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

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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 medical procedures which facilitate transplantation and are normally carried out in an Intensive Care Unit (ICU) setting across NHS Scotland.

Views are sought in particular from the clinical community who have experience of the deceased donation and transplantation pathway, and their representative organisations and bodies. Views from members of the public, patients' groups and others are also welcome.

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

1. Introduction

1. On 11 June 2019 the Scottish Parliament passed the Human Tissue (Authorisation) (Scotland) Act 2019[1] ('the 2019 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 intention is that this framework will strengthen the processes supporting donation following circulatory death (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 donation and transplantation process.

4. The Scottish Government intended to introduce the opt-out system and statutory framework for pre-death procedures in autumn 2020. Due to the COVID-19 pandemic, implementation of the Act has been revised to 26 March 2021.

[1] http://www.legislation.gov.uk/asp/2019/11/pdfs/asp_20190011_en.pdf

5. 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. Following consultation, The Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations 2020[2] ("the Type A Regulations"), which specified the permitted Type A procedures, were considered by the Scottish Parliament and approved on 4 March 2020.

6. Type B procedures are procedures which are likely to be less routine, or novel, in the context of transplantation. This means they may need some additional authorisation or additional requirements before they could be undertaken.

7. In developing the proposals for Type B regulations, 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 B pre-death procedures is implemented.

8. This consultation seeks views on the proposed list of Type B procedures that will be specified in the Regulations; how they may be authorised and what conditions may be applied to them.

[2] https://www.legislation.gov.uk/sdsi/2020/9780111043981/contents

2. Background

9. In a public consultation[3], 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, the 2016 consultation document highlighted the importance of ensuring that the processes which support donation and transplantation work well and are underpinned by a clear legal framework. This included ensuring that there are clear processes for authorisation of 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, 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. Such routine medical tests help ensure the best matching and safety of transplantation for the patient receiving the donated organ. Analysis[4] of the responses showed that the majority of respondents were in favour of these tests (or procedures) being carried out, either via 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] https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/supporting_documents/00511160.pdf
[4] https://consult.gov.scot/health-protection/organ-and-tissue-donation-and-transplantation/results/organ-and-tissue-donation-and-transplantation-analysis-of-responses.pdf

2.1 Pre-death procedures legal framework

12. Responding to the growth in DCD donation over the last decade and taking into account the response to the public consultation in 2016, the 2019 Act provides a 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.

13. In practice the statutory framework applies only to patients who are not yet deceased, such as in cases where donation is planned following circulatory death, or, more rarely, prior to confirmation of death using neurological criteria.

14. 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.

15. 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.

16. The Act requires that a pre-death procedure, as defined above, may only be carried out where certain minimum conditions are met, which are intended to reflect current clinical practice in NHS Scotland:

    a) 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);

b) 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);
c) the carrying out of the procedure is necessary;
d) the carrying out of the procedure is not likely to cause more than minimal discomfort to the person, and;
e) the carrying out of the procedure is not likely to harm the person.[5]

17. These apply to both Type A and Type B procedures and in addition, due to the nature of Type B procedures, other requirements may be applied to them (see from paragraph 42 for the proposed requirements).

18. Additionally, for both Type A and Type B procedures, in line with the wider approach to deceased donation, 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 a duty to inquire about a potential donor's most recent views about donation there is also a duty to inquire about a person's most recent views on completion of pre-death procedures. Procedures may only be carried out where the person carrying them out has no knowledge that the potential donor would be unwilling for them to be carried out, taking into account any evidence about their views provided as part of the duty to inquire.

2.2 Authorisation for Type B pre-death procedures

19. The 2019 Act requires that, in order to be carried out, pre-death procedures must be authorised. The Act explicitly sets out how Type A procedures may be authorised, which includes by virtue of a person authorising donation, either expressly or deemed.

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

20. As Type B procedures are those procedures which are more novel in this context and which a person might not reasonably expect to be carried out to facilitate transplantation. The Act does not enable Type B procedures to be authorised by virtue of authorising donation. The Act enables the ways in which Type B procedures may be authorised to be set out in regulations and is therefore part of the subject of this consultation. Views are sought on proposed ways to authorise Type B procedures, outlined from paragraph 55.

2.3 Type B pre-death procedures

21. Aside from the medical procedures which are considered to be routine, which may be specified as Type A, the Act enables the specifying of procedures that are more novel in the context of transplantation - Type B procedures. Because Type B procedures are likely to be less routine, or novel, they may need some additional authorisation or additional requirements before they could be undertaken, beyond the minimum standards as to authorisation and pre-conditions that are set out in the Act.

