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

Analysis of consultation responses

February 2020

Scottish Government
Riaghaltas na h-Alba
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Contents

Executive summary

Introduction

1. Between 30 October and 11 December 2019 the Scottish Government undertook a public consultation to gather views on a list of medical procedures to be prescribed as Type A pre-death procedures, which will be specified by the Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations.

2. Type A procedures are those medical procedures which are currently routinely carried out to facilitate transplantation and which Scottish 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.

The respondents

3. The consultation received 19 responses, which included a response submitted via e-mail. Responses were submitted by nine organisations and ten individuals. These figures do not include clinical stakeholders and organisations that the Scottish Government engaged with during the consultation period.

4. All individual respondents were health professionals with a working knowledge of deceased organ and tissue donation. Organisational respondents were largely those working to deliver deceased donation or clinical representative organisations.

Overview of findings

5. The consultation was undertaken to establish if the proposed medical procedures to be specified were both accurate and comprehensive. Taking into account the relatively small number of respondents, there was little overarching variation or groupings which could be consistently drawn between organisational and individual respondents, or by respondent type, to the questions posed.

Question 1 – procedures not for inclusion

6. Notwithstanding the above, responses did however collate around one topic within the consultation, in response to Question 1, which asked if any proposed procedures for inclusion in the Type A regulations should be removed. A variety of respondents, primarily with experience of intensive care units (both individual and organisational) commented that both computerised tomography (CT) and magnetic resonance imaging (MRI) scans should be removed from the proposed list of Type A procedures. Both these medical procedures require that a patient is transferred to the relevant radiological department within a hospital.

7. Where explanation was provided, respondents focused primarily on the need to move a patient, in order to carry out these scans. It was highlighted that such movement would be routinely completed with agreement of the patient's family.

Therefore, it was suggested these procedures would more appropriately require an additional form of authorisation to that required if listed as Type A.

Question 2 – missing procedures

8. In response to Question 2 a number of respondents suggested a variety of medical procedures for inclusion as Type A pre-death procedures. These are set out in detail on page 13. Such medical procedures could be considered less common or not currently carried out for the purposes of increasing the likelihood of a successful transplantation.

9. Where further explanation was provided, it was highlighted by respondents that there is a clinical requirement to have the widest diagnostic information available for each potential donor.

Question 3 – amendments to wording

10. Responses to Question 3 provided some suggestion for amendment of the proposed list to potentially be less prescriptive in its wording, for example, in relation to the manner in which a urine sample could be taken. Other comment to this question posed more general points on the wider function of the proposed list, in relation to continuing clinical practice and how specifying pre-death procedures will affect their completion in a clinical setting, if at all.

Question 4 – other comment

11. Following and related to Question 2, some responses to Question 4 also emphasised the need for the widest variety of diagnostic procedures to be specified as Type A pre-death procedures, to ensure that potential donor suitability can be established.

12. More broadly, beyond the proposed Type A list, other respondents used this Question to reflect on both the requirements and ongoing implementation of the Human Tissue (Authorisation) (Scotland) Act 2019 ('the 2019 Act'). For example, some respondents commented that the prescriptive nature of setting out medical procedures in a list by regulation may be problematic. It was commented that this approach may be unable to keep pace with advancing medical science and practice.

13. Other responses to the consultation variously highlighted other aspects related to the wider implementation of the 2019 Act. For example, it was noted that the requirement to raise awareness of pre-death procedures and how they are authorised must be both robust and accessible for members of the public. It was commented that this information should make clear that medical procedures being specified as Type A pre-death procedures are established clinical practice and are not a new aspect of donation

Introduction and background

14. Between 30 October and 11 December 2019 the Scottish Government undertook a public consultation to gather views on a list of medical procedures that will be prescribed as Type A pre-death procedures in regulations. Undertaking consultation is a requirement set out by the 2019 Act.[1] The regulations will be enacted on the same day the new deemed authorisation system ('opt out') is implemented in autumn 2020.

15. The consultation paper contained four questions, which sought views on whether a proposed list of medical procedures that will form the content of the Human Tissue (Authorisation) (Specified Type A Procedures) (Scotland) Regulations was both accurate and comprehensive.

