

Equality Impact Assessment – Results

Title of Policy	The Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations 2021
Summary of aims and desired outcomes of Policy	<p>The purpose of this policy is to specify medical procedures that are Type B pre-death procedures; how they may be authorised and what conditions must be met in order for them to be carried out under the Human Tissue (Authorisation) (Scotland) Act 2019 ('the 2019 Act').</p> <p>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.</p> <p>Type B procedures are those medical procedures which Ministers consider are appropriate to be carried out subject to further provision as to the circumstances of carrying out, authorisation or manner of carrying out to those included in the provisions of the 2019 Act.</p> <p>In line with the overall aim of the 2019 Act which seeks to facilitate, as part of a wider package of measures, an increase in the number of successful organ and tissue donations for transplant in Scotland, it is important to ensure that the processes which support donation and transplantation work well and are underpinned by a clear legal framework.</p> <p>Specifying Type B pre-death procedures will help ensure there is full transparency and clarity about what may be involved as part of the deceased donation process.</p>
Directorate: Division: Team	Directorate for Population Health Health Protection Division Human Tissue (Authorisation) (Scotland) Act 2019 – Implementation team

Executive Summary

1. This Equality Impact Assessment (EQIA) was undertaken to assess the impact of specifying medical procedures as Type B pre-death procedures, on protected characteristic groups.

2. The EQIA process has identified that enabling the specified medical procedures to be carried out, by specifying them in the regulations, could have some impact on Religion or Belief as a protected characteristic. However the EQIA has demonstrated that any potential impact has been directly addressed and mitigated. This is achieved through the safeguards and authorisation requirements included in the regulations and also in the statutory framework set out by the 2019 Act.
3. The setting out of specified procedures as part of a statutory framework governing their authorisation and carrying out will ensure the interests of potential donors are protected. This includes where individuals whose Religion or Belief may form part of their views on deceased organ and tissue donation, as well as for the public in general.

Background

4. As set out during the passage of the 2019 Act through Parliament, Type B pre-death procedures are medical procedures which are likely to be less routine, or novel, in the context of transplantation. Because of this, the Regulations governing these procedures will require additional conditions to be satisfied before they can be carried out and they will also require explicit authorisation.
5. A public consultation was held between 08 October and 20 November 2020 on the proposed content of the Type B Regulations. This consultation focused on the proposed procedures, how they may be authorised and what conditions should be applied before they can be carried out.

The Scope of the EQIA

6. Following engagement during the development of the 2019 Act and the Type A regulations, it has been identified that the enabling of pre-death procedures to be carried out through the creation of Regulations may have an impact on the protected characteristic of Religion or Belief.

Key Findings

7. It had been previously identified that for members of the Jewish faith, the carrying out of pre-death procedures, specifically where they may require moving or excessive touching of a patient when they are near death may not be fully compatible with some specific religious requirements fulfilled at that time.¹ This will also depend on the individual's circumstances and the care they are receiving.

Duty to inquire

8. The duty to inquire included in the 2019 Act seeks to ensure that donation or pre-death procedures do not go ahead against the views of the potential donor.

¹ <https://www.gov.scot/publications/human-tissue-authorisation-specified-type-procedures-scotland-regulations-analysis-consultation-responses/pages/4/>

Those working in donation, as part of a new statutory duty to inquire, will be required to check with any potential donor's family members about the latest views the person held on donation, including in the particular circumstances as they have arisen. This takes into account the fact that the point at which death occurs can be an important factor in decision making about deceased donation for some people of particular faiths. This reflects current clinical practice whereby taking account of an individual's religion or beliefs forms part of the palliative care pathway, including in relation to donation where this is authorised.

9. Inquiries are also required to be made into the views of the potential donor about the carrying out specified pre-death procedures, so that they do not go ahead against a potential donor's views. These inquiries would include exploration of a person's views about donation and pre-death procedures in relation to their Religion or Belief.

Authorisation

10. As well as investigations being carried out into the views of the potential donor, it is also the case that Type B pre-death procedures will only be able to be carried out if they are authorised by the potential donor themselves or by their nearest relative.
11. Due to the circumstances of deceased donation, where a person who might become a donor will be unconscious and very close to death, it is unlikely that the person will be able to expressly authorise a procedure to be carried out. In the vast majority of cases it is anticipated that authorisation for a Type B procedure will be sought from the nearest relative, unless the donor has made a specific authorisation in advance. When considering whether to authorise a procedure, a nearest relative will be required to take account of the views of the potential donor as brought forward under the duty to inquire. This presents another opportunity for a person's Religion or Belief to be explored and brought to the fore of the authorisation process for Type B procedures.
12. No other protected characteristics have been identified as being potentially impacted by these Regulations.

Conclusion

13. Taking into account the above it is the case that the Regulations, working in tandem with the 2019 Act, contain safeguards to mitigate against any potential infringement of a person's Religion or Belief which might be caused by the carrying out of a Type B pre-death procedure, by ensuring that the potential donor's latest views are fully explored.