22. Where Scottish Ministers are satisfied that the procedure may be carried out, but subject to additional, appropriate safeguards, including requirements as to authorisation, the procedure may be specified as a Type B procedure.

23. This will enable the donation and transplantation process to keep pace with medical developments which may have an impact on the nature and necessity of pre-death procedures. This means the system of authorisation will be able to respond appropriately and flexibly to developments in practice, while also ensuring that appropriate safeguards apply to the carrying out of these procedures and provide reassurance about how these more novel procedures may be authorised.

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

25. It should be noted that not all DCD donors will require a Type B procedure to be carried out. The Type A Regulations contain the majority of procedures that will be required to progress a potential DCD donor safely for transplantation.

2.4 Ongoing care

26. The new statutory framework 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.

27. To fall within the scope of the Act and therefore 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.

28. 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.

2.5 Updating the regulations

29. Setting out pre-death procedures in affirmative[6] regulations (a form of secondary legislation) 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. The appropriate conditions and authorisation methods related to any newly proposed procedures would also require to be considered, to ensure that they remained proportionate to the nature of the procedure(s) in question.

[6] Affirmative regulations are subject to a greater degree of scrutiny and can only be brought into force after the Parliament has voted to approve them, following consideration by the relevant Parliamentary committees.

30. It is intended that future proposals for amendment of the regulations would be considered by a sub-group of the Scottish Donation and Transplant Group (SDTG), taking advice from bodies such as the Research, Innovation and Novel Technologies Advisory Group (RINTAG) and others with specialist expertise on the proposed procedure(s) such as the Scottish Intensive Care Society, which is represented on SDTG, to consider whether the proposed changes should be recommended to Scottish Ministers. Such changes would be subject to consultation before regulations are laid for scrutiny by the Scottish Parliament.

2.6 Public Information

31. 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.

32. Once approved by the Scottish Parliament, it is the intention that the Organ Donation Scotland website will list and explain what the specified Type B procedures are and information about when these procedures may be carried out and how they may be authorised. Raising awareness about pre-death procedures will encourage greater transparency about what can be involved as part of the donation process.

3. The Type B regulations

33. Type B procedures are medical procedures which a person might not expect to be authorised by authorising donation, including deemed authorisation for donation. 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.

34. There are three components to the proposed regulations, listed below. The Scottish Government is seeking your views on these three aspects:
    - the medical procedures which should be specified as Type B;
    - the circumstances in which the specified Type B procedures may be carried out;
    - how the specified Type B procedures may be authorised.

35. The 2019 Act permits different procedures to be treated differently in the regulations, to allow a proportionate approach to each type of procedure. This may be in the conditions which have to be met before the procedure can be carried out, or in how they are authorised.

36. However, it is proposed that the same conditions and authorisation methods apply to all of the proposed procedures for these regulations and your views are sought on this approach.

Consideration of rights of the patient

37. In setting out the framework in the Act for pre-death procedures, due regard was taken of the rights of individuals under the European Convention on Human Rights (ECHR), in this case the patient who may undergo pre-death procedures. The regulations to which this consultation refers will support the framework by identifying which pre-death procedures can be specified as Type B, as well as any additional conditions and authorisation requirements which must be met.

38. As with the development of the provisions in the Act, consideration must be given to each distinct pre-death procedure in terms of its justification, the authorisations and safeguards to be put in place for its use, and its compliance with the wider ECHR standards. This includes consideration of the invasiveness of the procedure and its impact on a patient's bodily integrity and privacy, as protected by Article 8 ECHR. Any possible interference with an individual's rights under Article 8 must be necessary in pursuit of a legitimate aim and proportionate to that aim. This means that the statutory framework must build in appropriate safeguards in proportion to the invasiveness of each procedure.

3.1 Proposed list of Type B Procedures

39. The Scottish Government is proposing that the medical procedures listed below will be specified as Type B pre-death procedures, and is seeking views on this proposed list. An explanation of what each procedure involves and its purpose is included in **Annex A.**

- Carrying out radiological imaging which requires moving a patient from their existing location, including:
    - Magnetic Resonance Imaging (MRI)
    - Computerised Tomography (CT) scan
    - And;
        - X-ray
        - Ultrasound
        - Transthoracic echocardiography[7]
- Bronchoscopy
- Skin biopsy
- Scraping or swabbing of a body orifice (**other than** mouth, nostril or ear canal).

