



Scottish Government
Health Protection Division
St. Andrew's House
Regent Road
Edinburgh EH1 3DG

14 March 2017

Dear Sir/Madam,

Organ and Tissue Donation and Transplantation - A consultation on increasing numbers of successful donations: written response from the British Transplantation Society Ethics Committee

Thank you for inviting us to respond to your consultation. I am responding as Chairperson of the British Transplantation Society Ethics Committee, and on behalf of the Society, with agreement from the Executive Committee.

The British Transplantation Society (BTS) represents all disciplines in transplantation including clinicians, nurses, pharmacists, scientists involved both in basic research and histocompatibility laboratories, ethicists and other professions allied to medicine. The overall vision of the BTS is to be the national professional voice of transplantation in the UK developing scientific, clinical and ethical practice for the benefit of patients. This vision is supported by four strategic objectives: (1) to influence personal and political opinion and operational strategy regarding transplantation issues; (2) to promote professional standards and ethics across the multi-disciplinary transplantation community; (3) to contribute to the development of transplantation and integral associated services; (4) to support scientific and clinical research relevant to the practice of transplantation.

The BTS recently surveyed its members on the principle of an opt out system. A total of 190 members responded to the survey. Of those 127 (2/3) voted in favour of considering an opt out system of organ donation and 63 (1/3) voted against considering an opt out system of organ donation.

Our response focuses on ethical issues set out in the consultation, including in places reference to practical issues that we consider may have bearing on these. Where we consider relevant we have referred to the Human Transplantation (Wales) Act 2013 (hereafter The Welsh Act), which came 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.

Yours sincerely

Dr Antonia J Cronin MA PhD MRCP
Chairperson, BTS Ethics Committee

Lorna Marson
President, BTS

Consultation Questions

Question 1 - What do you think of the principle of a soft opt out system for Scotland?

The BTS can see no fundamental ethical objection to the principle of a soft 'opt-out' system of deceased organ donation for transplantation in Scotland. 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) or refusal/objection 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. The consultation rightly identifies the need to protect such individuals. In our view it is not 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. 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'.¹ 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.

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

The opt-out laws are probably the best known of the various mechanisms which attempt to achieve increases in donation. As the consultation sets out they have been adopted in many countries, notably in Western Europe,² in contrast to the English-speaking countries,³ 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',⁴ which do. However

¹ 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>

² 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.

³ 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).

⁴ A. Rithalia, C., McDaid, 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

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.

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.⁵ 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'.⁶ 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.⁷ 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.⁸ In April 2013, NHS Blood and Transplant (NHSBT)⁹ 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 2007-08.¹⁰ One way forward for Scotland therefore could be to assess more fully the impact of the change in law to a soft opt-out system of deceased organ donation in Wales before implementing legal change.

The key changes we would make to the current authorisation system are:

- (a) Incorporate education about organ donation and transplantation into the National Curriculum (Curriculum for excellence), as has already been developed through Scottish government.**
- (b) Increase resources available in hospitals to help facilitate the donation process;**
- (c) Strengthen the Specialist Nurse in Organ Donation (SNOD) network;**
- (d) Give more information about donation to potential donors;**

sought. Spain's law is 'soft', since doctors take active measures to ascertain that the next of kin do not object to organ recovery.

⁵ 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>.

⁶ 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>

⁷ Organ Donation Taskforce Report at 15.2.

⁸ 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

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

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

- (e) Continue to record and catalogue the reasons why potential donor families refuse to donate, and use the information gathered to devise strategies to help reduce refusal and overrule rates;
- (f) Undertake a consultation on reciprocity.

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?

In our view this question is not immediately relevant for an opt out system. What should happen in these circumstances will depend on why the family opposes the donation. If for example, the family opposes donation because the patient has expressed refusal to donate since the ODR entry was made, donation should not proceed (see below). If they oppose it because they are not sure whether the person would have wanted donation to go ahead in the circumstances, then the overall benefit test should be applied to assess whether donation should go ahead. If they oppose donation for their own reasons, such as religious ones, donation should proceed. A recent paper on the role of the family in donation published by the (now disbanded) UK Donation Ethics Committee explores these distinctions more fully.

In the context of an opt out system some have suggested that 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 or authorisation. We consider that this view is similar to that set out in The 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 the deceased'.¹¹ 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. 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. NHSBT has reported that since 2010 over 500 families in the UK 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

¹¹ Human Transplantation (Wales) Act 2013 s 4(4).

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.

Question 4 – if there was a soft opt out system, what do you think of the proposed checks?

Question 4(a) – If you think these are not sufficient, what other checks would be needed (apart from those set out under step 3 below)?

We fully support high profile awareness-raising campaigns in particular those that will continue on a regular basis after implementation. Attention should be given to assessment of the effectiveness and penetration of the campaign. This is particularly important to ensure that a change in legislation does not disadvantage the BAME community. Education campaigns should be based on an analysis of the main reasons for refusals for consent and ODR overrides. 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 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.

