The Human Tissue (Authorisation) (Scotland) Act 2019

Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations: Analysis of consultation responses

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Executive summary

Introduction

1. Between 8 October and 20 November 2020 the Scottish Government undertook a public consultation to gather views on a list of medical procedures to be prescribed as Type B pre-death procedures, which will be specified by the Human Tissue (Authorisation) (Specified Type B Procedures) (Scotland) Regulations.

2. Type B procedures are medical procedures which are likely to be less routine, or more novel, in the context of transplantation. This means they may need some additional authorisation or additional requirements before they could be undertaken and the consultation also sought views on these aspects of the regulations.

The respondents

3. The consultation received 15 responses. Responses were submitted by 5 organisations and 10 individuals.

4. All individual respondents had 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 and to seek views on the proposed authorisation methods and additional requirements. 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, to the questions posed.

<u>Question 1 – procedures not for inclusion</u>

6. In response to Question 1, which asked if any proposed procedures for inclusion in the Type B regulations should be removed, the majority of respondents commented that no procedures needed to be removed from the Type B list. A smaller number of responses (2 individuals) indicated that X-ray, Ultrasound, Transthoracic echocardiography be removed from the list because they can be performed at the bedside. It was also suggested by an individual that MRI be removed as the transportation and time needed to perform this procedure would not bring benefit.

Question 2 – missing procedures

7. In response to Question 2, which asked if there were any medical procedures that may be missing from the proposed Type B procedure list, over half of respondents responded that the list was comprehensive and no other procedures needed to be included. Responses from just under half of respondents suggested the inclusion of a procedure. The procedures proposed for inclusion included Transoesophageal echo, Lumbar Puncture, and blood drawing for the purpose of genetic testing. Adding Transoesophageal echo to the list was suggested by both individual and organisational respondents.

8. One organisational response also suggested clarification on paragraph 39 of the Type B consultation, in relation to moving patients to carry out imaging procedures, as the intention of the statement is not clear in regard to whether it is the moving of the patient that introduces risk, or the nature of the procedure itself.

Question 3 – amendments to wording

9. In response to Question 3, which invited respondents to consider the wording of the procedures on the proposed Type B list, the majority of responses indicated that no amendments were needed. A smaller number of respondents indicated that clarification on the stipulation for movement of patients and intention behind this stipulation was needed.

Question 4 – Type B carried out only if Type A is insufficient

10. In response to Question 4, all respondents indicated that they agreed with 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 – Two registered medical practitioners to confirm requirements

11. Question 5 asked respondents to share their views on the proposed condition that the agreement of 2 registered medical practitioners (RMPs), 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.

12. The majority of respondents agreed with this condition, with and without notes or caveats. Three respondents disagreed with this condition, which centred mainly on the perceived lack of necessity of the condition. One organisational respondent did not express direct support or disagreement with the condition, but sought clarity on a number of points.

13. There were some themes which ran across the comments expressed by those in favour of this condition, those in disagreement, and those seeking clarification. Comments centred on the potential challenges or appropriateness posed by a transplant clinician fulfilling the role of RMPs and clarification needed on the seniority of staff fulfilling the RMP role.

Question 6 – Conditions applied to all specified procedures

14. In response to Question 6, which invited respondents to share their views on the approach that the conditions should apply to all specified procedures, the majority of respondents agreed with the approach that these conditions should apply to all specified procedures.

15. About a quarter did not agree with the approach for reasons centring on challenges in achieving the approach in practice.

Question 7 – Express authorisation or nearest relative authorisation

16. Question 7 invited respondents to share their views on the proposition that all specified procedures are able to be carried out either with express authorisation by the individual or with nearest relative authorisation.

17. The majority of respondents agreed with the proposition set out in the question, with and without caveats and clarifications to their support.

Introduction and background

18. Between 8 October and 20 November 2020 the Scottish Government undertook a public consultation to gather views on a list of medical procedures that will be prescribed as Type B pre-death procedures in regulations and the associated authorisation requirements and additional conditions. Undertaking consultation before the laying of the regulations is a requirement set out by the 2019 Act. The intention is that the regulations will be enacted on the same day the new deemed authorisation system ('opt out') is implemented in March 2021.

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

20. Type B procedures are medical procedures which are likely to be less routine, or more novel, in the context of transplantation. This means they may need some additional authorisation or additional requirements before they could be undertaken and the consultation also sought views on these aspects of the regulations.

