

National Assembly for Wales
Constitutional and Legislative
Affairs Committee

**Report on the Human
Transplantation (Wales) Bill**

March 2013



Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales

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Remit and Powers

The Constitutional and Legislative Affairs Committee was established on 15 June 2011 with a remit to carry out the functions and exercise the powers of the responsible committee set out in Standing Orders 21. This includes being able to consider and report on any legislative matter of a general nature within or relating to the competence of the Assembly or the Welsh Ministers.

Current Committee membership



David Melding (Chair)
Deputy Presiding Officer
Welsh Conservatives
South Wales Central



Suzy Davies
Welsh Conservatives
South Wales West



Julie James*
Welsh Labour
Swansea West



Eluned Parrott
Welsh Liberal Democrats
South Wales Central



Simon Thomas
Plaid Cymru
Mid and West Wales

In accordance with Standing Order 17.48, Mick Antoniw AM substituted for Julie James AM.



Mick Antoniw
Welsh Labour
Pontypridd

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The Committee's Recommendations

Conclusion 1: We believe that, as currently drafted, the Bill does not achieve the necessary level of clarity for a Bill of such public importance. In our view, some of the Bill's provisions are unclear and have the potential to cause confusion, potentially undermining the Bill's central objective of increasing the number of organs and tissues available for transplant. (Page 15)

Conclusion 2: We also have some concerns about the balance between what is on the face of the Bill and what is left for subordinate legislation, and also the procedures to be used in making subordinate legislation. (Page 15)

Conclusion 3: We are surprised that the Bill relies so heavily on the *Human Tissue Act 2004* as a base and does not seek to clarify definitions, concepts and developments in this field within the framework of a new consolidated Welsh law that reflects the distinctive policy approach being adopted in Wales. (Page 15)

Recommendation 1. We recommend that the Minister tables an amendment to make the preparation of a communication plan a statutory requirement of the Bill. (Page 17)

Recommendation 2. We recommend that the Minister tables an amendment applying a superaffirmative procedure to regulations made under section 8(2). (Page 23)

Recommendation 3. We recommend that the Minister considers tabling an amendment to make it clear that section 8 of the Bill applies to living adults only. (Page 23)

Recommendation 4. We recommend that during the Stage 1 debate the Minister clarifies how section 27(4) of the *Human Tissue Act 2004* and section 17 of the Bill relate to sections 5 and 6 of the Bill, and, accordingly, the implications of all these provisions on codes of practice to be provided as a consequence of section 14. (Page 27)

Recommendation 5. We recommend that an amendment should be tabled to the Bill to make it clear that qualifying relationships will not be ranked for the purposes of information provided under section

4(4)(b). In our view, this is more appropriate than including such information in a code of practice because it provides greater certainty. (Page 27)

Recommendation 6. We consider that novel transplants should be dealt with on the face of the Bill. Accordingly, we consider that the Minister should table amendments to the Bill to specify clearly how novel transplants should be dealt with. If such provisions were to require regulation-making powers or a separate code of practice, they should be subject to a superaffirmative procedure. (Page 28)

Recommendation 7. Subject to recommendation 6, we recommend that the Minister tables an amendment to section 14(4)(a) of the Bill to ensure that all codes of practice dealing with transplantation activities in Wales should be subject to the affirmative procedure. (Page 28)

Recommendation 8. We recommend that an amendment is tabled to the Bill to apply a superaffirmative procedure to the order-making power to be introduced as a consequence of section 14(3)(f), which provides for the definition of qualifying relationships in respect of section 27(4) of the *Human Tissue Act 2004* to be amended. (Page 28)

Recommendation 9. We recommend that an amendment is tabled to the Bill to apply a superaffirmative procedure to the order-making power under section 17(4), which permits the definition of qualifying relationships for the purposes of the Bill to be amended. (Page 30)

Recommendation 10. We recommend that the Minister clarifies, preferably by amendment, the provisions of the Bill that are subject to section 17(2) and those that are subject section 27(4) of the *Human Tissue Act 2004*, including if necessary, whether they apply in specific circumstances only. (Page 30)

1. Introduction

1. On 3 December 2012, the Minister for Health and Social Services, Lesley Griffiths AM ('the Minister'), introduced the Human Transplantation (Wales) Bill ('the Bill') and accompanying Explanatory Memorandum.¹
2. The National Assembly's Business Committee referred the Bill to the Health and Social Care Committee for consideration on 20 November 2012, setting the deadline of 22 March 2013 for reporting on the general principles.
3. The Constitutional and Legislative Affairs Committee considered the Bill at its meeting on 4 February 2013, taking evidence from the Member in Charge Lesley Griffiths AM, Minister for Health and Social Services. Following her appearance before us, we wrote to the Minister seeking further information on 13 February 2013² and we received a reply on 4 March 2013.³

The Committee's remit

4. The Constitutional and Legislative Affairs Committee's ("the Committee") remit is to carry out the functions of the responsible committee set out in Standing Order 21⁴ and to consider any other constitutional or governmental matter within or relating to the competence of the Assembly or Welsh Ministers.
5. Within this, the Committee considers the political and legal importance and technical aspects of all statutory instruments or draft statutory instruments made by the Welsh Ministers and reports on whether the Assembly should pay special attention to the instruments on a range of grounds set out in Standing Order 21.