In our view the proposed checks in step two are problematic for the following reasons.

1. Requiring written evidence that the (deceased) person had more recently opted in is too onerous. It is also contrary to the Human Tissue Authority (HTA) guidelines developed for the Welsh context, which do not stipulate that such evidence must be written.
2. There is an asymmetry between this first check and the suggestion in step two that verbal evidence is sufficient to overrule recorded consent/authorisation. This asymmetry is particularly problematic given that someone who has opted in in a deemed consent/authorisation jurisdiction has in effect gone further than necessary. If anything, verbal evidence should be sufficient for overruling refusal, but written evidence should perhaps be required for overruling recorded consent/authorisation given that recording it was not necessary.
3. if there is no evidence either way it may be more important to let families overrule than in a non-deemed consent/authorisation jurisdiction for at least two reasons. First, the fact that there is no evidence calls into question whether the person wanted to donate, so that grounds for overrule are stronger than where an ODR consent/authorisation exists. Second, surveys have shown that over one third of people in Wales are still unaware that they need to opt out of donation if they don't want their organs to be taken. Ultimately this may undermine the rationale of for deemed consent/authorisation.

Question 5 - In any opt out system, what do you think should happen if a deemed authorisation donation was likely to distress the potential donor's family?

Our response to this question should be considered together with our response to question 3. In our view the important factor here is not distress per se, but rather the cause of the distress. If the family is distressed because they have given evidence

that the person did not want to donate, donation should not proceed. If the family is distressed because they are not sure that the patient would have wanted to donate in these circumstances, whether donation is still of overall benefit to the patient should be reconsidered. But if the family is distressed because they disapprove of donation for religious reasons etc., donation should proceed.

Questions 6 - If there was a soft opt out system, what do you think about the categories of people set out under step 3 for whom explicit authorisation would still be needed from the person themselves or family member?

The categories set out seem appropriate.

Question 7 - In what circumstances do you think an adult should be viewed as not having the capacity to make their own decisions about donation and therefore should not be subject to any deemed authorisation provisions?

An adult should be viewed as not having the capacity to make their own decision about donation and therefore should not be subject to any deemed authorisation provision only where s/he lost capacity before the deemed consent/authorisation legislation was introduced. If capacity was lost after implementation of the legislation consent/authorisation could be deemed provided there was sufficient chance to opt out.

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

In our view children under the age of 16 years should only be donors with explicit authorisation. At the age of 12 years children can consent to treatment and organ donation, but they may not be aware of the deemed consent/authorisation requirements at that age.

Question 9 - For children who are in care, what are your views on allowing a local authority which has parental responsibilities and rights for a child to authorise donation for the child if no parent is available?

In our view a local authority which has parental responsibilities and rights for a child should be allowed to authorise donation for the child in those circumstances.

Question 10 - In any opt out system, what provisions do you think should apply to the less common types of organs and tissue?

The BTS supports the development of novel organ and tissue donation and endorses the robust process that has evolved to facilitate this. In our view deemed authorisation provisions should apply to all organs and tissues donated for the purpose of transplantation.

Question 11 - Which tests do you think medical staff should be able to carry out on a donor before they withdraw life-sustaining treatment to check if their organs or tissue are safe to transplant, both where a patient's authorisation for donation is 'deemed', as well as where the donation is explicitly authorised:

The tests listed constitute current standard clinical practice. We consider that medical staff should be able to carry out all the tests listed.

Question 13 - Where it is agreed a patient's condition is unsurvivable and it will not cause any discomfort to them, what do you think about medical staff being allowed to provide any forms of medication to a donor before their death in

order to improve the chances of their organs being successfully transplanted, such as providing antibiotics to treat an infection or increasing the dose of a drug the patient has already been given?

In our view appropriately qualified medical staff should be able to provide such forms of medication.

Question 14 - What do you think about allowing people to appoint one or more authorised representatives to make decisions for them?

We have no objection to allowing people to appoint one or more authorised representatives to make decisions for them.

Question 14 (a) – If you think this should be allowed, in what circumstances to you think an authorised representative would be useful?

An appointed authorised representative may be helpful for example where there is disagreement among family members.

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

No

16. What do you think about providing Chief Medical Officer (CMO) guidance to encourage clinicians to refer almost all dying or recently deceased patients for consideration as a potential organ or tissue donor?

We fully support this proposal. We consider CMO guidance should be provided to encourage more referrals.

17. What do you think about making it a procedural requirement for clinicians to involve a specialist nurse for organ donation, tissue donor coordinator or another individual with appropriate training in approaches to families about donation, wherever that is feasible?

We fully support this proposal. We consider that it should be a procedural requirement for clinicians to involve a SNOD/TDC or another individual with appropriate training in approaches to families about donation.

18. Do you think there are particular impacts or implications for any equalities groups from any of the proposals in this consultation, either positive or negative?

Yes. We consider that it is essential to ensure any documentation, education material and media campaigns related to the proposed change in legislation are appropriate, available and accessible to all groups.

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.