21. Pre-death procedures are medical procedures and tests, normally carried out in the intensive care unit (ICU) of a hospital, that will facilitate donation and transplantation of organs and tissue from a potential donor.[1] In the clinical community these are also referred to as ante-mortem interventions.

Policy context

22. The Human Tissue (Authorisation) (Scotland) Act 2019 sets out a dedicated statutory framework for the authorisation and carrying out of medical procedures for the purpose of facilitating transplantation. These are referred to as 'pre-death procedures' in the Act. Scottish Ministers may, by regulation, specify pre-death procedures as either Type A or Type B. The purpose of this consultation was to determine those medical procedures that would be appropriate to be specified as a Type B pre-death procedure and to seek views on the proposed authorisation methods and additional conditions.

[1] 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)

About the respondents and responses

23. 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, as well as faith representatives. The consultation received 15 responses.

24. Responses were submitted by 5 organisations and 10 individuals (Table 1.0).

Table 1.0: Types of respondent

Category	Number of respondents
Organisations	5
Individuals	10
Total	**15**

25. All individual respondents to this consultation had a knowledge of the operation of the deceased donation pathway. Organisational respondents included NHS organisations and clinical representative bodies.

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

Table 1.1: Organisation/ Group Type

Category	Number of respondents
NHS Bodies	3
NHS Organ Donation Committee	1
Professional representative organisation	1

Responses to individual questions

27. Table 1.2, shows response rates to individual questions.

Table 1.2: Question response

Question		Number of responses
Q1	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.	15
Q2	If there is any medical procedure not listed in the Type B procedures list, which you think should be included in this	15

	category, please comment here, and provide reasons why you think it should be included.	
Q3	If you think that any amendments to the wording in the Type B procedures list are required, please comment here.	13
Q4	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.	15
Q5	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.	15
Q6	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.	15
Q7	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.	15

Approach to the analysis

28. 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 aims to identify areas of agreement or disagreement and present all views in a fair and balanced way.

Proposed Type B list

29. The consultation proposed that the medical procedures listed below should be specified as Type B pre-death 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[2]

- Bronchoscopy
- Skin biopsy
- Scraping or swabbing of a body orifice (other than mouth, nostril or ear canal).

[2] 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. The consultation paper 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.

The questions

Q1. Procedures not for inclusion

> 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.

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

31. Altogether, 14 respondents (9 individuals and 5 organisations) directly commented on Question 1. One further individual indicated no comment on this question. Responses fell into two main categories. By majority, respondents felt that the list was comprehensive, and a small minority (2 respondents) felt that one or more procedures should be removed, namely X-ray, Ultrasound, Transthoracic echocardiography, and MRI. One organisational respondent indicated a lack of consensus on whether any procedures should be removed from the list.

List is comprehensive

32. A large majority of individual and organisational responses to the question indicated the view that the no procedures needed removal from the Type B list and that those listed were deemed appropriate, with 11 responses in total (6 individual and 5 organisational).

33. A few of these respondents made additional comments. An individual respondent noted concern about distress that might be caused to families if, or when, patients are moved for testing. Another individual response explained that testing of skin biopsy and skin scraping samples may be a logistical challenge for outlying hospitals as on-site testing might not be available out of hours, and would thus require being sent to an off-site lab, delaying the return of results. Two respondents (organisational and individual) commented that the potential donor and their family are at the centre of all decisions taken in the peri-mortem phase, and that these regulations protect the potential donor, family, and clinicians against Type B regulations being carried out if evidence exists indicating that the patient would not have been in favour.

Procedures should be removed

34. A smaller number of responses (2 individuals) indicated that particular procedures should be removed from the list, namely: X-ray, Ultrasound, Transthoracic echocardiography, and MRI.

35. The individual who suggested that X-ray, Ultrasound, Transthoracic echocardiography be removed commented that these procedures can be

performed at the bedside without discomfort to the patient, and therefore should not be included in the Type B procedure list.

36. The individual who responded that MRI should be removed from the list commented that the transportation and time needed to perform this procedure would not bring benefit.

Additional comments

37. One organisational response explained that consensus among their cohort of ICU consultants was not reached in regards to whether the Type B procedures list should be amended. The response indicated concerns over the inclusion of Bronchoscopy, Skin Biopsy, and Scraping of Body Orifice on the list as they may cause significant discomfort for patients, but did not suggest their removal. Feedback from this organisation also emphasised their understanding that these procedures may improve the ability of transplant teams to assess suitability of an organ for transplantation and potentially improve outcomes for recipients.