16. Pre-death procedures are routine medical procedures and tests normally completed in an ICU to facilitate donation and transplantation of organs and tissue from a potential donor.[2] In the clinical community these are also referred to as ante-mortem interventions.

Policy context

17. In practice, solid organs for transplant have to be removed immediately after the death of a donor and quickly transported to the transplanting hospital. This means there are significant time constraints and some of the procedures that are necessary to assess the suitability of organs and tissue for transplantation, or to increase the likelihood of successful transplantation for the recipient, need to be carried out shortly before death, such as in the case of patients who donate following circulatory death (DCD donation).

18. Pre-death procedures include, for example, the taking of a blood or urine sample, completion of an x-ray or tests on the heart such as an electrocardiogram or echocardiogram. All of these medical procedures may be considered to be routine in a clinical setting. For example, patients in intensive care will have had a urinary catheter inserted.

19. The 2019 Act sets out a clear and dedicated statutory framework for the authorisation and carrying out of these procedures. In order for any pre-death procedure to be completed the requirements of the statutory framework 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 that there is no suggestion that the person would have objected to these being carried

[1] http://www.legislation.gov.uk/asp/2019/11/section/23 (section 16B)
[2] In 2018/19, there was 30 DCD donors in Scotland. Donation following diagnosis of death by neurological criteria (brain death) (DBD donation) accounts for the majority of deceased donation in Scotland and the rest of the UK. In 2018/19 there were 68 DBD donors in Scotland. (https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/17138/nhsbt-scotland-summary-report-sep-19.pdf)

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.

20. The 2019 Act requires that such procedures must be prescribed by regulation, and can either be defined as Type A or Type B procedures. The purpose of this consultation was to determine those medical procedures that would be appropriate to be specified as a Type A pre-death procedure and are also reflective of current clinical practice.

About the respondents and responses

21. The consultation was sent to all NHS Boards, NHS Organ Donation Committees, NHS Blood and Transplant (NHSBT), the Scottish National Blood Transfusion Service (SNBTS) and a number of clinical representative organisations such as the Scottish Intensive Care Society. The consultation received 19 responses, which included a response submitted via e-mail.

22. Responses were submitted by nine organisations and ten individuals (Table 1.0). These figures do not include clinical stakeholders and organisations that the Scottish Government engaged with during the consultation period (Table 1.2).

Table 1.0: Types of respondent

Category	Number of respondents
Organisations	9
Individuals	10
Grand total	**19**

23. All individual respondents to this consultation were working within the clinical community. Organisational respondents included NHS organisations and representative bodies, one local authority and one faith representative organisation.

24. A list of organisational respondents is provided in Annex C of this report. For the purposes of analysis, the organisational respondents were grouped into five categories, as shown in Table 1.1

Table 1.1: Organisation/ Group Type

Category	Number of respondents
NHS Bodies	2
NHS Organ Donation Committee	3
Professional representative organisation	2
Local authority	1
Faith/religion organisation	1

Engagement Exercises

25. In addition to responses received by the Scottish Government the Scottish Government met with the relevant NHS bodies and others involved in delivering deceased donation and transplantation detailed in Table 1.2.

26. The outcomes of these meetings have been included in the qualitative analysis in this report and are referred to only where they contributed distinctive, or new, information and/or views.

Table 1.2: Engagement with stakeholders

Date	Organisation/ Group
08 November 2019	Scottish National Blood Transfusion Service
12 November 2019	NHS Lothian, Director, Edinburgh Transplant Centre
15 November 2019	Golden Jubilee National Hospital, Surgical Transplant Team
22 November 2019	NHS Blood and Transplant

Responses to individual questions

27. As shown in Table 1.3, response rates to individual questions varied, with the most responses in relation to Questions 1 and 2.

Table 1.3: Question response

Question		Number of responses
Q1	If there is anything in the Type A procedures list that you think should **not be included**?	13
Q2	If there is anything **missing** from the Type A procedures list?	14
Q3	If any amendments to the **wording** in the Type A procedures list are required?	9
Q4	If you would like to comment on any other aspect of this consultation?	11

28. Not all of the comments made in relation to each question were necessarily directly relevant to the question being posed – some related to other consultation questions, or to other issues not directly covered by any of the questions in the consultation document, but to wider points regarding the implementation of the 2019 Act. These points were primarily put forward in response to Question 4.

