

HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM - Dr Rick Thomas on behalf of the Christian Medical Fellowship

Introduction

Our main concern is that the altruistic ethos of 'donation as a free gift' would be endangered by an ill-judged if well-intentioned proposal to move from voluntary donation to deemed authorisation.

Nothing in this submission should be interpreted as a rejection of the practice of donation of organs after death where this is done with due sensitivity to medical, cultural and ethical considerations. As an organisation that represents Christian doctors and other healthcare professionals, we take our starting point from Christ who healed the sick and who gave himself for the good of others, and welcome the benefits that have come through organ transplantation.

1. Strengths and Weaknesses of 'Deemed Authorisation'

a) Opt-out schemes lack an evidence base of effectiveness

The assumption behind the Scottish government's proposal is that opt-out schemes increase the number of available organs for transplantation. If this assumption were supported by hard evidence then it could certainly be seen as a strength. However, in reality such evidence is lacking. Spain is often cited as an example of how successful an opt-out scheme can be, yet this does not bear closer examination. Spain changed to an opt-out scheme in 1979 and donation-rates did not increase. After a decade of disappointment, Spain invested in staff training, the appointment of transplant coordinators to talk with families at the crucial time, and supportive infrastructure changes. It was these changes that made the difference.¹

Wales introduced an opt-out scheme in 2015 and to-date there is no sign of increasing donation-rates.² Moreover, the same data reports a shrinking pool of potential donors in that six percent have already opted out.

A recent study³ found that ambiguous signals of underlying preference that are attached to default opt-out systems make it more likely that families will veto decisions to donate as

¹ Matesanz r et al. Spanish experience as a leading country: what kind of measures were taken? *Transplant Int*, 24, 2011. Pp 339-340.

² *Organ Donation and Transplantation Activity Data: WALES*, NHS Blood and Transplant, 2018, Summary figures, page 1.

³ Yiling Lin, Magda Osman et al. Underlying wishes and nudged choices. *Journal of Experimental Psychology: Applied*, Aug 2018.

compared with active choice systems (opt-in, mandated-choice) where the donor's preference is not open to doubt.

Other countries with opt-out systems include Sweden, Bulgaria and Luxembourg, all countries with lower donation-rates than the UK. Schemes with variations on deemed authorisation in France and Brazil actually led to falling numbers of organ 'donations'. Countries in which opt-out schemes appear to have led to increased donation-rates are those that have adopted so-called 'hard' schemes in which families of the deceased are given no say.⁴ In Scotland, a culturally-insensitive, hard opt-out scheme that ignores the needs and feelings of relatives at a distressing time would very likely be rejected by the public. It is therefore of great concern that the draft Bill appears to state that nearest relatives would *not* be legally entitled to have a final say as to the removal of commonly donated types of organ and tissue. It is disingenuous for the Scottish Government to characterise its proposed scheme as a 'soft' opt-out scheme if the intention is to so limit the say given to near relatives.

An interesting exception to the rule that opt-out schemes fail to significantly increase donation rates appears, at first sight, to be Belgium. Within five years of introducing an opt-out scheme in 1986, donation-rates rose by 55%. But even here, it seems that success is due to factors other than a simple change in the law. Doctors there are encouraged to approach relatives in all cases and do not proceed with organ retrieval if, in their opinion, it would cause distress to the family. In practice, less than 10% of families do object, compared with 20% - 30% elsewhere in Europe.⁵ The training and deployment of skilled medical staff is the key.

Boyarsky has shown that countries with the highest rates of deceased donation have 'national and local initiatives, independent of presumed consent, designed to attenuate the organ shortage'.⁶ **The single most influential factor so far identified is ensuring that clinicians specifically trained for the purpose routinely approach the families of potential donors.** Fabre believes that 'the highest levels of organ donation can be obtained while respecting the autonomy of the individual and [the] family and without presumed consent'.⁷

While there is no evidence that presumed consent/deemed authorisation *per se* works to increase donation rates, the Nuffield Council on Bioethics has shown that UK rates of family consent or authorisation were 69% when a Specialist Nurse in Organ Donation approached the family, but just 28% when the approach was made by other staff without the specialised training. Investing in the provision of more such nurses to talk to the families of potential

⁴ *BBC News Online*, 10.09.17, see <http://www.bbc.co.uk/news/health-41199918> (accessed 21/02/2018)

⁵ Michelsen P. 1996. Presumed consent to organ donation: ten years experience in Belgium. *J R Soc Med*, 89:663-66.

⁶ Boyarsky BJ et al. 2012. Potential limitations of presumed consent legislation. *Transplantation*, 93:139.

