

HTA's Response to the Scottish Consultation on increasing numbers of successful donations

Introduction

- 1.** The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Scottish Government's consultation on increasing the numbers of successful organ and tissue donations.
- 2.** As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), the HTA is charged with ensuring that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.
- 3.** The HT Act, in terms of consent for deceased organ and tissue donation, covers England and Northern Ireland and requires consent for a number of activities - including organ donation - to be an active and positive act. In Wales, a deemed consent system for organ and tissue donation after death is operational as a result of the implementation of the Human Transplantation (Wales) Act 2013.
- 4.** There are similar provisions in Scotland to that of England and Northern Ireland under the Human Tissue (Scotland) Act 2006, and whilst the word "authorisation" is used in place of "consent", there is a requirement that this is a positive act.
- 5.** When the word "organ" is used in this document, it should be read to include whole organs, part organs, and tissue.

The role of the HTA

6. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Scottish Government.
7. In addition, the HTA does not have responsibility for regulating deceased donation in Scotland, however, we do licence establishments who undertake organ donation and transplantation. As such, this consultation response is with a view to sharing our experience of organ donation and transplantation regulation in the rest of the UK.
8. This consultation response document seeks to highlight the parts of the proposal which may require further consideration and development.
9. The HTA notes the broader ethical dimension of the Scottish Government's proposals - however, it is outside the remit of the HTA itself to participate in such discussions.

The consultation

10. We understand that the main features of the Scottish Government's proposals are split into two sections:
 - i. The first chapter seeks views on alternative ways of potentially **increasing the proportion of cases** where organ and/or tissue donation is authorised; and
 - ii. the second chapter looks at **whether hospital clinicians should be encouraged to refer to a specialist nurse-organ donation (SNOD)** those patients who are expected to die in an intensive care unit or

emergency department in circumstances which would potentially enable them to be an organ donor.

As stated in the introduction above (paragraph 6) – the HTA does not support or object to the proposals of the Scottish Government, nor, as a statutory regulator, can it hold a position on the promotion of organ donation.

- 11.** The focus of this consultation response will be on the first part of this consultation, specifically on the subjects of authorisation (or consent), public awareness, and public perception and assurance.

Authorisation/Consent

- 12.** The consultation document notes that authorisation for donation is just one of many factors that affect the donation rate. The HTA notes that the opt-out system recently adopted in Wales requires more time and monitoring before any significant impact can be reliably tracked (as referenced in the consultation document).
- 13.** The current opt-in system in Scotland allows anyone to register their wish to donate, or not to donate, via the Organ Donor Register (ODR). A change to this system could allow donation where authorisation is “deemed” on the basis that an individual hasn’t opted in or opted out. This would be a “soft” form of opt out system similar to that introduced in Wales.
- 14.** We note that under deemed authorisation there are ‘excepted’ categories proposed – such as people lacking capacity to take a decision on organ donation, - with checks undertaken by a SNOD or Tissue Donor Co-ordinator (TDC). These categories and checks provide further safeguards to protect individual’s wishes.

15. Express authorisation would still be required for less common or novel types of organ or tissue donation, e.g. limbs, facial tissue transplants, which is consistent with the Welsh opt out legislation.
16. We note that that the family will still be involved in the donation process under the Scottish Government's proposals - this means that a key safeguard remains in place and they can still be asked to provide the medical and social information normally necessary for the donation to proceed safely.

Public Awareness

17. The consultation document notes that people in Scotland can currently choose to opt out actively via the Organ Donation Scotland website – the HTA would add that an important distinction to keep in mind is that on the introduction of a wholly opt out system, there is a critical requirement for a comprehensive public awareness campaign to ensure people are suitably informed on the new requirements.
18. The HTA would consider that an awareness raising element would be fundamental to ensuring the success of any system of deemed authorisation, so that the public can be confident that wishes are being followed. We note that there are three steps detailed in the proposed soft opt out system with the first being “high-profile awareness raising campaigns”.
19. It is reassuring that detail around these awareness-raising campaigns reference the needs of people who speak little or no English, and those with disabilities or learning difficulties who may need extra support to understand the new system. We note that when someone who did not have the capacity to take a decision on donation dies, this would only be authorised with “explicit authorisation”.

20. We also encourage the commitment to support the wishes of groups who may be deemed “harder to reach”, should they want to opt out, such as prisoners and others who may not have internet access.

