Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations

Consultation: draft content

October 2019

Scottish Government
Riaghaltas na h-Alba
gov.scot

Important note when reviewing this consultation document, its content and questions.

The Scottish Government is seeking views, in accordance with the Human Tissue (Authorisation) (Scotland) Act 2019, on specified procedures which facilitate deceased transplantation and are normally carried out in an Intensive Care Unit (ICU) setting across NHS Scotland.

Views are primarily sought from the clinical community who have experience of the deceased donation and transplantation pathway, and their representative organisations and bodies.

This consultation paper and its annex outline the context in which procedures take place, including the new framework as provided for in the Human Tissue (Authorisation) (Scotland) Act 2019. Please review the paper before answering the questions.

Contents

Introduction

1. On 11 June the Scottish Parliament passed the Human Tissue (Authorisation) (Scotland) Act 2019[1] ('the Act'). The 2019 Act amends the Human Tissue (Scotland) Act 2006 and provides for a deemed authorisation system of deceased organ and tissue donation for transplantation in Scotland. This is more commonly referred to as an 'opt-out' system, replacing the current 'opt-in' model.

2. The Act also introduces a dedicated statutory framework governing the authorisation and carrying out of medical procedures before death, where these are for the purpose of increasing the likelihood of successful transplantation – termed in the Act as 'pre-death procedures'. It does not cover medical procedures that are primarily for the care and treatment of the patient; considerations around these interventions will continue to be governed by the Adults with Incapacity (Scotland) Act 2000.

3. This framework is being put in place both to provide greater legislative clarity around what is and is not permitted in relation to pre-death procedures, but also to ensure that in progressing towards deceased donation, potential donors' interests are fully protected. The Scottish Government intends to introduce the opt-out system and statutory framework for pre-death procedures in autumn 2020.[2]

4. The 2019 Act establishes two types of pre-death procedures - either 'Type A' or 'Type B'. Type A procedures are those medical procedures which would be considered routine within the context of facilitating transplantation, and are procedures a person may reasonably expect to be carried out by authorising donation, including where authorisation for donation is deemed. Type B procedures are likely to be less routine, or novel, and so may need some additional authorisation (for example authorisation by a nearest relative) or additional requirements before they could be undertaken.

5. Both Type A and Type B procedures will be set out in Regulations (a form of secondary legislation) and considered by the Scottish Parliament. This approach means that, subject to consultation, the procedures can be changed, including added to or amended, ensuring that the new framework can be responsive to developments in clinical practice.

6. The Scottish Government will discuss with the Scottish Donation and Transplant Group arrangements which might be put in place to ensure that there is a clear process for proposing and considering any future amendment to these Regulations, once enacted.

7. Once the new framework is enacted a pre-death procedure may only be carried out if it is included in the list of procedures (Type A or Type B) specified in

[1] http://www.legislation.gov.uk/asp/2019/11/pdfs/asp_20190011_en.pdf
[2] https://www.gov.scot/news/autumn-2020-for-organ-donation-opt-out-system/

Regulations by Scottish Ministers, and brought into force by the Scottish Parliament.

8. This consultation seeks views on the list of Type A procedures that will be specified in the Regulations. These are set out on page 9. See below for more information about Type B procedures.

Background

9. In a public consultation, published in December 2016, the Scottish Government sought views on how increasing numbers of donations of organ and tissue for transplant might be achieved in Scotland, including plans to move to a soft opt-out system of deceased donation. The proposed opt-out system attracted significant support in the consultation and will be given effect to by the 2019 Act, once brought into force.

10. As well as considering this wider system of authorisation for deceased donation, it was made clear in the 2016 consultation document that it was important to ensure the processes which support deceased donation and transplantation work well and are underpinned by a clear legal framework. This included ensuring that there are clear processes for authorisation for medical procedures which may be carried out on a person before they die to help facilitate successful transplantation, and requirements which must be satisfied before these procedures can be carried out.