¹ National Assembly for Wales, *Human Transplantation (Wales) Bill*, Explanatory Memorandum, December 2012:

<http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum>

² Letter from the Chair of Constitutional and Legislative Affairs Committee to Minister for Health and Social Services, 13 February. Available from:

<http://www.senedd.assemblywales.org/mgCommitteeDetails.aspx?ID=219>

³ Letter from Minister for Health and Social Services to Chair of Constitutional and Legislative Affairs Committee, 4 March 2013. Available from:

<http://www.senedd.assemblywales.org/mgCommitteeDetails.aspx?ID=219>

⁴ National Assembly for Wales, *Standing Orders of the National Assembly for Wales*, December 2012

6. The Committee also considers and reports on the appropriateness of provisions in Assembly Bills and UK Parliament Bills that grant powers to make subordinate legislation to the Welsh Ministers, the First Minister or the Counsel General.

2. Background

Purpose of the Bill

7. The Explanatory Memorandum describes the purpose of the Bill:

“The Human Transplantation (Wales) Bill prescribes how consent is to be given in Wales to the removal, storage and use of human organs and tissues for the purpose of transplantation. The Bill covers the donation of organs and tissues for transplantation both from deceased and living donors. In relation to deceased donation, it gives effect to the Welsh Government’s commitment to introduce a soft opt-out system of organ and tissue donation in Wales. A soft opt-out system is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process. The overarching aim of the Bill is to increase the number of organs and tissues available for transplant, which will benefit the people of Wales by reducing the number of people dying whilst waiting for a suitable organ to become available and improving the lives of others.

“The Bill sets out in one place the main provisions relating to consent for transplantation activities in Wales. However, in order to maintain an effective cross-border regime in terms of the operation of the UK-wide organ transplantation programme, there is an inevitable interplay with the Human Tissue Act 2004 (the 2004 Act), which is the current legislative framework for England, Wales and Northern Ireland. As a result, the Bill restates, for Wales, certain sections of the 2004 Act directly related to consent for the purposes of transplantation. However, certain other provisions of the 2004 Act not directly related to consent have not been restated but continue to apply in Wales ... in most respects the Welsh Government has no intention of changing the settled law in this area; the main

change brought about by the Bill is to introduce the concept of **deemed consent**.⁵

8. The Explanatory Memorandum explains that:

“The effect of this Bill will be to introduce, for people over the age of 18 who both live and die in Wales⁸, a concept called **deemed consent**. Deemed consent will exist alongside **express consent** as one of the ways in which a person can give their consent to the donation of organs for transplantation. People will be given the opportunity of taking an express decision, for example to formally “opt out” of organ donation by placing their name on a register. But if they choose not to do so, despite having had the opportunity, then they will be treated as though they had no objection to being a donor (or in other words their consent will be deemed). Based on the experience of other countries in Europe with similar systems, we would hope to see an increase in the number of organs available for transplantation as a result.”⁶

9. Section 4 of the Bill introduces the concept of deemed consent. Deemed consent is the default position in all cases in Wales apart from those listed as exceptions in sections 5 (Excepted Adults) and 6 (Children).⁷

10. The Explanatory Memorandum also explains that:

“It is not intended to alter the way in which organs and tissues are collected or allocated, and existing arrangements with [NHS Blood and Transplant] will continue. This means Wales will still share a transplant waiting list with the rest of the UK and organs will be allocated on the basis of clinical need and suitable match. Welsh residents have benefited from being part of the UK-wide arrangements for many years and there are no plans to alter this as we introduce the new arrangements for consent to donation in Wales ... The Secretary of State has agreed in principle to make an order pursuant to section 150 of

⁵ Explanatory Memorandum, paragraphs 1 and 2

⁶ Explanatory Memorandum, paragraph 12

⁷ For those people to whom deemed consent can apply there are further possible exceptions under section 4. These are described in paragraphs 17 – 24 of Annex A (the Explanatory Notes) to the Explanatory Memorandum.

the Government of Wales Act 2006, amending Section 1 of the 2004 Act. This will allow organs and tissues retrieved under deemed consent in Wales to be used for transplantation in England and Northern Ireland.”⁸