Approach to the analysis

29. All consultation questions were open questions, with ‘free text’ boxes for respondents. Comments made in response to each question were analysed qualitatively. The aim was to identify the main themes and the full range of views expressed in relation to each question, together with areas of potential agreement or disagreement in the views of different types of respondent. This analysis seeks to ensure that differing views on the consulted list, from both professionals and organisations, are presented in a fair and balanced way.

Proposed Type A list

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

The questions

Procedures not for inclusion (Q1)

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.

30. The consultation paper sought views from respondents on whether the proposed Type A pre-death procedures list contained any procedures that should not be included.

31. Altogether, 13 respondents (six individuals and seven organisations) commented on Question 1, of which 10 directly commented on the question. One organisational response to Question 1 did not address the question directly, but overall their response did not highlight any specific requirement to remove any procedure proposed to be specified as Type A.

32. Four individuals did not respond to the question. Two organisations responded, but only to indicate either they had no comment or this question was not applicable for them.

33. Generally, organisational responses to the question were split on the theme of their reply i.e. on whether the list is comprehensive or requires change.

34. Individual respondents made reference to their own clinical experiences when considering this question and, as with organisational responses, variation emerged when answering this question.

35. However, consensus did emerge to a certain degree between both organisational and individual respondents around two procedures that were suggested for removal and this is set out below.

Procedures should be removed

36. Respondents commenting that procedures *should* be removed from the Type A procedure list fell into both organisational and individual categories, with no clear distinction between the two groups and respondent types as to their responses. Instead, the clinical experiences of each respondent informed both the views of individuals as well as organisational replies, with experience of working to achieve DCD donation.

37. Responses requesting the removal of procedures as Type A did however coalesce around two specific procedures: computerised tomography (CT) scanning and magnetic resonance imaging (MRI). Seven responses (three individuals and four organisations) requested these procedures should not be included in a prescribed Type A list.

CT and MRI

38. Respondents focused on and were consistent in explaining why CT and MRI should not be considered as a Type A procedure. It was generally set out that this was due to the risks associated with transferring a patient to carry out these procedures. Respondents set out that a number of wider considerations are also related to this and which also informed their recommendation that CT/MRI should be removed.

The movement of a patient

39. All respondents (both individual and organisational) recommending the removal of CT and MRI highlighted the risks associated with moving the patient from ICU, to the location where these scans would take place.

40. It was indicated by some respondents that, due to the need to move a patient, they would expect specific agreement to be sought from a donor's family before these procedures could be completed, rather than authorisation for the procedure to be deemed via being prescribed as a Type A procedure.

41. Discussions with clinical stakeholders throughout the consultation period provided further context to this point, highlighting that every ICU and hospital is potentially different in the location of imaging units. Some ICU's are immediately next to CT and MRI facilities, while others may be several floors away and these factors may currently be taken into account in deciding whether carrying them out would be appropriate.

Other considerations regarding CT/MRI

42. Respondents set out other considerations related to a requirement to move a patient, including:

- *Balance of risk/benefit*: some respondents, both individual and organisational, commented that the completion of a CT or MRI is not currently routine practice for facilitating DCD donation. It was also advised that similar results might be obtained reliably using other methods not requiring movement of the patient. Therefore, such respondents advised that there might not be sufficient justification for moving a patient outwith ICU.
- *Potential impact on ICU staff:* Two respondents linked the need to move the patient to a corresponding impact on the wider ability of the ICU to function effectively, describing an impact on staff time to complete such scans. This impact is as a result of the overall time consuming nature of completing these imaging techniques.
- *Potential impact on donor family:* One respondent referenced the impact it can have upon the donor family, in terms of time spent away from their loved one.

Ultrasound scanning

43. Related to the above responses regarding movement of a patient, two organisational respondents suggested the removal of ultrasound scanning from the Type A list.

44. Some ultrasound scanning can take place outwith ICU. Like the imaging procedures discussed above, this may require movement of a patient to the relevant unit. Other forms of ultrasound scanning can however be completed at the beside in ICU and will not require any movement of a patient.