⁷ Fabre J et al. 2010. Presumed consent is unnecessary. *BMJ*, 341, 7779:923

donors makes the difference, not presumed consent laws. These nurses parallel the role of the transplant coordinators in Spain.⁸

b) Deemed authorisation is not the same as informed consent

Organs taken without consent are not donated but confiscated. ‘Deemed authorisation’ is not equivalent to consent. Presuming upon consent turns volunteer donors into conscripts. If organs are taken for transplantation without explicit consent there is no giving, there is only taking without asking. Obtaining explicit written consent is required by law for medical treatment because it ensures that consent is valid and that people have thought about the implications. For example, written consent is required for fertility treatment, storing sperm, eggs and embryos, donation, surrogacy, disclosure of information and, where applicable, parenthood and withdrawing consent.⁹ Since Montgomery,¹⁰ the duty of doctors to ensure understanding and fully-informed consent by their patients has been underlined. In our view, deemed authorisation fails to meet the required standard, leaving health trusts vulnerable to possible litigation.

c) Deemed authorisation is unsafe

Silence is not consent. It cannot be taken to imply ‘no objection’ to the ‘opt out’ message. It cannot guarantee that those who have not opted out are aware of the implications of their non-decision. Transplantation presupposes a prior, explicit, free and conscious decision on the part of the donor (or their legitimate representative). Under an opt-out scheme, many will be unaware that they are on a donor register because it is virtually impossible to cover everyone in a public information campaign, to be sure that everyone has access to the message, hears or sees the message, understands the message, has considered the message and made a positive choice to opt in. Relying on a lack of stated objection to imply agreement is therefore not safe.

Similarly, authorising the nearest relative of a person lacking mental capacity to understand deemed authorisation is unsafe.

‘Deemed authorisation’ will, on at least some occasions, amount to imposed consent. To remove organs under these conditions is immoral because it violates a person’s autonomous wishes about what should happen to their body after death.¹¹

d) Opt-out schemes capitalise on inertia

There is a significant need for organs for transplantation. Rather than follow the example of Spain by investing in training and infrastructure, the Scottish Government appears to be

⁸ <http://nuffieldbioethics.org/news/2017/ethics-tank-calls-discussion-wishes-organ-donation-death> (accessed 07.08.18).

⁹ <https://www.hfea.gov.uk/about-us/how-we-regulate/> (accessed 07.08.18).

¹⁰ *Montgomery (Appellant) v Lanarkshire Health Board (Respondent)* [2015] UKSC 11 On appeal from [2013] CSIH 3

¹¹ Veatch RM and Pitt JB. 1995. The myth of presumed consent: ethical problems in organ procurement strategies, *Transplantation Proceedings*, 27:1889-9.

setting its hope on the assumption that most people will not opt-out of the proposed scheme. Instead of investing in schemes to promote altruistic donation and providing more Specialist Nurses as Transplant Coordinators in every acute hospital across the country, it is **willing to gamble the lives of those on transplant waiting lists on the inertia of unintentional donors**. And this despite evidence from other jurisdictions that such a strategy will fail. The Scottish Government wants to follow an ideology that consistently has been shown to lack a credible evidence-base and, as the experiment in Wales illustrates, leads to an overall fall in the number of potential donors as people (whose organs might have become available) register their objection to presumed consent by deliberately opting out.

e) Opt-out schemes are not future-proof

In every area of life, the trend is towards greater protection of data and consent. The law around data sharing is being strengthened; permission to share personal information has to be explicit and affirmative. Consent cannot be assumed or presumed. It will not be possible in the future to allow pre-ticked boxes on forms. The whole emphasis of modern life is towards the rights of privacy and the need to have express and informed consent before sharing a person's details. **An opt-out scheme for organ donation takes the most personal of property – our organs – and makes them liable to a pre-ticked box, essentially.** There is a very real risk that, in today's UK culture, such a move will be met by a significant reaction, and some of those who would have been willing to become organ donors will instead be outraged by the presumption and deliberately opt-out. The losers will be those on waiting-lists.

f) Opt-out schemes undermine the care of the dying

Were an opt-out scheme to be adopted in Scotland, it is hard to see how it would not also undermine the care of dying patients or those with severe brain injury or abnormality. Such patients would inevitably be seen as 'organ resources' by professionals wanting to acquire scarce organs for transplantation.

This concern is heightened by the recent judgment of the Supreme Court¹² to permit the withdrawal of nutrition and hydration from those with prolonged disorders of consciousness (PDOC) without application to the Court of Protection. To withdraw or withhold food and fluids from a person who is not about to die, with the intention of bringing about their death, is a form of euthanasia. Draft BMA guidance, issued in the light of this ruling, appears to recommend involuntary euthanasia by stealth, a means to end the lives of those who lack capacity and whose quality of life is deemed by others not to be worth living. The quest for organs for transplantation can only reinforce this trajectory. If euthanasia of those with PDOC is introduced via this 'back door', it will become impossible to resist the claims of those seeking voluntary euthanasia, certainly as long as patient, family and clinicians

¹² An NHS Trust and others (Respondents) v Y (by his litigation friend, the Official Solicitor) and another (Appellant) [2018] UKSC 46.

agree. Euthanasia as a source of organs for transplantation is already a reality in Belgium and the Netherlands.