40. As noted earlier, once the new framework is enacted, a Type B pre-death procedure may only be carried out if it is included in the list of procedures

[7] X-ray, ultrasound and transthoracic echocardiography are all specified as Type A pre-death procedures provided they are carried out without moving the patient from their existing location. It is proposed that, along with MRI and CT scans, these imaging techniques will be specified as a Type B procedure where the patient requires to be moved.

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

41. We would like to know your views on the proposed procedures listed as Type B procedures, particularly in regards to the questions below:

- **Question 1**. If there is any proposed medical procedure in the Type B procedure list that you think should **not be included**?

- **Question 2**. If there is any medical procedure not listed in the Type B procedures list, which you think **should be included** in this category?

- **Question 3**. If you think that any amendments to the **wording** in the Type B procedures list are required?

3.2 Circumstances in which Type B Procedures may be carried out

42. Due to the non-routine nature of Type B procedures, conditions which are additional to those contained in the Act (set out at paragraph 16) may be applied before they can be carried out.

43. The conditions outlined below may be considered to broadly reflect current practice around the carrying out of medical procedures in general to facilitate transplantation. However, specifying these in the regulations would make them a legal requirement. The Scottish Government would welcome views on their inclusion.

<u>Taking account of Type A procedures</u>

44. The first proposed condition is:

- that a Type B procedure may only be carried out where no Type A procedure could be used to provide the necessary information.

45. The Act already contains requirements that a pre-death procedure (whether Type A or Type B) may only be carried out where it is necessary to do so. What is proposed as an additional safeguard for Type B procedures is to include a specific requirement that Type B procedures can only be utilised where the carrying out of the specified Type A pre-death procedures would not provide the necessary diagnostic information.

46. This would reflect current practice around medical procedures more broadly, whereby interventions are required to be proportionate and a lesser intervention should be utilised where possible.

Registered Medical Practitioner agreement

- The second proposed condition is that a Type B procedure may only be carried out with the agreement of two Registered Medical Practitioners (RMPs). This would involve both RMPs being satisfied that the conditions for carrying out the pre-death procedures are met (specifically those set out in section 16E (2) (c) to (e) of the Act, and replicated above at point (c) to (e) of **paragraph 16** earlier in this paper. These are namely around the necessity of the procedure, that it is unlikely to cause more than minimal discomfort, and unlikely to cause harm to the patient) and;
- That a record of this agreement is made in writing.

47. Donation and transplantation is a multidisciplinary field and involves many different medical professionals working together. Requiring agreement from two RMPs that a procedure should be carried out would reflect current practice in many cases but would also provide an additional level of assurance comparative to the carrying out of less routine procedures to facilitate transplantation.

48. In practice, agreement would likely be between the intensive care consultant who is primarily responsible for the patient's care, and another RMP, which might include the transplant surgeon who would carry out the retrieval operation after the patient's death. The Scottish Government has considered the whether the

Regulations should include reference to particular specialisations of RMP. For example this could be to require the agreement from RMPs of a particular specialism, or to preclude a specific type of RMP from agreeing to the procedure, for example not permitting the agreement to be given by an RMP involved in the donation process.

49. There is a balance to be struck between ensuring there is a robust process in place to manage the carrying out of a Type B procedure in a hospital setting, alongside ensuring that the Regulations are not overly prescriptive. On balance, and taking into consideration the requirements around authorisation, family involvement, broader safeguards in the Act and the wider ethical framework surrounding donation in Scotland, the Scottish Government is not proposing that there should be further specification of a particular RMP or RMPs who may agree to a Type B procedure.

Recording of agreement

50. In order to ensure there is clarity about such agreement that the procedure may be carried out, and that the necessary conditions have been met, the Scottish Government has considered the need to make it a legal requirement that the agreement of two RMPs to carry out the procedure is recorded in writing. It is established clinical practice that medical interventions carried out on a patient are formally recorded in their medical record, so in practice the fact that there is such agreement could be included there, or on other documentation related to the donation. The Scottish Government proposes that this is a reasonable condition, which formalises the recording requirement in line with broader clinical practice.

Applicability of proposed conditions

51. The Scottish Government proposes that both conditions described above would apply and have to be met for all of the proposed specified Type B procedures, before those procedures could be carried out.

52. As part of this proposal, the Government has considered the applicability of conditions applying only to certain procedures i.e. a form of 'sliding scale' of conditions that need to be met based upon, for example, the invasiveness of any specified Type B procedure.