Q2. Additional procedures which should be listed

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.

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

39. Thirteen out of 15 respondents directly responded to Question 2. Two respondents (both individuals) indicated no comment. Responses fell into three categories. Over half of respondents responded that the list was comprehensive and no other procedures needed to be included, and responses from just under half of respondents suggested the inclusion of a procedure. The procedures proposed for inclusion included: Transoesophageal echo, Lumbar Puncture, and blood drawing for the purpose of genetic testing.

List is comprehensive

40. Eight respondents (5 individual and 3 organisational) responded that the list was comprehensive, and additions were not needed.

41. One of these organisational respondents indicated that while no additions to the Type B list were required, the need to make additions to the Type B list will likely arise as advances in medical procedures are made. In light of this, this group suggested that express and deemed authorisation should be the requirement for any procedure deemed necessary for the donation process, as making additions to the Type B procedures regulations may require considerable time, and so making it difficult for the Type B list to keep pace with medical advancement.

Procedures should be added

42. Five respondents (3 individuals and 2 organisational) provided suggestions for procedures to be included as Type B procedures that were not present on the consulted list.

43. As with Question 1, there was no clear distinction between either individual or organisational respondents in the theme or content of their responses regarding suggested additions to the Type B list. One procedure was suggested by both individual and organisational respondents.

Suggested procedures

44. In total, there were 3 medical procedures suggested for inclusion in the Type B list, suggested by 5 respondents:

- Transoesophageal echo (TOE)

- Lumbar Puncture
- Blood drawing for the purpose of genetic testing

45. Four respondents (2 individual and 2 organisational respondents) suggested that TOE be added, or considered for inclusion on the list. Reasons provided by 2 respondents (organisational and individual) for the inclusion of TOE centred on the view that this procedure could provide more detailed and sufficient information on the heart in a patient being considered for heart donation than a transthoracic echocardiogram, which appears on the consulted list of procedures. Another reason provided by an organisational respondent is that inclusion of this procedure will 'future-proof' the Type B regulations, and this procedure is likely to be used within the decade. The fourth respondent (individual) did not explain their reasoning.

46. The inclusion of the lumbar procedure was suggested by an organisational respondent, a suggestion based on a limited number of occasions in the past where these tests have been requested to rule out meningitis and the results have been a factor in the acceptance of organs.

47. The inclusion of blood drawing for the purpose of genetic testing was suggested by an individual respondent. This respondent did not explain their reasoning.

Additional comment

48. One organisational response also suggested clarification on paragraph 39 of the Type B Consultation, which includes the language: "Carrying out radiological imaging which requires moving a patient from their existing location, including…" The respondent commented the intention of the statement is not clear, and they assume it means that it is the moving of the patient that introduces risk, not the nature of the procedure itself. The suggestion is that the legislation should put focus on the logistics, not the procedure. They also explain that their reading of the legislation is that it stipulates that the limitations on moving a patient to undertake a procedure would not extend to moving a patient for the purposes of withdrawing life-sustaining treatment outside of the intensive care setting.

Q3. Amendments to wording (Q3)

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

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

50. Thirteen responses were received for this question, one of which indicated 'not applicable'. Two respondents did not make any comment in response to this question. Responses fell into 2 categories. By majority, responses indicated that no amendments were needed. A smaller number of respondents indicated that amendments to wording were need to clarify the stipulation regarding movement of patients and intention behind this stipulation.

No Amendment Needed

51. Nine respondents (5 individuals and 4 organisational) responded that no amendments to the wording of the Type B procedures list were required.

Amendments Needed

52. Three respondents (2 individual and 1 organisational) made suggested amendments to the wording of the Type B procedures list.

Proposed amendments

53. All 3 respondents suggested that rewording is needed to provide greater clarity regarding stipulations about the movement of patients to different locations for procedures.

54. Two respondents (individual and organisational) commented that clarification of the intention of these stipulations would be useful. Comment was made that it is currently unclear if the movement of the patient or the procedure itself introduces risk to the patient. Additionally, further clarification was requested on whether the limitations on moving a patient to undertake a procedure would not extend to moving a patient for the purposes of withdrawing life-sustaining treatment outside of the intensive care setting.

