

HEALTH AND SPORT COMMITTEE

HUMAN TISSUE (AUTHORISATION) (SCOTLAND) BILL

SUBMISSION FROM NUFFIELD COUNCIL ON BIOETHICS

What do you think are the key strengths and weaknesses of the proposals to introduce ‘deemed authorisation’ for those who have not made their wishes on organ donation known?

Decisions about deceased donation should be based on the known wishes of the donor, as far as these can be discovered. We therefore strongly endorse Organ Donation Scotland’s emphasis on the importance of talking to family members about wishes to become, or not become, an organ donor.

However, where the wishes of individuals are not known, we would like to highlight three key concerns in relation to the introduction of a deemed authorisation model.

A lack of evidence for the introduction of deemed authorisation

There is no clear evidence that changing the system of authorisation for organ donation from ‘opt-in’ to ‘opt-out’, in itself, achieves higher rates of donation. This point has been made in a number of recent publications, for example:

- Recent statistics published by [NHSBT](#) show that the introduction of an opt-out system in Wales in 2015 has had no significant positive impact, yet, on the number of organ donors.
- The English Department of Health’s own [impact assessment](#) of the introduction of an opt-out system, published in November 2017, addresses the question “*would opt-out change the OD consent rate?*” The response is as follows:
“The evidence is inconclusive. While it seems that moving to an opt-out system is unlikely to decrease the consent rate, there is no unambiguous evidence that opt-out by itself increases consent rates. There is evidence that in some cases, when opt-out is implemented alongside other pro-organ donation policies, consent rates increase. However, the available evidence does not allow the individual contribution of changing the system of organ and tissue donation to opt-out to be identified. There is currently insufficient evidence from the experience of opt-out in Wales to conclude whether it has had a positive impact on consent rates.”
- A 2009 [systematic review](#) of opt-out studies, which looked at five ‘before and after’ studies in countries that had reported an increase in

donation rates after the introduction of 'presumed consent', concluded that:

"...presumed consent alone is unlikely to explain the variation in organ donation rates between countries. Legislation, availability of donors, organisation and infrastructure of the transplantation service, wealth and investment in health care, and public attitudes to and awareness of organ donation may all play a part, but their relative importance is unclear".

The Scottish Government's own [assessment](#) also exercises similar caution on the evidence to support opt-out organ donation, stating: *"Although there is little firm evidence that opt out legislation in isolation causes increases in organ donation and transplantation, there is encouraging evidence that, as part of a package of measures, opt out legislation can lead to increases in organ donation and transplantation."*

"There is a strong body of evidence that highlights the importance of non legislative measures, such as improving infrastructure."

We would like to suggest that, in the context of organ donation, policy-makers should focus on what a "strong body of evidence" indicates, rather than what "little firm evidence" suggests. An evidence-based approach to policy-making would therefore support focusing on improvements to infrastructure, support for families, and levels of public awareness, rather than immediate legislative change.

The Nuffield Council is strongly in favour of increasing the number of organs available for transplant across the four nations of the UK. However, we are concerned that introducing an opt-out system via this Bill without solid evidence that such a system will increase, rather than decrease, the number of organs available for transplant, may do more harm than good to Scotland's organ donation endeavours.

Trust in the system: evidence

Linked to our point above on a lack of evidence to support the assertion that the introduction of an opt-out system will increase the number of organs available for transplant, we suggest that the Scottish Government has an obligation to communicate this openly. At present, the assertion that "there is insufficient robust evidence to conclude that opt-out legislation alone will increase deceased donation" is part of a 40-page [policy memorandum](#) that accompanies the Bill, but which is unlikely to be read by members of the public. The limits to evidence should be communicated in a more open way: the Scottish Government may risk future criticism if the introduction of an opt-out system does not live up to public expectation.

Role of the family

In the absence of a record of the deceased's wishes (including any evidence of objection), information as to their likely wishes should be sought from those close to the deceased person, who are usually best placed to know their wishes, and who themselves, in their bereavement, have a stake in how their relative's body is treated. Should the Bill be passed, the emotions and trauma which relatives experience at the point when organ donation questions are raised must be taken into account, proper support from skilled professionals should be available (see below), and clear objections by families should be respected.

The important role of specialist organ donation nurses

In addition to the concerns set out above, we would also like to emphasise the positive impact that specialist nurses for organ donation (SNODs) have in supporting organ donation decisions.

We welcome the fact that the [policy memorandum](#) that accompanies the Bill recognises the crucial role that SNODs play in supporting bereaved families when faced with the prospect of donation. We would like to emphasise that the involvement of SNODs in discussions with relatives at the appropriate time has had one of the greatest impacts on consent /authorisation rates for organ donation. According to NHSBT's most recent [activity report](#), SNODs were involved in **85.6%** of all organ donation approaches for potential donations. The consent / authorisation rate when nurses were *not* involved in an approach was **22.1%**; where they were involved, the rate was **70.5%**. Where nurses were involved and the patient was known to be on the Organ Donation Register at the time of potential donation, the consent rate was **95.8%**.

We welcome the Bill's provision for the role of SNODs to continue, and emphasise the importance of enabling that their contribution to organ donation remains supported through funding, including so that future SNODs can be trained. For example, the Bill proposes to change the time of authorisation so that it may be given shortly before the potential donor's death (section 1(4)), a shift from the current situation where authorisation can only be given after a potential donor's death. It is important that SNODs receive adequate training to deal with this change in timing of authorisation.

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

We welcome the fact that the Bill includes an option for people to opt-in to organ donation via express authorisation. Individuals' opportunity to be altruistic and to make active decisions on their own behalf must remain integral parts of the organ donation system.