53. On balance, it is considered that these conditions are proportionate and appropriate to be applied to all the proposed Type B procedures which are included in the consultation. In addition, it is important that the effect of the Regulation is well understood and so having the conditions apply equally to all specified procedures is likely to assist with implementation.

54. We would like to know your views on the proposed conditions that are required to be met before a specified Type B procedure can be carried out, particularly in regards to the questions below.

- **Question 4**. We would like to know your views on the proposed condition that a Type B procedure may only be carried out if there is no Type A procedure which can provide the necessary information.

- **Question 5**. We would like to know your views on the proposed condition that the agreement of two Registered Medical Practitioners, which will confirm the requirements for the Type B procedure to be carried out have been met, must be obtained and that the existence of such agreement must be recorded in writing.

- **Question 6.** It is proposed that these conditions should apply to all specified procedures. We would like to know your views on this approach.

3.3 Ways in which Type B Procedures may be authorised

55. Specified Type B pre-death procedures may only be carried out where authorisation for them to be carried out is in place. The Scottish Government is seeking views on what authorisation requirements should be in place.

56. The Scottish Government has considered what form of authorisation for Type B procedures could be set out in the regulation. Authorisation methods that have been considered are:
    - Nearest relative authorisation;
    - Express authorisation;
    - Court approval.

57. The Scottish Government does not propose that express authorisation or court approval should be required for the carrying out of Type B procedures included in this consultation. These authorisation methods are discussed further below.

Express authorisation

58. The Scottish Government recognises that whether a person wishes to donate organs and tissue after death is first and foremost a matter for them – this is reflected in the provisions of the 2019 Act, including in the duty to inquire. Similarly, whether a person would wish to undergo certain medical procedures is ordinarily, where they have capacity, a matter for them. It is therefore proposed that, similar to the approach to Type A procedures, a person will be able to make an advance authorisation for a Type B procedures if they wish, in writing.

59. If a potential donor has authorised donation, either expressly or deemed, every effort should be made to support their decision being fulfilled. In progressing towards deceased donation however, potential donors' interests must be fully protected and the pre-death procedures framework seeks to ensure that they are. Requiring that express authorisation should be in place for Type B procedures would contribute towards this and provide assurances that less routine procedures are only carried out where there is authorisation for them from the potential donor.

60. However there are a number of significant practical issues with requiring express authorisation for Type B procedures. Given the circumstances in which deceased

donation takes place, it would be extremely rare to be able to obtain express authorisation for a specific pre-death procedure from the potential donor at the time they will be considered. Those who are progressing as potential DCD donors are unconscious and will therefore not have capacity to expressly authorise a pre-death procedure.

61. Although a public mechanism could be established to record specific authorisations in advance for such procedures, for example similar to, or as part of the NHS Organ Donor Register, this would not address any potential donor who is progressing via deemed authorisation for donation i.e. adults who have decided not to record a donation decision in life.

62. Express authorisation is unlikely to be achieved in practice for the reasons outlined above. Requiring express authorisation therefore could act as a barrier to donation ever proceeding in cases where certain information identifying the viability of an organ for donation could only be obtained by carrying out a specific Type B procedure.

63. Taking all these factors into consideration, whilst it is important that a person should be able to authorise Type B procedures during life if they wish, it is not proposed that express authorisation from the donor for such procedures should be required.

Court approval

64. Court approval has also been considered as a potential authorisation method, however it is considered to be disproportionate to the Type B procedures proposed in this consultation.

65. The time critical setting in which deceased donation takes place would present practical problems in making any form of application to a court. Furthermore, the introduction of such an authorisation process for Type B procedures would lengthen a process that is already very difficult for families. The potential time it might take for any such application to be considered would present a real risk

that a potential donor would be unable to be progressed to donation, and would likely cause their family distress by unduly lengthening and complicating the donation process.

66. Given such considerations, in practice it is unlikely that clinicians would seek to gain court approval and therefore, if it was required, it would act in almost all cases as a barrier to Type B procedures ever being carried out.

67. Additionally, it may be considered to be disproportionate to require court approval for a Type B procedure to be carried out where that approval may instead be given by a nearest relative who, in certain circumstances, would also be permitted to authorise donation for transplantation and Type A procedures for their loved one. Since court approval would never be sought as a substitute for the views of the nearest relative, there is a risk that introducing an extra level of decision-making for Type B procedures could undermine the role of the nearest relative for transplantation in general.