Legislative Competence

11. In terms of the National Assembly’s legislative competence to make the Bill, the Explanatory Memorandum states that:

“The National Assembly for Wales has legislative competence to make provision relating to consent to the removal, storage and use of organs and tissues for the purpose of transplantation pursuant to Part 4 of the Government of Wales Act 2006. Subject 9 under the heading Health and Health Services of Schedule 7 to the Government of Wales Act 2006, is relevant in this context ...”⁹

Summary of the Bill

12. The Bill contains 20 Sections and no schedules. The main provisions of the Bill:

- impose a duty on the Welsh Ministers to promote transplantation (section 2);
- provide that certain activities done in Wales for the purpose of transplantation are lawful if done with consent (section 3);
- set out how consent is given to transplantation activities, including the circumstances in which consent is deemed to be given in the absence of express consent (sections 4 to 8);
- make it an offence for transplantation activities to be done in Wales without consent (section 9);
- make amendments (sections 14 and 15) to the Human Tissue Act 2004, including in relation to a code of practice issued under that Act which—
 - o gives practical guidance to persons that do transplantation activities, and

⁸ Explanatory Memorandum, paragraph 20

⁹ Explanatory Memorandum, paragraph 4

- lays down the standards expected in relation to the doing of such activities, including how consent is to be obtained.¹⁰

¹⁰ Section 1 of the Human Transplantation (Wales) Bill, as introduced:
<http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-e.pdf?>

3. Legislative Competence

Evidence from the Minister

13. In terms of discussions with the UK Government about the Bill and in particular its legislative competence, the Minister said:

“... we have had very detailed discussions with the UK Government at an official level. The only Minister whom I met was the previous Secretary of State for Wales. Discussions around competence have happened. We believe that we have the competence ... We have also secured the section 150 Order, in relation to taking competence from the Secretary of State, for the Bill.”¹¹

14. She subsequently indicated that she had not had any indication from the UK Government that competence may be disputed.¹²

Our view

15. We note that it has not been confirmed whether the Secretary of State has any concerns or issues regarding the competence of the National Assembly to make this legislation under Schedule 7 to the Government of Wales Act 2006.

¹¹ Constitutional and Legislative Affairs (“CLA”) Committee, *RoP* [paragraph 12], 4 February 2013

¹² CLA Committee, *RoP* [paragraphs 13-14], 4 February 2013

4. General observations on the Bill and on the powers to make subordinate legislation

Evidence from the Minister

16. The Minister explained the approach to the use of delegated powers in the Bill:

“The Bill provides for the introduction of a soft opt-out system for organ and tissue donation. As such, there are relatively few secondary legislation-making powers in the Bill ... The secondary legislation-making powers allow for additional detail to be provided and for operational detail in the Bill to be amended. We believe that this is much more proportionate than amending the Bill each time a relatively minor practical change is identified. However, it does not alter in any way the major principles that are set out in the Bill.

“The powers of Welsh Ministers to make secondary legislation mirror the current powers of the Secretary of State under the Human Tissue Act 2004. Our policy is to take a different approach to the existing legislative framework only when the policy intent for an opt-out system demands it.”¹³

17. Noting that in most instances, use of the affirmative procedure was specified for making subordinate legislation, the Minister was asked whether she had thought about using the superaffirmative procedure in some cases. She replied by saying:

“The superaffirmative is quite a new procedure and it affects more wide-ranging powers. We believe that this Bill contains very specific powers, which is why we chose the affirmative over the superaffirmative. However, we did consider it ... It is a sensitive and emotive topic and is a decision taken at times of great difficulty for families. We think it is appropriate for the National Assembly to debate any proposed secondary legislation because it is such an emotive topic. There is also wide public interest in the Bill, which is another reason why we chose the affirmative procedure, because it would reassure the

¹³ CLA Committee, *RoP [paragraphs 7-8]*, 4 February 2013

public that matters had received appropriate attention from elected representatives.”¹⁴

Our view

18. This Bill covers many emotive and ethical issues, and, given its content, will affect virtually every adult in Wales. It is therefore a matter of considerable public importance. For that reason, there needs to be absolute clarity in the intention of the Bill and how its objectives are to be delivered.

Conclusion 1: We believe that, as currently drafted, the Bill does not achieve the necessary level of clarity for a Bill of such public importance. In our view, some of the Bill’s provisions are unclear and have the potential to cause confusion, potentially undermining the Bill’s central objective of increasing the number of organs and tissues available for transplant.

19. We have particular concerns about the clarity of section 2 (duty of the Welsh Ministers to promote transplantation), section 8 (activities involving material from (living) adults who lack capacity to consent), section 14 (codes of practice) and section 17 (interpretation). We comment on the specific issues we have identified relevant to each section in Chapter 5.

