is the Special Health Authority responsible (among other things) for optimising the supply of organs for transplantation and providing statistics on transplantation activity.

<sup>10</sup> NHSBT Organ Donation and Transplantation Activity Report 2012/13.

the deceased'.<sup>11</sup> This apparent legal curtailment of their influence is more marked than in the 'soft' opt-out law of Spain, which requires doctors to take active measures to ascertain that the next of kin do not object on their own account, though less than in the relatively 'hard' law of Austria; under which donation is allowed to proceed unless evidence of the deceased's prior objection is known to the doctors, who are not obliged to seek the views of the donor's relatives. These powers of objection also seem to be inferior to those allowed under the now repealed Human Tissue Act 1961, which, in spite of its different wording, had features strongly resembling those of an 'opt-out' law. However, we consider that the donor family's influence in practice is likely to be significantly greater than it appears to be in the Welsh statute and your proposal. Existing practice suggests that even if the law permits donation, family opposition will be able to prevent it. Under the Human Tissue Act 2004 and Human Tissue (Scotland) Act 2006 this often proves decisive, even where the donor has already given express consent or authorisation to donation. For example in 2012-2013 NHSBT reported that 105 families were recorded as having 'overruled' their relatives wish to be an organ donor. In these cases the donation teams most probably declined to exercise their right of retrieval to avoid confrontation and distress to donor families. They were able to do so because the 2004 and 2006 Acts do not impose a duty to comply with a donor's wish to donate. If express consent can often be overturned by family pressure, it seems likely that deemed consent, where the donor's wishes remain unknown, will also be overturned in the same way, and possibly more often, despite the donor family's apparent lack of legal authority. In order to maintain public trust and transparency in the system it may be helpful to undertake social scientific research to investigate this issue and provide an evidence base on it.

**4. Do you think an individual should be able to appoint a proxy to the make the final decision regarding transplantation on their behalf? Please indicate "yes/no/undecided" and explain the reasons for your response.**

Not discussed

**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.**

Not discussed

**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?**

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<sup>11</sup> Human Transplantation (Wales) Act 2013 s 4(4).

Not discussed

**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.**

Members of the Committee were concerned about the way in which this time frame (which seems arbitrary) was set out in the proposal. In particular the document is not explicit about the way in which decisions related to residency will be reached. This may create additional burdens for healthcare staff and donor families at a time of stress and bereavement.

**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?**

Rather than setting out a specific time limit it may be helpful for the Scottish Parliament to adopt the approach taken by the Welsh Act which states that the soft opt-out system ‘will only apply to those people who live and die in Wales, who have had enough time to understand the law and have had an opportunity to opt out, if that is their wish’. To simplify the determination of residence, the Welsh Government has outlined a three-stage test which must be satisfied in practice in order for the provisions of section 4 to apply to a potential donor. The criteria are:

- (a) whether the person’s current address is in Wales
- (b) whether the person normally lives at that address for the majority of the time; and
- (c) whether the person has lived at that address (or another address in Wales) for at least six months before they died.

It is expected that use of postcodes and other rapid identifiers will be used to provide rapid verification, which will also be checked with the next of kin. If the criteria cannot be safely satisfied, consent will not be deemed to be given, although express consent from the relatives may still be sought.<sup>12</sup>

**9. Do you think 6 months is a long enough period to run a campaign prior to change over?**

No. In our view public awareness and understanding of the opting-out (deeming) process is an important requirement of implementing the new law. A single 6-month campaign is unlikely to be adequate. A rolling programme of public education is far more likely to be needed to ensure long-term confidence in the general understanding about organ donation. This would apply probably most specifically as individuals reached the age where their consent/authorisation could be deemed

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<sup>12</sup> Human Transplantation (Wales) Bill Explanatory Memorandum 3 December 2012, ‘Residency’ para 24-27 at <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%20Transp>

but would also need to accommodate inevitable changes in the make-up of the adult population (e.g. higher education students, people moving to Scotland from other parts of the UK or elsewhere) as well as the general ongoing need to keep the population informed and educated. Training and support for professionals will also be an important element of this.

The Welsh Government's ongoing public awareness campaign, designed to maximise understanding of the deeming process, will peak at 6 months prior to the new Act's implementation date and continue indefinitely thereafter. This programme is fully set out in the Explanatory Memorandum and Notes which accompany the legislation. Further duties include: ensuring that Local Health Boards have adequate resources, promoting yearly campaigns to reinforce public understanding and reporting annually on progress to the Welsh Assembly.

**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?**

Not discussed

**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?**

One of the main barriers to donor family consent is faith and cultural concerns, specifically among the Black and minority ethnic groups (BME) community. The BTS Ethics Committee supports the view that ongoing structured and meaningful engagement with faith communities is necessary in order to ensure appropriate understanding of organ donation and transplantation and the proposed legal changes.

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

1. We would like to draw attention to the fact that from mid-2015 the NHS Organ Donor Register will be changed to allow 4 registration options:

- (a) Yes – all organs
- (b) Yes – specify organs
- (c) Nominate a representative
- (d) No

Introducing a further different system may cause unnecessary confusion.



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2. The proposal contains conflicting statements about the number of people waiting for a transplant. The number of people registered on the UK transplant waiting list has fallen each year for the last four financial years.

Yours sincerely

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