POLICY NOTE

THE HUMAN TISSUE (AUTHORISATION) (SPECIFIED TYPE A PROCEDURES) (SCOTLAND) REGULATIONS 2020

SSI 2020/XXX

The above instrument was made in exercise of the powers conferred by sections 16B(1) and (2) of the Human Tissue (Scotland) Act 2006, as inserted 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 medical procedures that are Type A pre-death procedures.

Pre-death procedures are medical procedures carried out on a person for the purpose of increasing the likelihood of successful transplantation of a part of the person's body after the person's death, and which are not for the primary purpose of safeguarding or promoting the physical or mental health of the person. Type A procedures are those medical procedures which Ministers consider are appropriate to be carried out in accordance with the provisions of the 2019 Act and not requiring any further restrictions or requirements.

Policy Objectives

The overall aim of the 2019 Act seeks to facilitate, as part of a wider package of measures, an increase in the number of successful organ and tissue donations in Scotland. As part of this, it is important to ensure that the processes which support donation and transplantation work well and are underpinned by a clear legal framework.

Without pre-death procedures, donation will unlikely to be able to proceed in cases of donation following circulatory death. Currently, around 40% of deceased donation in Scotland happens after a person has died following circulatory death (DCD).[1] This is where the donor has been pronounced dead following cessation of the heart and respiratory activity. Donation after diagnosis of death by neurological criteria (also known as donation after brain death, or DBD), where the donor has been pronounced dead using neurological criteria, accounts for the rest of deceased donation.

The statutory framework

The 2019 Act sets out a dedicated statutory framework for the authorisation and carrying out of pre-death procedures and provides that Scottish Ministers may, by regulation, specify pre-death procedures as either Type A or Type B. Type B procedures are those procedures which Ministers consider appropriate to specify subject to further provision as to the circumstances of carrying out, authorisation or manner of carrying out.

[1] https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17138/nhsbt-scotland-summary-report-sep-19.pdf

Before any pre-death procedure can be completed the requirements of the statutory framework set out in the 2019 Act must be met. This includes that the procedures must be authorised, which for specified Type A procedures will include by virtue of a potential donor authorising donation, (either expressly or deemed). Additionally, the framework requires that a duty to inquire is carried out before the completion of pre-death procedures and there is no suggestion that the person would have objected to these being carried out. In practice the duty to inquire will mean that procedures will not be carried out without the consultation of a potential donor's family.

The framework also only permits a procedure to be carried out in certain circumstances and, particularly, not prematurely and not if it is likely to cause more than minimal discomfort or likely to harm the patient.

To ensure that the public is aware of these procedures and that they may be authorised via authorisation for donation, the 2019 Act includes a duty on Scottish Ministers to promote information and awareness about pre-death procedures.

Specified Type A procedures

The medical procedures set out in this instrument as Type A reflect the routine procedures which are currently frequently carried out to facilitate deceased donation and increase the likelihood of successful transplantation.

Consultation

The Scottish Government has consulted with intensive care consultants, transplant surgeons and 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.

A public consultation was undertaken on a draft list of Type A procedures from 30 October to 11 December 2019. The consultation was also shared directly with all NHS Boards, NHS Organ Donation Committees, NHSBT, SNBTS and relevant clinical representative organisations such as the Scottish Intensive Care Society.

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

As a result of this consultation a small number of changes were made to the proposed Type A list in order to more appropriately reflect current practice.

Where agreement to publish responses has been provided, these have now been published on the Scottish Government consultation hub website, alongside an outline of the response to the consultation: https://consult.gov.scot/population-health/human-tissue-regulations-2019/.

Impact Assessments

An Equality Impact Assessment (EQIA) has been completed for this instrument. There are no negative impacts arising from this instrument.

A pre-screening exercise has been completed for a Children Rights and Wellbeing Impact Assessment (CRWIA) for this instrument. There are no children's rights and wellbeing issues arising from this instrument.

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

Financial Effects

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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