Nearest relative authorisation

68. Taking into account the above considerations, the Scottish Government is proposing that a Type B procedure may be carried out either if a patient has given express authorisation for this procedure in advance (which is unlikely to apply in most cases), or with authorisation from the potential donor's nearest relative[8], or person with parental rights and responsibilities in the case of a child[9].

69. Donation and transplantation is progressed with the involvement of the potential donor's family and this will remain the case under the deemed authorisation system. Under current practice families are involved in discussions about what

[8] For the purposes of the Act, the Nearest Relative is the person who, at the relevant time, is highest in the included list of relations.

[9] Authorisation may be given on behalf of a child by a person with parental rights and responsibilities in relation to them, including a local authority. Where there is no person with parental rights and responsibilities or that person is incapable of providing authorisation, section 10A of the Act sets out who is permitted to authorise donation on behalf of a child.

procedures might be required in order to progress donation, and are carried out with support from the family.

70. Formalising this practice and requiring a specific authorisation from the nearest relative, or person with parental rights and responsibilities in the case of a child, would broadly be in line with current practice while providing assurance that more novel procedures will not proceed without specific authorisation and with support of the potential donor's family.

71. Furthermore, as previously noted, the law already permits a nearest relative to authorise donation and Type A procedures on behalf of an adult, or a person who has parental rights and responsibilities to authorise on behalf of a child, in certain circumstances, and so enabling this kind of authorisation would be in line with other aspects of the legislation.

Applicability of authorisation methods

72. On balance, it is considered that a requirement for either express or nearest relative authorisation is a proportionate and appropriate method to be applied to all the Type B procedures proposed in this consultation.

73. We would like to know your views on the proposed way in which Type B procedure can be authorised, particularly in regards to the question below.

- **Question 7**. It is proposed that all specified procedures are able to be carried out either with express authorisation by the individual or with nearest relative authorisation. We would like to know your views on this approach.

4. Questions

The Type B Procedures

We would like to know your views on the proposed medical procedures to be specified as Type B Procedures:

- Carrying out radiological imaging which requires moving a patient from their existing location, including:
    - Magnetic Resonance Imaging (MRI)
    - Computerised Tomography (CT) scan
    - And;
        - X-ray
        - Ultrasound
        - Transthoracic echocardiography
- Bronchoscopy
- Skin biopsy
- Scraping or swabbing of a body orifice (**other than** mouth, nostril or ear canal).

- **Question 1**. If there is any proposed medical procedure in the Type B procedure list that you think should **not be included**, please comment here, and provide reasons why you think they should be removed.

- **Question 2**. If there is any medical procedure not listed in the Type B procedures list, which you think **should be included** in this category, please comment here, and provide reasons why you think it should be included

- **Question 3**. If you think that any amendments to the **wording** in the Type B procedures list are required, please comment here.

Circumstances in which Type B Procedures may be carried out

- **Question 4**. We would like to know your views on the proposed condition that a Type B procedure may only be carried out if there is no Type A procedure which can provide the necessary information.

Question 5. We would like to know your views on the proposed condition that the agreement of two Registered Medical Practitioners, which will confirm the requirements for the Type B procedure to be carried out have been met, must be obtained and that the existence of such agreement must be recorded in writing.

- **Question 6.** It is proposed that these conditions should apply to all specified procedures. We would like to know your views on this approach. Please give the reasons which underpin your view.

Ways in which Type B Procedures may be authorised

- **Question 7**. It is proposed that all specified procedures are able to be carried out either with express authorisation by the individual or with nearest relative authorisation. We would like to know your views on this approach. Please give the reasons which underpin your view.

5. How to respond

Responding to this Consultation

74. We are inviting responses to this consultation by **20 November 2020.**

75. 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/consultation-specified-type-b-procedures. 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 **20 November 2020.**

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

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

Handling your response

77. 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.

78. 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.

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

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

Next steps in the process

81. 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.

82. 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

83. 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

84. 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.

85. 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.

86. 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

87. 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.

6. Annex A: Proposed procedures in detail

Imaging carried out away from the bedside (x-ray, ultrasound, transthoracic echocardiography and CT/MRI scan)

88. Most x-rays on patients in intensive care are carried out at the bedside using portable units, and will not require transfer to a radiology department. X-rays are used to image a part of the body (usually the lungs or bones) and involve moving a body part to allow a radiographic plate to lie under the area, to allow the image to be captured.

89. Ultrasound can be carried out either at the bedside or in a radiology department. The procedure is commonly used to image areas of soft tissue. The procedure involves exposing the area to be imaged, ultrasound jelly being placed on the skin and the use of a probe to send ultrasonic waves to image the body part. An image is displayed on a monitor to allow diagnostic information to be viewed. A transthoracic echocardiogram is a type of ultrasound imaging technique.