Conclusion 2: We also have some concerns about the balance between what is on the face of the Bill and what is left for subordinate legislation, and also the procedures to be used in making subordinate legislation.

20. In particular, we believe that the issue of novel transplants needs to be dealt with clearly on the face of the Bill and greater use made of a superaffirmative procedure. We comment on these specific issues in Chapter 5.

21. More generally, we note that the Bill builds on the *Human Tissue Act 2004*.

Conclusion 3: We are surprised that the Bill relies so heavily on the *Human Tissue Act 2004* as a base and does not seek to clarify definitions, concepts and developments in this field within the

¹⁴ CLA Committee, *RoP [paragraph 10]*, 4 February 2013.

framework of a new consolidated Welsh law that reflects the distinctive policy approach being adopted in Wales.

In our view, given that the Bill will affect virtually every adult in Wales, a better approach would have been to ensure that the law is set out in a single legislative text to ensure that it is easily accessible by the general public.

5. Powers to make subordinate legislation – observations on specific powers

Delegated powers to make subordinate legislation

22. The Bill contains 5 delegated powers to make orders and regulations (as well as powers in relation to codes of practice). Section 18 of the Bill identifies the procedures to be applied to each delegated power, except with respect to codes of practice. Procedures relevant to codes of practice are to be inserted into the *Human Tissue Act 2004* by virtue of section 14 of this Bill.

Section 2 – Duty of the Welsh Ministers to promote transplantation

23. Section 2 includes a specific duty on Welsh Ministers to educate those resident in Wales about the circumstances in which consent can be deemed.

24. During her evidence, the Minister indicated that a communication plan will sit alongside the Bill.¹⁵

Our view

25. We note that section 2 provides Welsh Ministers with a duty to promote transplantation. We also note that throughout her evidence the Minister has emphasised the importance of communications and has referred to the preparation of a communication plan.

26. We agree that communication is of crucial importance: it will be a vital part of the delivery of the policy objectives of the Bill. As a consequence, we consider that it would be appropriate for the Minister to strengthen this section of the Bill.

Recommendation 1: We recommend that the Minister tables an amendment to make the preparation of a communication plan a statutory requirement of the Bill.

¹⁵ CLA Committee, *RoP [paragraph 30]*, 4 February 2013

Section 7 - Appointed representatives

27. Section 7 provides that an adult may appoint a representative to give consent to any of the activities set out in section 3 (authorisation of transplantation activities).

28. Section 7(10)(b) empowers Welsh Ministers to prescribe in regulations that persons of a particular description cannot act under an appointment in relation to somebody who dies in Wales (subject to the affirmative procedure).

29. The Minister provided an example of the type of person who could be covered by regulations made under this section, namely “people who lack capacity”¹⁶ adding that:

“... we will liaise with the Human Tissue Authority on any potential areas that we may wish to set out in regulations”.¹⁷

30. A lawyer accompanying the Minister expanded on the nature of the provision:

“Under the Human Tissue Act 2004, the power to make regulations is vested in the Secretary of State, but the power has not been used. Here, there is a power for the Welsh Ministers to make regulations, and it is envisaged that that power will be used. It is very important, for anyone who appoints a representative to make an important decision about organ donation et cetera, that that person is fit for purpose. The regulations could cover anything. Capacity is one of the issues we have mentioned, but it could also cover the suitability of the person. I cannot think of an immediate example. Obviously, we will be working through the detail of that through discussion and liaison with the Human Tissue Authority. However, it is all about the suitability of an appointed representative”.¹⁸

¹⁶ CLA Committee, *RoP [paragraph 18]*, 4 February 2013

¹⁷ CLA Committee, *RoP [paragraph 18]*, 4 February 2013

¹⁸ CLA Committee, *RoP [paragraph 21]*, 4 February 2013

31. She added that:

“There is a secondary issue here, which is that the Human Tissue Act 2004 will continue to apply in Wales, if and when our Welsh legislation is made. There is an inevitable interplay between the Welsh legislation and the Human Tissue Act 2004, because the two pieces of legislation will be relevant. So, wherever possible, we are trying to minimise the movement away from the position in the Human Tissue Act 2004. We want to cause minimum disruption to the existing system and ensure that there is a uniformity of approach, wherever possible, while acknowledging that the Welsh legislation will change the trigger for consent to donation by introducing a deemed consent system.”¹⁹

32. The Minister added that, in terms of the type of people that could be excepted or exempted, this issue could be looked at in the communication plan but indicated that she would provide further information to the Committee in writing.²⁰