21. We note this phrase in the “**Benefits of and disadvantages**” section of the consultation document [emphasis ours]:

If there is **sufficient ongoing awareness-raising** through a range of media to ensure that people who do not want to donate have sufficient opportunity to easily opt out, then it may be acceptable to authorise donation on the basis that the person has chosen not to opt out.

This awareness raising – and as mentioned above – is crucial to ensure the system works, and the evaluation of how effective the awareness-raising has been, is fundamental to public and professional confidence in the introduction of the opt out system.

Public Perception and Assurance

22. The consultation document states:

the Scottish Government would consider the introduction of an opt out model if such a step would be supported by the general public and by stakeholders, and if it can be introduced in a way that will do no harm – either to the public perception of organ donation and trust in the NHS, or to the operation of processes required to take donation forward.

The HTA would recommend this approach that prioritises “no harm” to public perception of organ donation. As a regulator that puts the interests of the public

and public confidence at the centre of its work, this is an important principle where any large-scale change is proposed.

- 23.** We recognise the approach that if a person has recorded a “no” on the ODR, their family will not be approached and donation will not be considered.
- 24.** We are pleased to see the assurance that sufficient safeguards for groups of people who are less likely either to be able to sufficiently understand the meaning or implications of opting in or out, or may be unaware of the legislation due to not having lived in Scotland for very long, are in place. This includes those who have not been resident for at least 12 months before their death, and children under 12 years old.
- 25.** We note that the consultation document does reference the likelihood that regardless of how successful an awareness-raising campaign is, a number of people won’t opt in or out, possibly because they don’t want to think about death, or they just don’t get round to it. In Wales, it has been made clear to people that anyone neither opting out or in has been made aware that their consent will be deemed. We are aware that the great majority of people who have been surveyed do support donation, and agree that should people be given sufficient information to make their own decisions, and they are competent to do so, that it is their responsibility to explicitly opt out if they don’t want to be a donor.
- 26.** As noted in the consultation document, there is a great risk to the NHS as a whole, and to organ donation as a principle, and this will need to be very carefully considered to avoid the perception that organs are being removed without appropriate consent.

27. We recognise the position where donation may not proceed even if someone has not opted out, should it be likely to cause severe distress or conflict with the family – this avoids the system becoming too rigid.

Areas for further consideration

28. The HTA would highlight the following areas as those which require further consideration and development, and which will be key to the effective implementation and operation of the proposed system.

29. It is not for the HTA itself to comment on the principles of the proposal, but rather to offer advice and guidance to ensure the Scottish Government has the information it needs.

30. The key message the HTA wishes the Scottish Government to take from this response is that communication and collaboration are vital.

31. During the development phase this primarily means communication with stakeholders on the proposals and a continued dialogue with all interested parties, most notably those who oppose the proposal.

Communications

32. To reiterate a theme above - the commitment made in the consultation document to an effective and sustained communications campaign is noted by the HTA, but more detail about the “high-profile awareness raising campaigns” would be useful.

33. Communication will be vital in ensuring that every person living in Scotland and the bordering counties is aware of the proposed system and how it will affect

them. In order for the individual's decision to remain paramount they must be aware of the action they are required to take, if any, to make their wishes known.

- 34.** Communication with all Scottish residents and those living in the border counties will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English and those living in deprived areas, amongst others.
- 35.** It will be important to develop a communications plan which ensures people who move to Scotland are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, record their wishes.
- 36.** Young people are widely considered to be challenging to engage with on such matters, and the HTA would encourage the Scottish Government to explore a wide range of channels in order for there to be confidence in the proposed system. For example, the Welsh Government communicates with all students taking up a place at Welsh Universities prior to their course starting, to ensure they are aware of the options.
- 37.** Any risk of a particular group or groups of Scottish residents being left behind on this matter due to poor communication must be actively addressed by the Scottish Government. Without an effective, comprehensive, targeted and continued communications campaign – and subsequent evaluation of its effectiveness - the proposed system cannot be said to hold the decision of the individual in life as a core principle. Indeed, without proper communication an individual may not be in receipt of the information they require to know what their

silence on the matter of organ donation after their death will be considered to mean.

- 38.** During the implementation phase, communication with Scottish residents will need to be effective, targeted and consistent, and collaboration with key stakeholders will be necessary to make sure all risks are managed and addressed.
- 39.** Finally, post implementation the importance of continued communication with Scottish residents cannot be overstated, as it will be the efficacy of this which will allow the Scottish Government to state that the wishes of the individual in life remain paramount, and that no erosion of this principle has occurred.