45. These organisations advised they could not support the consulted Type A list if it would permit a patient being removed from ICU.

46. As discussed above, it was made clear by clinical stakeholders that in a clinical setting removal of a patient from ICU would routinely necessitate agreement of the family. In the view of respondents on this matter, deeming authorisation for patient removal from ICU may not align with such practice.

Other comment – faith

47. Similar comments regarding movement of a patient to those outlined above were made by a representative faith organisation.

48. The respondent set out the overall position for their faith community in relation to medical tests and end of life care, specifically addressing the movement of a person of that faith at the time of their death. It was explained that, in most circumstances, their faith requires that a person is neither touched nor moved when near to death to avoid hastening this moment, or touched immediately following death.

49. However the respondent acknowledged that for those of their faith who may be in ICU at the end of life, this context is different for such persons. The response highlighted that moving a patient at the end of life in a hospital setting may be required. The respondent noted that this potential medical requirement will have to be reconciled to the requirements of their faith during end of life care and is a consideration that person's family would have to address.

50. In this context, the respondent did not support prescribing any Type A pre-death procedures that involve potentially moving a patient outwith ICU.

List is comprehensive

51. Four respondents (two individuals and two organisations) indicated that the provided list was comprehensive in the context of DCD donation and the procedures within this list would be suitable to be categorised as Type A, under the new statutory framework.

52. Respondents who advised that the proposed list was comprehensive did so with reference to their own clinical experience, and with reference to the general requirements of DCD donation in a clinical setting.

Additional procedures which should be listed (Q2)

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

53. The consultation paper asked if there were any medical procedures that may be missing from the proposed Type A list.

54. 13 out of 19 respondents provided an answer to Question 2. Of these, nine respondents (individual and organisational) provided a variety of suggestions for procedures to be included as Type A procedures that were not present on the consulted list. The remaining respondents either responded to indicate they had no comment (two) or that no procedure was missing and the list was comprehensive (two). Six respondents did not respond to this question.

55. As with Question 1, there was no clear distinction between either individual or organisational respondents in the theme or content of their responses. There was some crossover between different respondents in what procedures were suggested, which are highlighted below, but this was minimal.

56. One organisational respondent did not specifically highlight any missing procedures in their answer, but instead emphasised that the new statutory framework should, as far as possible, support appropriate clinical judgement within the parameters of the new regulatory framework.

Procedures should be added

Suggested procedures

57. In total, there were nine medical procedures suggested for inclusion in the Type A list, suggested by eight respondents. These respondents were either individuals, a representative organisation or NHS body. The following procedures were put forward for inclusion as appropriate to be categorised as a Type A procedure:

- Administration of heparin;
- Administration of steroids;
- Bronchoscopy;
- Oesophageal doppler;
- Pulmonary artery floatation catheterisation (PAFC);
- Taking of stool samples;
- Transoesophageal echocardiogram (TOE);
- Skin biopsy;

- Swabbing or scraping of orifices other than inside of nose, mouth and ear

58. Generally, reasons provided for the inclusion of each of these procedures (where provided by the respondent) were to ensure that clinicians had the widest possible diagnostic options available to them under the new statutory framework. A number of respondents made this point in response to Question 4, rather than Question 2.

59. This point was drawn out further in direct engagement with clinical stakeholders who advised that in circumstances where a patient's condition did not permit a certain method (which may be as set out in the Type A list), other methods of obtaining that information could be inadvertently closed to them, which could mean donation would not proceed.

List is comprehensive

60. Two organisational respondents advised in their response that nothing was missing from the consulted list.

Amendments to wording (Q3)

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

61. The consultation paper invited respondents to consider the wording of the procedures on the proposed Type A list.

62. 13 of 19 respondents responded to this question. Five of these responses indicated that the respondent had either no comment on the list in this regard or it was 'N/A'. Of the remaining eight respondents that submitted a comment (five organisations and 3 individuals) each respondent highlighted different parts of the consulted list or used their response to this question to more widely reflect or comment upon the new statutory framework governing pre-death procedures set out in the 2019 Act.

Proposed amendments

63. Some respondents noted that the proposed wording for the collection of a urine sample ('taking of a urine sample by way of a urinary catheter') could be too restrictive as not all patients might have a urinary catheter already inserted due to their clinical condition.