33. In a letter dated 4 March 2013, the Minister explained that:

“... it is important for a person to have confidence in the person they appoint to make decisions about organ donation and Welsh Ministers may wish to prescribe who may not act in this capacity in regulations in order to give the requisite level of protection to individuals. People appointing a representative should have confidence the person they choose is someone who is capable of understanding the issues around organ donation and who will then be able to go on and make a decision on their behalf. As I indicated in Committee, the main category of person exempted therefore is likely to be those who lack capacity, since it is unlikely such a person would be able to understand the issues involved in organ donation and come to a decision on behalf of the deceased. There might well be other suitability considerations and we are liaising with the Human Tissue

¹⁹ CLA Committee, *RoP [paragraph 25]*, 4 February 2013

²⁰ CLA Committee, *RoP [paragraphs 30 and 32]*, 4 February 2013

Authority on any potential areas we may wish to set out in regulations.”²¹

34. As regards the procedure that would apply to the making of these Regulations, a lawyer accompanying the Minister indicated that use of a superaffirmative procedure had been considered. However, the affirmative procedure was considered to be appropriate and proportionate. In making this point, the Minister’s lawyer noted that the equivalent procedure in England was subject to the negative procedure.²²

Our view

35. We note the Minister’s views and are content that the affirmative procedure, in accordance with section 18(3), is appropriate for making Regulations under section 7(10).

Section 8 - Activities involving material from (living) adults who lack capacity to consent

36. Section 8 applies where a living adult lacks capacity to consent to donation and no decision is in force. According to the Explanatory Memorandum:

“This section has the same effect as section 6 of the Human Tissue Act 2004, except that the power to prescribe in regulations when deemed consent can apply will be held by the Welsh Ministers as regards a transplantation activity in Wales. Section 8(2)(a) (the person’s best interests) restates on the face of this Bill a provision made by the Secretary of State in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2004. For example, it could be in the best interests of the person who lacks capacity to donate relevant material to a close relative. Deemed consent in this context is separate from the deemed consent provisions set out in section 4, which relate to deceased donors. However, the

²¹ Letter from Minister for Health and Social Services to Chair of Constitutional and Legislative Affairs Committee, 4 March 2013

²² CLA Committee, *RoP* [paragraph 27], 4 February 2013

basic premise of taking action without the express consent of the individual is the same.”²³

37. Section 8(2)(b) empowers Welsh Ministers to prescribe in regulations when deemed consent can apply as regards a transplantation activity in Wales.

38. The Minister explained that:

“The only circumstance where consent of a living adult lacking capacity is deemed is when it is in the person’s best interests; for instance, to donate relevant material to a close relative. This is something that we are looking at in the drafting of the provision to ensure that it is very clear.”²⁴

39. A lawyer accompanying the Minister added that:

“It might be in the best interests of the individual who lacks capacity if there is a brother or a sister involved. It does happen; it might be in the family member’s best interests and then it is deemed to be in the individual’s best interests for them to donate.”²⁵

40. She also explained that:

“... the Welsh Government’s policy is not to change in any sense the arrangements for living donation ... it is a very complicated, very emotive and sensitive subject matter. Also, the Mental Capacity Act 2005 comes in here, as does case law. ‘Best interests’ is a theme that runs throughout the legislation.”²⁶

41. The Minister indicated that consideration had been given to applying the superaffirmative procedure to the regulation-making power in section 8(2)(b) but said that:

“... we have allowed the same level of scrutiny through the current Parliamentary process, which is done through the affirmative procedure.”²⁷

²³ Explanatory Memorandum, Annex A – Explanatory Notes, paragraph 34

²⁴ CLA Committee, RoP [paragraph 53], 4 February 2013

²⁵ CLA Committee, RoP [paragraph 72], 4 February 2013

²⁶ CLA Committee, RoP [paragraph 66], 4 February 2013

²⁷ CLA Committee, RoP [paragraph 55], 4 February 2013

42. In seeking to explain why these issues would not be better dealt with on the face of the Bill or via a superaffirmative procedure, an official accompanying the Minister said:

“Currently, each case is dealt with on a case-by-case basis. I think that the Human Tissue Authority would set up a panel to look at each case on an individual merits basis because it could be so different in every case.”²⁸

43. In her letter of 4 March, the Minister said that having considered further the issues surrounding section 8:

“... I have decided to bring forward a Government amendment to clarify this provision. The change I propose to make will be to amend section 8(2) to retain the power for Welsh Ministers to set out in regulations the circumstances for deeming the consent of a living adult who lacks capacity but to remove the “best interests” test currently at section 8(2)(a). This brings the provision closer to section 6 of the 2004 Act. My intention would then be to set out the best interests test in regulations rather than on the face of the Bill, as has been done by the Secretary of State in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006. The regulations would be subject to the affirmative procedure. This would remove any queries which have arisen in relation to section 8(2) about whether this leaves potential for Welsh Ministers to prescribe circumstances other than those which are in a person’s best interests for their consent to be deemed.”²⁹

Our view

44. We note the Minister’s comments and welcome her letter of 4 March clarifying her intentions regarding section 8.

45. Section 8 concerns issues of considerable ethical importance. Given this, and the Minister’s intention to remove the best interests test from the face of the Bill and incorporate it within regulations, we believe that a superaffirmative procedure should apply to regulations made under section 8(2).

