POLICY NOTE

THE HUMAN TISSUE (EXCEPTED BODY PARTS) (SCOTLAND) REGULATIONS 2020

SSI 2020/388

The above instrument was made in exercise of the powers conferred by sections 6D(5) and 59(1)(b) of the Human Tissue (Scotland) Act 2006, as amended by the Human Tissue (Authorisation) (Scotland) Act 2019 ("the 2019 Act"). The instrument is subject to affirmative procedure.

Purpose of the instrument:
The purpose of this instrument is to specify parts of the body that deemed authorisation will not apply to, once the 2019 Act is brought into force.

The instrument lists parts of the body that would be considered novel or rare transplants, and will not be able to be removed for transplant purposes with deemed authorisation. Their removal for transplant is instead subject to nearest relative authorisation, where authorisation for donation is established and in place.

Background

1. The 2019 Act amends the Human Tissue (Scotland) Act 2006 to provide for a deemed authorisation system of deceased organ and tissue donation for adults[1] in Scotland. This is commonly referred to as an 'opt out' system of donation.

2. The overall aim of the 2019 Act is to seek to facilitate, as part of a wider package of measures, an increase in the number of successful organ and tissue donations available for transplant in Scotland.

3. As part of the ongoing implementation of the 2019 Act, there is a requirement to implement secondary legislation which will specify the parts of the body that deemed authorisation will not apply to.

Policy Objectives

Extent

4. This statutory instrument only applies to deceased adult donors who may become potential donors via deemed authorisation. It does not extend to potential donors who have recorded an express authorisation ('opted in') e.g. they have recorded a donation decision on the NHS Organ Donor Register in life.

5. Provisions in the 2019 Act set out that deemed authorisation may only proceed subject to a number of conditions. One of these conditions is that the part of the body being removed for transplant is not an excepted body part. Section 6D(5) of the 2006 Act states

[1] Section 60(1) of the 2006 Act sets out that an 'adult' is a person who is aged 16 years and older.

that an 'excepted body part' is part of the body specified in regulations made by Scottish Ministers.

6. This instrument is therefore to provide clarity for both the public and the clinical community as to the scope of the 2019 Act, with regards to which parts of the body will not be deemed to be authorised for donation and transplantation.

Effect

7. Throughout the parliamentary passage of the 2019 Act, it was made clear that deemed authorisation would only extend to what is considered the more common and routine transplants e.g. the heart, lungs, liver, kidneys.

8. As the primary intention of introducing deemed authorisation is to increase the number of routine transplant opportunities, the regulations ensure that rare or novel transplants will not be permitted for donors progressing via deemed authorisation, without further authorisation. This instrument lists a number of body parts which the transplant of is currently novel or rare e.g. a limb transplant. Removing these types of body parts for the purpose of transplantation will instead require nearest relative authorisation.

9. As well as nearest relative authorisation, retrieval remains subject to wider authorisation conditions set out by the 2019 Act being met before donation can proceed. This includes establishing that there is no knowledge that the potential donor would have been unwilling for the excepted part to be removed for transplantation purposes.[2]

10. The instrument takes into account the requirements of tissue donation, to ensure this is able to proceed in line with current clinical practice under deemed authorisation. It does so by making provision for tissue to be removed from certain parts of the body e.g. tendons from the foot or skin from the thigh, with deemed authorisation.

11. The instrument also makes provision for the removal of the trachea (windpipe) as part of a routine dual-lung or heart-lung transplant. The removal and transplantation of the trachea itself would be considered a novel transplant, and this part is therefore specified. However provision has been made to permit the trachea to continue to be removed, insofar as it is attached to a lung, with deemed authorisation.

12. Furthermore, the inclusion of body parts in this statutory instrument which cannot be removed for transplantation with deemed authorisation also acts a method of future-proofing the 2019 Act in respect of transplants that are currently carried out elsewhere in the world and may be likely to be carried out in the UK in future e.g. face transplantation.

Consultation

13. The Scottish Government has consulted clinical stakeholders, including the NHS organisations directly involved in delivering donation and transplantation services, NHS Blood and Transplant (NHSBT) and the Scottish National Blood Transfusion Service (SNBTS), to inform the drafting of this instrument.

[2] Section 10 (6G) of the 2019 Act https://www.legislation.gov.uk/asp/2019/11/pdfs/asp_20190011_en.pdf

14. A public consultation was undertaken on a draft list of excepted body parts from 14 February to 27 March 2020. The consultation was shared directly with all NHS Boards, NHS Organ Donation Committees, NHSBT, SNBTS and a number of clinical representative organisations, such as the Faculty of Intensive Care Medicine.

15. 13 responses were received. The majority of respondents were from individuals and organisations with experience of the deceased organ and tissue donation and transplantation pathway.

16. As a result of this consultation a small number of changes were made to the statutory instrument in order to more appropriately reflect current practice and terminology.

17. A list of those consulted and who agreed to the release of their responses has been published on the Scottish Government consultation hub website, where an analysis of responses is also available: https://consult.gov.scot/population-health/draft-content-human-tissue-excepted-body-parts/.

Impact Assessments

18. Impact assessments have not been prepared for this instrument. The intention and identified effect is to maintain the status quo, with regards to current clinical practice and ensuring there are robust authorisation processes in place for what are considered novel or rare transplants. This will mean there is no change to current practice or impact by bringing this SSI into force.

19. There is no impact on business (the legislation does not apply to activities that are undertaken by businesses) charities or voluntary bodies.

Financial Effects

20. The Minister for Public Health, Sport and Wellbeing confirms that no BRIA is necessary as the instrument has no financial effects on the Scottish Government, local government or on business.

Scottish Government
Directorate for Population Health

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