11. The 2016 consultation sought views on whether deemed, as well as explicit ('opt-in'), authorisation for donation should encompass authorisation for certain routine medical tests to be completed before death, to help facilitate transplantation. This included blood tests, X-rays, urine tests, tests on samples of chest secretions and tests on the heart. Currently completed under Chief Medical Officer guidance, such routine medical tests help ensure the best matching and safety of transplantation for the patient receiving the donated organ. A majority of respondents were in favour of these tests (or procedures) being authorised via an explicit or deemed authorisation for donation. The consultation also sought views on the administration of medication to facilitate transplantation, which also attracted support from the majority of respondents.[3]

Deemed authorisation for transplantation

12. Following the responses to the 2016 consultation and legislative passage through the Scottish Parliament, the 2019 Act introduces an additional form of authorisation called 'deemed authorisation'. This means that in the absence of an explicit authorisation (opt-in), or an opt out declaration, authorisation for deceased organ and tissue donation for transplantation may be deemed to have been given by a potential donor.

13. There are safeguards in the legislation which seek to ensure that donation does not proceed where a potential donor would have been unwilling to donate. This includes that inquiries should be made about a potential donor's last known views.

14. In addition, deemed authorisation for transplantation will not apply to certain groups listed below, who will continue to require explicit authorisation either from

[3] Page 45 – 48 https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/results/organ-and-tissue-donation-and-transplantation-analysis-of-responses.pdf

themselves or a nearest relative (or a person with parental rights and responsibilities in the case of a child):

- Children under 16 years of age;
- Adults who lack the capacity to understand a deemed authorisation system;
- Adults who have not been ordinarily resident in Scotland for more than 12 months.

Pre-death procedures: the legal framework

15. Responding to the growth in donation following circulatory death (DCD) over the last decade and taking into account the response to the public consultation in 2016 and subsequent scrutiny in the Scottish Parliament, the 2019 Act provides a dedicated statutory framework for the authorisation and carrying out of pre-death procedures. This framework is tailored to the practical and ethical issues relating to deceased donation and includes safeguards to protect the interests of the donor.

16. The Act provides that pre-death procedures are medical procedures that are:

- carried out for the purpose of increasing the likelihood of successful transplantation;
- not for the primary purpose of safeguarding or promoting the health of the person.

17. Further detail on the wider context of pre-death procedures and the new statutory framework is set out in Annex A.

Authorisation for Type A pre-death procedures

18. The 2019 Act requires that, in order to be carried out, pre-death procedures must be authorised. The Act does not require express authorisation for the carrying out of specified Type A pre-death procedures but sets out that where donation for transplantation has been authorised by the potential donor (either expressly or deemed), then Type A pre-death procedures are also authorised.

19. Where authorisation for donation for transplantation has been provided by a nearest relative (or a person with parental rights and responsibilities in the case of a child), they will also have to provide express authorisation for pre-death procedures.

20. In line with the wider approach to deceased donation, particularly in relation to deemed authorisation, the Act seeks to ensure that pre-death procedures are not carried out where the potential donor would have been unwilling for them to take place. Therefore, alongside the duty to inquire about a potential donor's last known views about donation for transplantation there is also a duty to inquire about a person's last known views on completion of Type A pre-death procedures.

Ongoing care

21. The new statutory framework for pre-death procedures does not affect the ongoing care of a patient, regardless of the timing of any treatment i.e. before or after the decision to withdraw life-sustaining treatment has been taken.

22. To fall within the scope of the Act and therefore be considered a pre-death procedure, the procedure has to be:

    - carried out for the purpose of increasing the likelihood of successful transplantation;
    - not for the primary purpose of safeguarding or promoting the health of the person.

23. Any medical procedure which cannot be categorised in this way, including all ongoing care of the patient, will not fall within the scope of the Act and its provisions.

Public Information

24. The 2019 Act places a duty on Scottish Ministers to make available information to the public and raise awareness about pre-death procedures; when they are carried out and how they are authorised as part of the donation process.