²⁸ CLA Committee, *RoP [paragraph 74]*, 4 February 2013

²⁹ Letter from Minister for Health and Social Services to Chair of Constitutional and Legislative Affairs Committee, 4 March 2013

Recommendation 2: We recommend that the Minister tables an amendment applying a superaffirmative procedure to regulations made under section 8(2).

46. However, we also have some wider concerns about the clarity of this section. In particular we note that while section 8 makes reference in the section heading to the application of these provisions to living adults, that it not clear from the provisions themselves. This is of concern because the section heading does not form a substantive part of the Bill.

Recommendation 3: We recommend that the Minister considers tabling an amendment to make it clear that section 8 of the Bill applies to living adults only.

Section 14 – Codes of practice

47. The Explanatory Memorandum explains the background to codes of practice and how the Bill deals with them:

“... the Human Tissue Authority is required to issue a code of practice which includes practical guidance and standards. These provisions have not been replicated or restated in the Bill as there is only one Authority and one Code. Amendments have therefore been made to the Human Tissue Act 2004 to reflect the Welsh legislation.”³⁰

48. Section 14 therefore amends the following sections of the 2004 Act: section 26 (preparation of codes), section 27 (provision with respect to consent), section 29 (approval of codes) and section 52 (orders and regulations).

49. The Explanatory Memorandum explains these provisions of the 2004 Act:

“Under section 26 of the 2004 Act the Human Tissue Authority must issue a code of practice for the purpose of “giving practical guidance” and “laying down the standards expected” in carrying on activities with bodies and organs (including

³⁰ Explanatory Memorandum, Annex A - Explanatory Notes, paragraph 41

transplantation). Section 26(3) of the 2004 Act includes a specific provision to say that the Code must deal with the issue of consent. Section 27 goes on to provide that the code must “include provision to the effect” set out in subsections (4) to (8), which includes ranking and other related practical matters, though the Authority may by virtue of subsection (3) include provision of different effect in “exceptional cases”. These 2004 Act provisions will continue to apply in Wales in respect of express consent given by qualifying relatives, but the code of practice will make clear that qualifying relations will not be ranked for the purposes of information provided under section 4(4)(b) of the Bill.”³¹

50. In particular, section 27(1) of the 2004 Act provides that in a code of practice dealing with consent, the Human Tissue Authority must lay down standards relating to obtaining consent from a person in a qualifying relationship. Section 27(4) of the 2004 Act sets out the hierarchy of people close to a deceased person who are eligible to give consent to certain activities.

51. Section 14(3)(f) of the Bill inserts a new subsection into section 27 of the 2004 Act to provide a power for Welsh Ministers to amend by order the hierarchy in section 27(4) in so far as it applies to section 5(4) or section 6(3) of the Bill. Section 5 of the Bill defines adults that are excepted from deemed consent (introduced by section 4). Where such adults have nevertheless expressed a decision to consent (express consent), section 5(4) identifies the circumstances in which the decision regarding consent is made by a qualifying relative. Section 6 of the Bill contains similar provisions in respect of children.

52. Therefore, the order-making power introduced by section 14(3)(f) of the Bill permits Welsh Ministers to amend the list of ranked qualifying persons contained in section 27 of the Human Tissue Act 2004 for the purpose of providing a code of practice covering the meaning of express consent for excepted adults (section 5(4)) and children (section 6(3)). The order-making power is subject to the affirmative procedure by virtue of an amendment, introduced by section 14(5) of the Bill, to section 52 of the 2004 Act.

³¹ Explanatory Memorandum, Annex A – Explanatory Notes, paragraph 29

53. Section 14(4)(a) of the Bill inserts a new subsection into section 29 of the 2004 Act, in particular applying the negative procedure to codes of practice that deal with transplantation activities in Wales.

