The Human Tissue (Excepted Body Parts) (Scotland) Regulations

Analysis of consultation responses

September 2020

Scottish Government
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Introduction

1. Between 14 February and 27 March 2020 the Scottish Government undertook a public consultation to gather views on parts of the body that deemed authorisation will **not** apply to, once an 'opt out' system of donation is brought into force.

2. The Human Tissue (Authorisation) (Scotland) Act 2019 ("the 2019 Act"), which will introduce an opt out system of organ and tissue donation in Scotland was due to be implemented in autumn 2020, replacing the current 'opt in' model. This would follow Wales, which introduced such a system in December 2015 and England, where an opt out system of donation came into force on 20 May 2020.

3. Due to the coronavirus (COVID-19) pandemic, implementation of the 2019 Act has been postponed until 26 March 2021.

4. As part of the ongoing implementation of the 2019 Act, there is a requirement to implement secondary legislation which will specify the parts of the body that deemed authorisation will **not** apply to.

5. The Scottish Government has committed to a significant public awareness campaign around the law change. This wider campaign of public awareness on organ and tissue donation will include accessible information being provided on parts of the body the new deemed authorisation system will apply to and not apply to.

Background

6. Setting out parts of the body that deemed authorisation will not apply to is intended to act as a safeguard in the new legislation for potential donors. The effect of The Human Tissue (Excepted Body Parts) (Scotland) Regulations ("the regulations") once in force, will ensure that deemed authorisation for transplantation will only apply to the commonly donated parts of the body. This was a stated aim and intention of the new law, ensuring that novel parts of the body will not be included for transplant under deemed authorisation, but instead require further authorisation from the nearest relative.

7. It should be noted that this policy follows clinical practice under the current 'opt in' system, provided for by the Human Tissue (Scotland) Act 2006. For example, nearest relative authorisation for donation would currently be taken for a novel transplant (e.g. a hand). Under the new system this process will remain the same in practice for potential donors progressing via deemed authorisation.

8. A nearest relative will be able to provide authorisation for removal and transplantation of any part listed within the regulations. However based on current practice, it would be rare that a family would be approached about the possibility of donation of excepted body parts.

9. The regulations will relate only to deemed authorisation which applies only to adults (age 16 and over). The regulations don't affect which organs/tissue may

be donated under express authorisation, although in practice it will be rare for the 'excepted body parts' as listed in the regulations to be donated for transplantation under express authorisation, due to the low level of clinical need.

About the respondents and responses

10. The consultation was circulated to all NHS Boards, NHS Organ Donation Committees, NHS Blood and Transplant (NHSBT), the Scottish National Blood Transfusion Service (SNBTS) and a variety of clinical representative organisations. The consultation received 13 responses, which included two responses submitted via e-mail following the closure of the consultation.

11. Responses were submitted by eight organisations and five individuals (Table 1.0).

Table 1.0

Category	**Number of respondents**
Organisations	8
Individuals	5
Total	13

12. Individual respondents to the consultation either indicated within their response they possessed a clinical background, or that they were familiar with the donation and transplantation pathway. Organisational respondents included NHS organisations, clinical representative bodies, a charity, a private business and a university ethics department.

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

Table 1.1

Category	**Number of respondents**
NHS Bodies	2
Professional representative organisation	3
Private company	1
University	1
Charity	1
Total	8

Responses to individual questions

14. As shown in Table 1.2, response rates to individual questions varied, with the most responses in relation to Questions 1 and 4.

Table 1.2

Question	Number of responses
Q1.a	12
Q1.b	6
Q2.a	9
Q2.b	5
Q3.a	9
Q3.b	6
Q4	11

15. It should be noted that throughout the consultation some responses offered alternative suggestions in answer to the questions and some simply indicated they agreed with the proposal, with no further comment.

16. Not all comments made in relation to each question was directly relevant to the question being posed. For example, providing comment or observation on other issues not directly covered in the consultation document matter, such as wider points regarding the implementation of the 2019 Act.