25. Raising awareness about pre-death procedures will encourage greater transparency about what can be involved as part of the donation process and, in particular, make clear that if a person authorises donation for transplantation (either expressly or deemed) then Type A pre-death procedures are also authorised.

Type B regulations

26. This consultation is about the medical procedures being specified as Type A pre-death procedures, listed on page 9. Type B procedures, which are those procedures which might be considered to be less routine, or novel, will be consulted on separately in due course.

27. Type B procedures are procedures which a person might not expect to be authorised by authorising donation, including via deemed authorisation. Therefore additional requirements may be put in place, both in terms of authorisation and also the circumstances or manner in which the procedures may be carried out. Views are not being sought on Type B procedures at this point, as there is focus on ensuring that the new statutory framework for pre-death procedures can reflect current clinical practice when it comes into force in autumn 2020, as set out by the Type A procedures.

The Type A procedures

28. The Scottish Government is proposing that the medical procedures listed below will be defined as Type A pre-death procedures, and are seeking views on this proposed list.

29. In developing the list of Type A procedures, the Scottish Government has continued to work closely with those directly involved in donation and transplantation across the NHS, with the aim of ensuring an effective regulatory framework for Type A pre-death procedures is implemented and accurately reflects current clinical practice.

30. As noted earlier, once the new framework is enacted, a pre-death procedure may only be carried out if it is included in the list of procedures specified in Regulations by Scottish Ministers, and approved and brought into force by the Scottish Parliament.

31. As outlined above, Type A procedures are those medical procedures which would be considered routine within the context of facilitating transplantation. They are medical procedures a person may reasonably expect to be carried out by authorising donation (including where authorisation for donation is deemed), within the framework and safeguards included in the Act.

32. It is important to note that the Regulations provide which medical procedures may be carried out and <u>not</u> the purpose for which they may be carried out. For example, ‘taking of a blood sample’ will include all purposes for which a blood sample would be taken i.e. all tests which require to be carried out on that sample.

Listed Type A procedures

Collection of bodily fluids and microbiological samples

Taking of a blood sample

Taking of a urine sample by way of urinary catheter

Taking of a chest secretion sample (excluding bronchoscopy)

Swabbing or scraping of the body including inside of the mouth, nostril or ear canal but excluding the swabbing or scraping of any part of any other body orifice

Radiological imaging with or without the use of contrast dye

Carrying out of an X-Ray

Carrying out a computerised tomography (CT) scan

Carrying out of magnetic resonance imaging (MRI)

Carrying out of ultrasound imaging

Carrying out of transthoracic echocardiography

Cardiovascular monitoring

Carrying out of electrocardiogram (ECG)

Cardiac output monitoring by way of an arterial line

Carrying out of central venous pressure monitoring

Arterial blood pressure monitoring including by way of an arterial line

Respiratory Monitoring and Support

Measuring of oxygen saturation

Sustaining the appropriate operation of any pre-established artificial ventilation

Administration of medication or other product

Administration of antimicrobials

Administration of intravenous fluids

Administration of medication to manage blood pressure

Administration of blood and blood components

Questions

33. Type A procedures are those medical procedures which would be considered routine within the context of facilitating transplantation. They are medical procedures a person may reasonably expect to have authorised if they have authorised donation (including where authorisation for donation is deemed).

34. The above procedures are grouped into classes, with individual procedures listed within each class. When answering the questions below please consider both the over-arching class of Type A procedure (in bold) as well as the individual types of procedure listed under each class.

Question 1. If there is anything in the Type A procedures list that you think should **not be included**, please comment here, giving reasons why.

Question 2. If there is anything **missing** from the Type A procedures list, please comment here, giving reasons why.

Question 3. If any amendments to the **wording** in the Type A procedures list are required, please comment here.

Question 4. If you would like to comment on any other aspect of this consultation, please comment here.