64. Engagement with clinical stakeholders during the consultation period indicated that such an occurrence will be rare, but nonetheless may be the case.

65. It was suggested that this may be amended in the Type A list to a less prescriptive description, to allow other methods to be carried out as Type A.

66. A further suggestion was made by one respondent regarding the phrasing to describe continuing artificial ventilation.

Other comments

67. Beyond direct suggestions as provided above, some respondents who provided a substantive response to this question did not directly answer it but instead posed questions or other considerations.

68. One organisational response was submitted that reflected more widely on the ability of the regulations to be amended as required timeously.

69. This respondent noted that it takes time and resources for all parties involved, so as a result the prescription of such a list should be sought to be future proofed as far as possible. Echoing discussions with clinical stakeholders throughout the consultation process and comments by other respondents made elsewhere, this comment highlighted that emerging medical technologies will likely mean that any set list will require amendment in the near future as newer technologies emerge and clinical practice develops.

Other comment on consultation (Q4)

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

70. The final question provided respondents the opportunity to submit more general or wide-ranging responses to the consultation paper. 13 respondents (six individual and seven organisation) submitted a response to this question.

71. Two respondents (one organisation and one individual) responded only to state ‘nil to add’. The remaining 11 respondents generally used this question to summarise points made in response to previous questions or to reflect more widely on the implementation of the 2019 Act.

72. A number of organisational and individual respondents suggested that the approach set out by the 2019 Act, which requires that pre-death procedures are specified in regulation, is overly prescriptive and may be impractical in the long term and could be unlikely to work in practice.

73. Related to this, some respondents commented that any list must be as comprehensive as possible to avoid procedures that may be required for a potential donor being unavailable. In relation to the duty to inquire about a potential donor’s views about pre-death procedures, two respondents noted that this could be potentially burdensome on families and could impact on the length of the donation process which in turn could affect the willingness of families to support the process.

74. Some respondents did state their support for the prescribed list of pre-death procedures or to note that, in principle, setting out a specified list could be helpful and provide clarity for the clinical community.

75. Other respondents commented more widely on the future operation of a deemed authorisation (opt-out) system in Scotland, and the importance of public information in order for such a system to function effectively. In relation to pre-death procedures, one clinical respondent highlighted the importance of awareness raising making clear that pre-death procedures are not new and are established medical procedures.

76. Related to awareness raising, one respondent, on behalf of a representative faith organisation, stated their support for and made a request that the Scottish Government include, within the public facing organ donor register for Scottish residents, an option for a person to indicate that their faith is important to them. The respondent put forward that this option to record a faith consideration as part of registration for deceased donation would provide further reassurance for members of a faith group that their faith and beliefs would be taken fully into account.

77. Some respondents expressed concern that a draft Type B pre-death procedure list has not yet been consulted upon and noted that it may be difficult to provide views on Type A in isolation. One respondent observed that progression of the Type B list separately might mean that procedures that are more appropriately classified as Type B, are suggested for inclusion on the Type A list. However others noted that the timescales for Type B regulations must not affect what is present on the Type A list. One organisational respondent cautioned that not having a Type B procedure list implemented at the same time as the Type A list could result in lost donor potential.

Annex A: Consultation questions

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.

Annex B: List of organisational respondents

A total of 9 organisations responded to the consultation:

Aberdeen City Council
NHS Ayrshire & Arran Organ Donation Committee
NHS Blood and Transplant (NHSBT)
NHS Greater Glasgow and Clyde Organ Donation Committee
NHS Tayside Organ Donation Committee
The Royal College of Surgeons of Edinburgh
Scottish Council of Jewish Communities (SCoJeC)
Scottish Intensive Care Society (SICS)
Scottish National Blood Transfusion Service (SNBTS)

This publication is available at **www.gov.scot**

Any enquiries regarding this publication should be sent to us at

The Scottish Government
St Andrew's House
Edinburgh
EH1 3DG

ISBN: 978-1-83960-581-9 (web only)

Published by The Scottish Government, February 2020

Produced for The Scottish Government by APS Group Scotland, 21 Tennant Street, Edinburgh EH6 5NA
PPDAS700506 (02/20)