One of the reasons given by people for not carrying a donor card is the fear that organs might be removed before their death. Another stated concern is that staff may 'over-readily apply a DNAR (do not attempt resuscitation) order in such circumstances, to provide organs for donation. Such fears need not be well-founded to have an effect.'¹³

g) Opt-out schemes undermine the grieving of the living

The thought of a brain-dead body being kept artificially ventilated and perfused, warm and pink and apparently 'alive' whilst their family is asked urgently for permission to whisk the body away to theatre for organ retrieval hovers in the public consciousness. Even worse, the fear that organs might be removed from a person before they were clinically truly dead was cited among reasons given for the abolition of the presumed consent law in Brazil.¹⁴

The body of the deceased tangibly connects him to his family. To mourn together in the presence of that body, unites family members in a common farewell and 'marks simultaneously the connection to, and final separation from, family flesh'.¹⁵ At the very moment of loss, to have to put on hold their natural instincts to gather around a peaceful corpse to say their unhurried goodbyes, all the time knowing that the still-warm body of their loved one is undergoing eviscerating surgery, will be too much for some to face. At best, a 'high-tech' death followed by the delay for retrieval, will disallow a period of quiet reflection and a family farewell in the minutes immediately following the death.

h) The introduction of opt-out schemes can trigger a negative effect

When presumed consent is introduced, a proportion of the public will always withdraw from donation and sign the opt-out register because they do not like the idea of the state presuming upon their consent or their bodies effectively becoming the property of the state. In Wales, one in 20 adults (approximately 5% of the population) withdrew from donation in response to the introduction of the new system.¹⁶ Yet before the introduction of presumed consent those people were potential donors in the event that they died in an intensive care unit and their families agreed to donation. Opting out therefore led to a drop in potential donor numbers. Under presumed consent their families cannot be asked about donation because the person concerned has specifically opted out. All their organs are lost.

2. Strengths and weaknesses of the plans for authorisation of pre-death procedures?

In the case of someone dying imminently from cardiovascular failure, and who has previously given informed consent that their organs can be made available for

¹³ BMA. *Organ donation in the 21st century: Time for a consolidated approach*. London. BMA. 2000:9

¹⁴ Csillag C. 1998. Brazil abolishes presumed consent in organ donation. *Lancet* 352:1367

¹⁵ Kass L. *Life, Liberty and the Defence of Dignity*. San Francisco, CA: Encounter Books. 2002:136.

¹⁶ McCartney M. When organ donation isn't a donation. *BMJ* 2017;356:j1028.

transplantation, authorisation to undertake pre-death procedures such as blood tests and tissue typing is clearly an advantage. Not only will precious minutes be saved and the chances of a successful outcome to transplantation thereby improved, but it might also be possible briefly to reduce the level of intrusion into the grief of bedside relatives.

Given the collaboration of relatives, then informed consent for pre-death procedures that cause no more than minimal distress should in future be understood as included in the consent to donate by those joining the register. Those already on the register should be informed of possible pre-death testing procedures and be invited to provide explicit authorisation for these procedures alongside their (already given) consent to donate after death.

Where no informed consent has been given, we believe it to be ethically unacceptable to presume consent, for the reasons given above. Pre-death tests and procedures therefore should not be performed in the absence of informed consent.

3. Do you have any other comments to make on the Bill?

When someone dies and they have not specifically opted in or out of organ donation, their family should be able to make the final decision.

The state should not take ownership of a deceased person's body. Under the law as it stands, it is the family who takes custody of the body and this should not change. They are the ones best placed to know how the deceased would most likely have felt about donation and this fact should weight the responsibility for decision-making towards them. This principle is already recognised in the Mental Capacity Act 2005 and the Adults with Incapacity (Scotland) Act 2000, in the role given to relatives in the framework for determining what is in the 'best interests' of those lacking capacity. Medical staff and/or transplant coordinators should have the opportunity to broker an agreement with them but the final decision should be the family's to take. To require clinicians to retrieve organs against the stated wishes of the family would put them in an invidious position. The care of the family will be their concern, as much as the care of those needing a transplant.

Under normal circumstances, the decision reached and properly recorded in life by a person should be respected after their death. If unforeseen circumstances arise, or if the family have reason to believe that the deceased was not in their right mind, or was not fully informed or aware of the need to opt-out, or was in some way under duress when making their decision, then the family should be able to revisit the decision.

It is likely that, at the time of agreeing to donate organs after death, many donors do not fully understand the practical consequences for family members. In their grief, relatives may not be able to come to terms with them and wise clinicians will not press ahead with retrieval where in their judgment it would cause overwhelming distress to the family.