How to respond

Responding to this Consultation

35. We are inviting responses to this consultation by **11 December 2019.**

36. Please respond to this consultation using the Scottish Government's consultation hub, Citizen Space (http://consult.gov.scot). Access and respond to this consultation online at https://consult.gov.scot/population-health/human-tissue-regulations-2019/. You can save and return to your responses while the consultation is still open. Please ensure that consultation responses are submitted before the closing date of **11 December 2019**

37. If you are unable to respond using our consultation hub, please complete the Respondent Information Form (Annex B) to:

    Opt Out Donation Legislation Team
    Scottish Government
    3 East
    St Andrews House
    Regent Road
    Edinburgh, EH1 3DG

Handling your response

38. If you respond using the consultation hub, you will be directed to the About You page before submitting your response. Please indicate how you wish your response to be handled and, in particular, whether you are content for your response to published. If you ask for your response not to be published, we will regard it as confidential, and we will treat it accordingly.

39. All respondents should be aware that the Scottish Government is subject to the provisions of the Freedom of Information (Scotland) Act 2002 and would therefore have to consider any request made to it under the Act for information relating to responses made to this consultation exercise.

40. If you are unable to respond via Citizen Space, please complete and return the Respondent Information Form included in this document.

41. To find out how we handle your personal data, please see our privacy policy: https://beta.gov.scot/privacy/

Next steps in the process

42. Where respondents have given permission for their response to be made public, and after we have checked that they contain no potentially defamatory material, responses will be made available to the public at http://consult.gov.scot. If you use the consultation hub to respond, you will receive a copy of your response via email.

43. Following the closing date, all responses will be analysed and considered along with any other available evidence to help us. Responses will be published where we have been given permission to do so. An analysis report will also be made available.

Comments and complaints

44. If you have any comments about how this consultation exercise has been conducted, please send them to the contact address above or at ODlegislation@gov.scot.

Scottish Government consultation process

45. Consultation is an essential part of the policymaking process. It gives us the opportunity to consider your opinion and expertise on a proposed area of work.

46. You can find all our consultations online: http://consult.gov.scot. Each consultation details the issues under consideration, as well as a way for you to give us your views, either online, by email or by post.

47. Responses will be analysed and used as part of the decision making process, along with a range of other available information and evidence. We will publish a report of this analysis for every consultation. Depending on the nature of the consultation exercise the responses received may:

    - indicate the need for policy development or review
    - inform the development of a particular policy
    - help decisions to be made between alternative policy proposals
    - be used to finalise legislation before it is implemented

48. While details of particular circumstances described in a response to a consultation exercise may usefully inform the policy process, consultation exercises cannot address individual concerns and comments, which should be directed to the relevant public body.

Annex A: Context of pre-death procedures

Practical context

49. During 2018/19, in Scotland, there were 30 DCD (donation following circulatory death) donors from a total of 98 deceased donors. DCD donation is where the donor has been pronounced dead following cessation of the heart and respiratory activity. Donation following diagnosis of death by neurological criteria (DNC), where the donor has been pronounced dead using neurological criteria (i.e. brain death) accounts for the rest of deceased donation.

50. In practice, to facilitate transplantation, organs have to be removed immediately after the death of a DCD donor and quickly transported to the transplanting hospital. This means there are significant time constraints and some of the vital tests which are necessary to ensure that the organs are likely to be successfully transplanted, and are a good match for the transplant recipient, need to be carried out shortly before death. These may include blood and urine tests, x-rays or tests on the heart such as an electrocardiogram or echocardiogram. All of these tests, or procedures, may be considered to be routine as part of the patient's care. For example, all patients in intensive care will have had a urinary catheter inserted, meaning that urine samples taken for the purposes of facilitating organ donation can be taken. Similarly, blood samples taken for the purposes of facilitating organ donation are likely to be taken from an existing line.

51. DCD donation had been carried out in Scotland and the rest of the UK since 2003. Before 2009/10 a far greater proportion of donation proceeded with DNC donors, however, there has been a significant increase in donors who have donated following circulatory death since that time. The increase in this type of donation is as a result of developments in clinical practice and processes and is now a very important element of deceased organ donation in Scotland.