17. 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 on the proposed content of the regulation. This analysis seeks to ensure that differing views on the consulted lists, from both individuals and organisations, are presented in a fair and balanced way.

Consulted parts and explanatory function

18. The consultation paper itself, under the subheading 'intention of the proposed regulations' sets out what parts of the body were consulted upon and how the regulations will function in practice. This can be reviewed on the Scottish Government website.

Listed parts – Group 1 (Q1)

Question 1a): Are there any parts of the body in group 1 that should not be listed? Please explain below.

19. Altogether, 12 respondents answered this question. Ten respondents confirmed that they believed the consulted Group 1 list did not require amendment to remove anything. Some respondents offered comments which were broader than the specific question – these are detailed in the analysis of responses to question 4.

20. Two individuals raised two separate matters as part of their comment on Group 1. These responses put forward that:

- The trachea should not be listed as part of Group 1, since this part of the body is removed and donated as part of both a 'dual lung block' or 'heart-lung block' transplant (i.e. the trachea is removed as routine for transplantation as part of these transplants). It was also noted that the trachea is used in relation to stem cell transplants for children.
- The labia and vulva 'are the same thing', whereas the consulted list included both terms separately.

Question 1b): If there is anything that is missing from group 1, please comment here giving reasons why.

21. Six respondents answered Question 1b. Four of these answers indicated that they did not believe there was anything missing from the consulted list.

22. Two respondents provided answers suggesting parts that might be included within Group 1. Both these related to tissues located in the breast, genital and anal areas, including the areola, scrotum, urethra and breast tissue.

23. A respondent also suggested that this regulation should, following the UK Department of Health and Social Care's comparable regulation applicable to England, address advanced medicinal therapy products (ATMP), as it is desirable for the regulations to be as consistent as possible, though noted that the regulation must reflect the Scottish legislative framework.

Listed parts – Group 2 (Q2)

Question 2a): Are there any parts of the body in Group 2 that should not be listed? Please explain below.

24. Overall, nine respondents answered Question 2a concerning Group 2. Seven respondents did not believe any part listed under this group needs to be removed and were content with the consulted list. One respondent offered comments which were broader than the specific question – this is detailed in the analysis of responses to question 4.

25. One substantive response to this question considered that the 'face' could be removed from Group 2 and instead placed in Group 1 i.e. no part of the face could be deemed for removal. This was proposed as it was noted the face 'is a body part that may be regarded as particularly sensitive and evoke strong feelings due to the perceived link between the face and personal identity'. It was also noted that movement of the face into Group 1 may more likely mirror current practice.

Question 2b): If there is anything that is missing from group 2, please comment here giving reasons why.

26. Five respondents answered Question 2b. Four of those respondents made clear that they either had 'no comment' on the consulted list or that the list was comprehensive and no additions were required.

27. One respondent provided a substantive response that set out the potential difficulty, particularly related to a face transplant, in making sure that legal definition relating to tissues are not over-specified. It was noted that these procedures are still incredibly novel. It was also stated by the respondent that the consulted definition for a 'face' did not capture all of the parts which may be included in a transplant, with reference to a specific case of facial transplant in America, and further additions may be required in order for the definition to be fully comprehensive.

Listed parts – Group 3 (Q3)

Question 3a): Are there any tissues that should not be listed? Please explain below.

28. Nine respondents answered Question 3a. All respondents to this question, both organisational and individual, stated that the consulted list of tissues that may be removed from a body part listed in Group 2 with deemed authorisation is comprehensive. One respondent offered comments which were broader than the specific question – this is detailed in the analysis of responses to question 4.

Question 3b): If there is anything that is missing from group 3, please comment here giving reasons why.

29. Five respondents provided a response to Question 3b. Four respondents stated that Group 3 was comprehensive and no further additions were required.

30. One individual respondent posed a question, asking for consideration if the retrieval of fascia lata tissue (tissue in the thigh area) should be included in Group 3 or whether it would already fall under the broader listed 'muscle', 'nervous tissue' or 'tendon' in Group 3.