55. An individual respondent also questioned why the imaging procedures are grouped into two sections.

Q4. Type B procedure carried out only if Type A insufficient

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.

56. Question 4 invited respondents to share their 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.

57. Fifteen of 15 respondents (5 organisational and 10 individual) directly responded to this question.

58. All 15 respondents responded that they agree with the condition that a Type B procedure may only be carried out if there is no Type A procedure which can provide the necessary information. Five of these respondents explicitly cited the view that this condition represents good, ethical clinical practice and protects the potential donor from unnecessary tests.

59. Two respondents included additional views on this condition including that evidence for Type B procedures should be explicit, and that if a Type B procedure cannot provide a definitive answer, then the Type B procedure should not proceed.

Q5. Two Registered Medical Practitioners to confirm requirements for Type B procedure

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.

60. Question 5 invited respondents to share their views on the proposed condition that the agreement of two Registered Medical Practitioners (RMPs), 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.

61. Fifteen of 15 respondents (5 organisational and 10 individual) gave direct responses to this question. The majority of respondents agreed with this condition, with and without caveats. About a quarter of respondents disagreed with this condition, and one organisational respondent did not express direct support or disagreement but sought clarity on a number of points. There were some themes which ran across the comments expressed by all respondents. These centred on the appropriateness of a transplant clinician fulfilling the role of an RMP and clarification needed on the seniority of staff fulfilling the RMP role.

Agreement with Condition

62. Three respondents (2 individual and 1 organisational) agreed with this condition without caveats or conditions.

Agreement with caveats or notes

63. Nine respondents (6 individual and 3 organisational) agreed with this condition with caveats or notes.

64. The focus of these caveats centred on greater specification on who may fulfil the RMP role. The nature of queries about this specification included:

    a. Three respondents (2 individual and 1 organisational) suggested that it may be useful to specify if a particular seniority of the medical practitioners, e.g. consultants or senior registrars, is needed.

    b. Three respondents (2 individual and 1 organisational) commented that one of the RMPs should be a clinician who is responsible for the patient.

c. One of these respondents was more specific on this point and noted that one of the RMPs should be an ICU clinician responsible for the patient at the time, and that it would be inappropriate for both RMPs to be surgeons.

d. Three respondents (1 individual and 2 organisational) commented that the RMPs should not be a clinician involved in the transplantation process as this poses a conflict of interest, and may risk public trust in the donation process.

e. An individual respondent noted that the condition may not be practical or achievable in clinical practice at times when a reduced number of trained medical practitioners are available.

f. One individual response questioned whether there is a need to specify the clinical areas or range of the RMPs if the goal is to ensure that RMPs are not from within the same team.

g. Another organisational respondent noted agreement that at least two RMPs should confirm the requirement for a type B procedure, however an additional registered medical practitioner may be required if consensus cannot be achieved.

Disagreement with Condition

65. Three respondents (all individual) commented that they did not agree with the condition described in Question 5.

66. All 3 of these respondents questioned the rationale of needing two RMPs' sign-off to proceed with a Type B procedure. The reasoning behind the disagreement with this aspect of the condition fell into two main categories:

    a. Two of the respondents (both individual) highlighted that a single senior medical practitioner should be able to make the decision to proceed with a Type B procedure, though one of these respondents caveated that this decision could be made by a senior clinician in collaboration with a SNOD.

    b. One respondent expressed concern about the involvement of a transplantation clinician as an RMP. This respondent noted that it would be a logistical challenge, and not in line with current practice, for an ICU consultant and transplant surgeon to discuss the appropriateness of a Type B procedure as transplant staff only arrive to the hospital in the event of organ or tissue retrieval.

No express support for, or disagreement with, the condition

67. One organisational respondent did not express direct support or disagreement with the condition, but sought clarity on a number of points:

a. The respondent highlighted that a single senior medical practitioner should be able to make the decision to proceed with a Type B procedure.

b. They expressed concern about the involvement of transplantation clinician as an RMP. One respondent (organisational) commented that greater clarity is needed on whether the RMP(s) making the decision could be the transplanting surgeon. This respondent also noted that if transplant surgeons are involved, then there is the risk that this could be viewed as a conflict of interest.

c. They suggested that it may be operationally difficult to achieve two senior RMPs out of hours, which may pose a challenge to meeting this condition, a concern iterated by a respondent in favour of the condition.

d. The respondent noted that it is not clear from the document where the decision should be recorded to evidence that the discussion has taken place.