90. For an MRI or CT scan, the patient is transported from the ICU on their bed to the radiology department. The patient will be transferred onto a set of mobile equipment to allow their treatment and monitoring to be continued while they are out of the ICU. They will remain sedated and kept comfortable during this process. While in the radiology department, the patient will be moved on to the scanner table and will have the scan performed. During the scan, it is sometimes necessary to inject dye to identify structures within the body. This dye in administered via a drip already placed in the patient. Occasionally it may be necessary to insert a drip for the purposes of the scan. At the end of the scan, the patient is transferred back onto their bed and taken back to the ICU.

Bronchoscopy

91. The procedure is carried out without moving the patient and the patient is kept comfortable during the procedure. As part of the routine care of the patient in the

ICU, they will already have a breathing tube inserted into their trachea to facilitate ventilation. A fine camera (bronchoscope) is passed down this breathing tube to allow visual inspection of the lungs. If secretions are present, these are removed via the bronchoscope. Samples of these secretion may be sent to a laboratory for analysis, to look for infection or malignancy.

Skin biopsy

92. The area to be biopsied will be identified and cleaned to ensure sterility. Local anaesthetic will be injected to the area and an incision will be made, not usually larger than 2cm. A dressing is applied at the end of the procedure. This may be carried out, for example, on a skin lesion to check for malignancy. The tissue is sent to a laboratory for analysis to provide relevant diagnostic information.

Scraping or swabbing of a body orifice (other than mouth, nostril or ear canal)

93. To swab an area, a swab (much like a cotton bud) is rubbed over the area to be sampled. This allows cells or secretions requiring sampling to attach to the swab to later be analysed in the laboratory. Scraping an area involves using an instrument specifically designed for this purpose to scrape off cells or layers of skin to later be analysed in the lab. The primary reason for doing these procedures would be to look for either malignant cells or infection.

7. Annex B: Further information

7.1 Practical context

94. Only around 1% of people die in circumstances where they might become an organ donor. Around 40% of deceased donations are from donors who die following circulatory death. In 2019/20 there were 35 DCD donors (donation following circulatory death) from a total of 109 deceased donors overall, during this period across Scotland. DCD donation is where the donor has been pronounced dead following cessation of the heart and respiratory activity. Donation following diagnosis of death using neurological criteria (DNC), where the donor has been confirmed deceased using neurological criteria (i.e. brain death) accounts for the rest of deceased donation.

95. 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.

96. DCD donation has 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.

97. 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 happy for that person to be a donor. 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.

98. 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.

99. 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

100. The carrying out of pre-death procedures to facilitate transplantation is required for tissue-only donation far less frequently than in relation to organ donation. This is because, 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 framework in the Act covers both organ and tissue donation for transplantation as it may affect organ donors who are also expected to donate tissue, following circulatory death.

7.2 Deemed authorisation for transplantation

101. Following the responses to the 2016 consultation and 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, or an opt out declaration, authorisation for deceased organ and

tissue donation for transplantation may be deemed to have been given. Unlike Type A procedures, Type B procedures are not directly linked to the introduction of the new deemed authorisation system. This is because authorisation for carrying out a Type B procedure is not linked to authorisation for donation being in place, which is the case for Type A procedures.

102. 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 most recent views.

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

8. Annex C: Respondent Information Form

Consultation on the Human Tissue (Authorisation) (Specified Type B 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

Question 1. If there is any proposed medical procedure in the Type B procedure list that you think should **not be included**, please comment here, and provide reasons why you think they should be removed.

Question 2. If there is any medical procedure not listed in the Type B procedures list, which you think **should be included** in this category, please comment here, and provide reasons why you think it should be included

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

Question 4. We would like to know your views on the proposed condition that a Type B procedure may only be carried out if there is no Type A procedure which can provide the necessary information.

Question 5. We would like to know your views on the proposed condition that the agreement of two Registered Medical Practitioners, which will confirm the requirements for the Type B procedure to be carried out have been met, must be obtained and that the existence of such agreement must be recorded in writing.

Question 6. It is proposed that these conditions should apply to all specified procedures. We would like to know your views on this approach. Please give the reasons which underpin your view.

Question 7. It is proposed that all the proposed specified procedures are able to be carried out either with express authorisation by the individual or with nearest relative authorisation. We would like to know your views on this approach. Please give the reasons which underpin your view.

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