54. A lawyer accompanying the Minister provided further clarification about how codes of practice fit into the transplantation regime:

“... this Welsh legislation, as the Human Tissue Act 2004, is a framework underpinned by the Human Tissue Authority codes of practice, which contain quite a bit of detail. One of the consent issues that is detailed in the code of practice is about family relationships and, when a discussion is happening in a hospital setting with family members, who do you go to, how do you go to them, and, if there is a dispute, what happens? All of that is detailed in the Human Tissue Authority code of practice, and that will continue. We will have a code that will detail the Welsh system, and what happens if somebody does not want to make a decision, or if somebody cannot make a decision or cannot be found, or if there is any dispute among the chain or the ranks—all of that is detailed in a code of practice.”³²

55. She also explained the circumstances in which the Welsh Government might wish to amend the list of qualifying relations:

“I believe, from memory, that aunts and uncles are not included in the list, and there is an ongoing debate on a UK basis as to whether they should be, and, if they were, where would they be ranked et cetera. New things develop and societal change might mean that the ranking needs to be changed anyway. The powers will allow for flexibility for that sort of thing ...”³³

56. The Minister qualified these comments by saying:

“... there is flexibility to add or change, but we would have to do it in light of best practice recommendations from NHS Blood and Transplant or the Human Tissue Authority.”³⁴

³² CLA Committee, *RoP [paragraph 93]*, 4 February 2013

³³ CLA Committee, *RoP [paragraph 95]*, 4 February 2013

³⁴ CLA Committee, *RoP [paragraph 96]*, 4 February 2013

57. She also said that she would look at whether the order-making power should be subject to a superaffirmative procedure, but in so doing indicated that, originally, it was not thought proportionate to do so.³⁵

58. When questioned about the code of practice in the context of novel transplants (for example relating to the face and hands), the Minister said:

“In Wales, under deemed consent arrangements, novel transplants ... would not proceed because this ... was covered in the code of practice. It is something that we are looking at in great detail because the Human Tissue Act, like the Bill, does not detail which organs and tissues can be transplanted; it just refers to relevant materials ...”³⁶

59. The Minister confirmed that novel transplants would be dealt with by a specific reference in a code of practice coming before the Assembly under the negative procedure,³⁷ adding:

“... the code will contain contentious material ... One issue of which we are mindful is the fact that the code is updated quite regularly. When considering which process to prescribe on the face of the Bill, it was thought that the negative procedure would be more appropriate. However, it is logical to listen to the argument that the code will contain sensitive information.”³⁸

60. She agreed to reflect on the procedure to be used and in her letter of 4 March 2013, she said:

“Having listened to the points made by the Committee I am persuaded this should be amended to allow for the affirmative procedure.”³⁹

Our view

61. Section 14 on codes of practice is a complex provision, particularly in terms of its interrelationship with sections 5 and 6 of the Bill. In addition, and linked to this, it is not clear the extent to

³⁵ CLA Committee, *RoP [paragraph 98]*, 4 February 2013

³⁶ CLA Committee, *RoP [paragraph 117]*, 4 February 2013

³⁷ CLA Committee, *RoP [paragraph 131 and 132]*, 4 February 2013

³⁸ CLA Committee, *RoP [paragraph 134]*, 4 February 2013

³⁹ Letter from Minister for Health and Social Services to Chair of Constitutional and Legislative Affairs Committee, 4 March 2013

which section 27(4) of the *Human Tissue Act 2004* (a ranked list of qualifying relationships) and section 17 (an unranked list of qualifying relationships) applies to sections 5 and 6.

Recommendation 4: We recommend that during the Stage 1 debate the Minister clarifies how section 27(4) of the *Human Tissue Act 2004* and section 17 of the Bill relate to sections 5 and 6 of the Bill, and, accordingly, the implications of all these provisions on codes of practice to be provided as a consequence of section 14.

62. We note the comment in paragraph 29 of the Explanatory Memorandum that the “code of practice will make clear that qualifying relations will not be ranked for the purposes of information provided under section 4(4)(b) of the Bill”. We do not consider that a code of practice is the appropriate vehicle to make this point; it should appear on the face of the Bill.

Recommendation 5: We recommend that an amendment should be tabled to the Bill to make it clear that qualifying relationships will not be ranked for the purposes of information provided under section 4(4)(b). In our view, this is more appropriate than including such information in a code of practice because it provides greater certainty.

63. Paragraph 20 of our report made reference to our concerns regarding how the new regime deals with novel transplants.

64. On introduction of the Bill, the Minister’s intention was that novel transplants should be dealt with through the code of practice, to be subject to the negative procedure. However, in her letter of 4 March, the Minister indicated that she intended to amend the Bill to ensure that all codes of practice would be subject to the affirmative procedure.

65. However, in our view, this does not go far enough. Novel transplants are an issue of significant ethical and public concern and importance. In addition what constitutes a novel transplant may change and develop over time, particularly with scientific and technological advances. In our view, any uncertainty surrounding these issues could undermine public confidence in the objectives of the Bill and organ donation more generally.

Recommendation 6: We consider that novel transplants should be dealt with on the face of the Bill. Accordingly, we consider that the Minister should table amendments to the Bill to specify clearly how novel transplants should be dealt with. If such provisions were to require regulation-making powers or a separate code of practice, they should be subject to a superaffirmative procedure.