52. DCD donation began to expand significantly after Guidance was issued by the former Chief Medical Officer in 2010 (CMO Guidance) which provided reassurance around the carrying out of some of these tests – including blood tests on a potential donor where it was clear that the person, or their family, were authorising donation. Similar Guidance was issued by the Department of Health for England and Wales in 2009, but this reflected the different legal regimes in those countries for people who are not capable of consenting to this type of medical procedure.

53. It was recognised in the 2010 CMO Guidance that the basis for medical consent to these tests and procedures for the purposes of transplantation should be considered further as practice develops.

54. The 2019 Act supports this consideration by setting out a clear and dedicated statutory provision for the completion of these tests that support DCD donation and transplantation.

Tissue

55. This matter does not directly affect tissue only donation as, for example, eyes can be retrieved from a donor up to 24 hours after the patient's death, while other forms of tissue can be donated up to 48 hours after death. This means the necessary tests can be carried out following the death of the patient. However, for completeness, the pre-death procedures framework in the 2019 Act makes no distinction between organs and tissues.

2019 Act – the framework

56. The Act sets out that to be considered a pre-death procedure, the medical procedure has to be:

- carried out for the purpose of increasing the likelihood of successful transplantation;
- not for the primary purpose of safeguarding or promoting the health of the person.

57. The Act also requires that a pre-death procedure, as defined above, may only be carried out where:

- in the view of the health worker primarily responsible for the person's medical treatment, for example the supervising consultant in ICU, the person is likely to die imminently (including as a result of withdrawing life sustaining treatment);
- where the person is receiving life sustaining treatment, the decision to withdraw that treatment has been taken by the person responsible for the person's medical treatment (i.e. supervising consultant);
- the carrying out of the procedure is necessary;
- the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and;
- the carrying out of the procedure is not likely to harm the person.[4]

58. The Act explains that the carrying out of a procedure is necessary if either of the following apply:

- it is necessary to carry it out for the purpose of ascertaining whether a part of the person's body is suitable for transplantation,
- it is necessary to carry it out for the purpose of increasing the likelihood of successful transplantation of a part of the person's body.

59. The process and requirements set out above in the 2019 Act are intended to reflect current clinical practice in NHS Scotland.

[4] This is set out in section 16E, subsection (2) of the 2019 Act. http://www.legislation.gov.uk/asp/2019/11/section/23

60. Training and guidance will be provided to NHS staff in advance of the implementation of the new statutory framework for pre-death procedures, to support the delivery of the new deemed authorisation system for donation for autumn 2020. The intention is that this framework will strengthen the processes supporting DCD donation and ensure clarity for clinicians on the legal framework governing these medical procedures. It will also provide transparency for the public about what is involved in the wider donation and transplantation process.

Annex B: Respondent Information Form

Consultation on the draft content of the Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations

Please Note this form **must** be completed and returned with your response.

To find out how we handle your personal data, please see our privacy policy: https://beta.gov.scot/privacy/

Are you responding as an individual or an organisation?

☐ Individual

☐ Organisation

Full name or organisation's name

Phone number

Address

Postcode

Email

The Scottish Government would like your permission to publish your consultation response. Please indicate your publishing preference:

☐ Publish response with name

☐ Publish response only (without name)

☐ Do not publish response

Information for organisations:

The option 'Publish response only (without name)' is available for individual respondents only. If this option is selected, the organisation name will still be published.

If you choose the option 'Do not publish response', your organisation name may still be listed as having responded to the consultation in, for example, the analysis report.

We will share your response internally with other Scottish Government policy teams who may be addressing the issues you discuss. They may wish to contact you again in the future, but we require your permission to do so. Are you content for Scottish Government to contact you again in relation to this consultation exercise?

☐ Yes

☐ No

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Any enquiries regarding this publication should be sent to us at

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