Any other comment (Q4)

31. 12 respondents submitted a response to Question 4. An open question, respondents used this question to reflect on the purpose of the Regulation itself. Respondents also provided comment on wider matters related to donation and transplantation, including the ongoing implementation of the 2019 Act, and how that might be carried out as effectively as possible.

Effect of the regulation and deemed donation

32. Some comment was expressed on whether donation for particular transplants may, in practice, require explicit as well as deemed authorisation. For example, the trachea as part of a dual lung or heart-lung block retrieval or the retrieval of abdominal wall composite tissue grafts as part of multi-visceral transplants. It was noted that the regulation should not have this potentially adverse effect on practice, and be drafted accordingly.

33. Furthermore, an organisational respondent requested that guidance should set out and clarify what parts of the body deemed authorisation does and does not apply to.

34. Linked to this point requesting clarity on specific parts of the body that deemed authorisation will or will not apply to in certain circumstances, one respondent noted that the consultation potentially overlooked the application of retrieved tissue for research purposes.

35. Similar to this theme, following discussion of this issue in the consultation paper, respondents also took time to highlight the cross border nature of organ and tissue donation. It was emphasised by some respondents that the legislative change in Scotland should not impact on the ability of donated organs to cross internal UK borders for transplantation. It was also noted that cross-UK consistency, especially with regard to solid organ donation, is desirable and important wherever possible.

Public awareness

36. Echoing what has been highlighted previously during public consultation surrounding the 2019 Act and deemed authorisation, the importance of public awareness regarding what deemed authorisation will and will not apply to was emphasised by a number of respondents. As part of this consideration, ensuring there is accessible public information was also highlighted as being just as important. Some respondents noted that the content of the consultation was potentially complex, and this information must remain accessible for all members of the public when it is explained as part of the new donation system.

37. Questions and further observations on this point were put forward. Another respondent suggested that there should be an ability to record a donation decision for what are prescribed as excepted body parts by a person themselves, in life.

Crown Office and Procurator Fiscal Service

38. One respondent put forward that these regulations should not adversely impact upon the ongoing agreement established between the Crown Office and Procurator Fiscal Service (COPFS) and the Scottish Donation and Transplant Group (SDTG). Primarily that the implementation of these regulations, and the legislation as a whole, should not impact upon the requirement that a COPFS investigation must be placed before organ donation requirements. The respondent also noted that this requirement should be reflected in public facing material.

Other comments

39. One respondent disagreed in both the manner and timing of the public consultation, noting that in Scotland, Wales and England the respective Governments had each consulted upon comparable regulations for a different period of time. It was suggested that the public consultation period for Scotland

was too short. This respondent also commented that the consultation itself should have been less targeted at the clinical community, in order to permit members of the public to potentially engage more effectively with this topic.

40. One respondent asked how the Scottish Parliament intended to monitor the potential success of the new opt out donation system as a whole.

Annex A: consultation questions

Question 1. Group 1: The parts of the body to be excluded from deemed authorisation in all circumstances:

a) Are there any parts of the body in group 1 that should not be listed? Please explain below.

b) If there is anything that is missing from group 1, please comment here giving reasons why.

Question 2. Group 2: The parts of the body to be excluded from deemed authorisation, if they are to be used in their entirety:

a) Are there any parts of the body in group 2 that should not be listed? Please explain below.

b) If there is anything that is missing from group 2, please comment here giving reasons why.

Question 3. Group 3: Tissues which form part of body parts listed in group 2 to be included in deemed authorisation:

a) Are there any tissues that should not be listed? Please explain below.

b) If there is anything that is missing from group 3, please comment here giving reasons why.

Question 4. Do you have any other comments on this consultation?

Annex B: list of organisational respondents

A total of 8 organisations responded to the consultation:

Faculty of Intensive Care Medicine (FICM)
Kidney Care UK
Lancaster University, Health Ethics and Policy Research Group
NHS Blood and Transplant (NHSBT)
The Law Society of Scotland
Tissue Solutions Ltd
Scottish National Blood Transfusion Service (SNBTS)
UK Renal Association

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