Additional note for consideration

68. Four respondents (two organisational and two individual) specifically, positively highlighted the aspect of the condition that states the agreement about a Type B procedure would be recorded. One of these individual respondents did not however agree that that level of consensus stipulated by the condition was needed.

Q6. Application of conditions to all specified procedures

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.

69. Question 6 invited respondents to share their views on the approach that the conditions should apply to all specified procedures.

70. Fourteen of 15 respondents (6 organisational and 8 individual) gave direct responses to this question. One respondent (individual) gave no comment. Responses fell into 2 categories; the majority of respondents agreed with the approach that these conditions should apply to all specified procedures, and about a quarter did not agree with the approach for reasons centring on challenges in achieving the approach in practice.

Agreement with Approach

71. Ten respondents (5 individual and 5 organisational) responded positively to the approach that the conditions should apply to all specified procedures.

72. Reasoning for respondents' agreement included:

    a. Four respondents (1 individual and 3 organisational) highlighted that applying conditions to all specified procedures will make the process simpler, more understandable, and will therefore enable staff to deliver it more consistently.

    b. One respondent (organisational) also commented that application of the conditions will provide further assurance to family members and others who might consider donation in the future.

Disagreement with Approach

73. Four respondents (all individual) responded that they did not agree that the conditions should apply to all specified procedures. Reasoning for respondents' disagreement included:

    a. Two respondents (individual) expressed concerns about the conditions working in practice, commenting that there would likely be cases in which 2 RMPs are unavailable to make a decision about a Type B procedure.

    b. One respondent (individual) shared the view that this approach created unnecessary complications, which should instead be seen as routine, and that any procedure required to facilitate donation should be done.

c. One respondent (individual) did not think that the application of these conditions should be required for minimally invasive swab collections.

Q7. All specified procedures carried out with express authorisation by potential donor/nearest relative

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.

74. Question 7 invited respondents to share their views on the proposition that all specified procedures are able to be carried out either with express authorisation by the individual or with nearest relative authorisation. Thirteen out of 15 respondents responded to this question. 2 respondents (both individual) noted 'no additional comments' or 'currently undecided on this matter'. By majority (12 respondents) agreed with the proposition set out in the question, with and without caveats and clarifications to their support, and one respondent indicated issue with the proposal as it is currently set out.

Agreement with proposition

75. Three respondents (2 individual and 1 organisational) agreed with the proposition set out in Question 7 without additional comments.

76. Nine respondents (6 individuals and 3 organisational) agreed with the proposition set out in Question 7, while also describing clarifications or caveats to their support, which centred on the challenges of obtaining express authorisation and the need to sufficiently inform the patient family, and take into account their wellbeing.

77. By majority, respondents' (3 individual and 4 organisational) comments focussed on the potential challenges of obtaining express authorisation from a potential donor. It was explained this was due to potential donors very rarely being conscious at the time of pre-death procedure discussions, and potentially insufficient information about Type B procedures on the ODR to which a patient may have previously registered a decision to donate. These respondents articulated that nearest relative authorisation was the more likely, preferred option and that it is consistent with current practice for these kinds of medical procedures and would be consistent with the approach to donation and Type A procedures, which nearest relatives may authorise in certain circumstances.

78. 2 organisational respondents commented on patient family experience and proper information provision in regards to nearest relative authorisation. One of these respondents expressed concerns about relatives' reluctance to provide authorisation for procedures that are painful. It was also stressed that relatives must be provided with open and honest information on the risks, including pain and discomfort, of Type B procedures. One of these respondents also noted that regardless of the potential donor's decision, patient families must be supported to avoid future regrets about their decision.

79. One respondent (individual) noted their agreement with the proposition, while also acknowledging the challenge of moving a patient with a relative present.

Issue with proposition

80. One respondent (individual) indicated issue with the proposal as it is currently set out. They commented that Type B procedures should be discussed with individuals or patient families, but as a complete set, rather than piecemeal seeking of authorisation for each test.

Annex A: Consultation questions

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 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.

Annex B: List of organisational respondents

A total of 5 organisations responded to the consultation:

NHS Ayrshire and Arran
NHS Blood and Transplant (NHSBT)
NHS Greater Glasgow & Clyde, Organ Donation Committee
Scottish Intensive Care Society (SICS)
Scottish National Blood Transfusion Service (SNBTS)

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