66. We consider that all other codes of practice should still be subject to the affirmative procedure given the nature of the information they are likely to contain.

Recommendation 7: Subject to recommendation 6, we recommend that the Minister tables an amendment to section 14(4)(a) of the Bill to ensure that all codes of practice dealing with transplantation activities in Wales should be subject to the affirmative procedure.

67. As regards the order-making power under section 14(3)(f) (see paragraph 51), we note the Minister's view that a superaffirmative procedure would not be proportionate. Given our views on the public importance of the Bill, we disagree.

Recommendation 8: We recommend that an amendment is tabled to the Bill to apply a superaffirmative procedure to the order-making power to be introduced as a consequence of section 14(3)(f), which provides for the definition of qualifying relationships in respect of section 27(4) of the *Human Tissue Act 2004* to be amended.

Section 17 – Interpretation

68. Section 17 of the Bill provides various definitions, including in section 17(2) a definition of qualifying relationship for the purposes of the Act. The Explanatory Memorandum explains that:

“A definition of qualifying relationship is included in addition to the reference to the ranking of those relationships in section 27(4) of the Human Tissue Act 2004. The 2004 Act defines the term (at section 54(9)) as well as giving the different relationships that form the definition a ranking through section 27(4) and the Code of Practice issued by the Human Tissue

Authority. Qualifying relationships will not be ranked for the purposes of section 4(4)(b) of this Bill (information that can prevent deemed consent), but will be for all other purposes.”⁴⁰

69. Section 4 introduces the concept of deemed consent as the default position in all cases in Wales apart from those listed as exceptions in Sections 5 (Excepted Adults) and 6 (Children).

70. Section 4(4)(b) however enables a person in a ‘qualifying relationship’ to the deceased to provide information that would lead a reasonable person to conclude that the deceased would not have consented. The definition of those in a ‘qualifying relationship’ for the purposes of section 4 is set out in section 17(2).

71. Section 17(4) empowers Welsh Ministers to amend by order the list in section 17(2) of what constitutes a “qualifying relationship”.

72. The order-making power under section 17(4) is subject to the affirmative procedure, but the Minister agreed to consider applying a superaffirmative procedure instead.⁴¹

We asked the Minister whether “the fact that there is one list in the Bill and a ranked list in the 2004 Act may cause confusion and undermine the communications campaign” to be undertaken on this Bill”.⁴² In response the Minister said:

“No, we do not believe that; it will be part of the communications campaign.”⁴³

73. Subsequently, we note that when questioned on this aspect of the Bill in the Health and Social Care Committee, the Minister said:

“Clearly, the unranked list is a cause of concern for some people, and I think that perhaps we do need to reflect on this. As we have come to the end of Stage 1, I think that perhaps we do need to have a further look at this”.⁴⁴

⁴⁰ Explanatory Memorandum, Annex A - Explanatory Notes, paragraph 48

⁴¹ CLA Committee, *RoP [paragraph 115]*, 4 February 2013

⁴² CLA Committee, *RoP [paragraph 119]*, 4 February 2013

⁴³ CLA Committee, *RoP [paragraph 120]*, 4 February 2013

⁴⁴ Health and Social Care Committee, *RoP [paragraph 87]*, 20 February 2013

Our view

74. We consider that, in line with recommendation 7, a superaffirmative procedure should apply to the regulation-making power under section 17(2).

Recommendation 9: We recommend that an amendment is tabled to the Bill to apply a superaffirmative procedure to the order-making power under section 17(4), which permits the definition of qualifying relationships for the purposes of the Bill to be amended.

75. As we have indicated in paragraphs 19, 61 and 73, and recommendation 3 of this report, we have some concerns regarding the clarity of section 17 of the Bill.

76. Also, we have already recommended (recommendation 4) that an amendment should be tabled to the Bill to make it clear that qualifying relationships will not be ranked for the purposes of information provided under section 4(4)(b).

77. More generally, from a reading of the Bill, it is unclear to which provisions the unranked and ranked lists apply. For example, section 17(2) defining “qualifying relationships” applies “for the purposes of this Act”; given this, it is therefore unclear to what extent and in what circumstances, section 17(2) and section 14(3)(f) (see paragraph 50 above), apply to sections 5(4) and 6(3) of the Bill.

Recommendation 10: We recommend that the Minister clarifies, preferably by amendment, the provisions of the Bill that are subject to section 17(2) and those that are subject section 27(4) of the *Human Tissue Act 2004*, including if necessary, whether they apply in specific circumstances only.

Section 19 – Commencement

78. Section 19(1) empowers Welsh Ministers to commence certain provisions in the Bill by order.

Our view

79. It is standard practice that no procedure is prescribed for commencement orders and we are content with this approach.