National Assembly for Wales
Legislation Committee No.1

Proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011

Committee Report
February 2011
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Legislation Committee No.1

Legislation Committee No. 1 was established by the National Assembly for Wales to consider and report on legislation introduced to the Assembly primarily by individual Assembly Members, committees and the Assembly Commission. The Committee is also able to consider and report on government legislation, as appropriate.

Powers

The Committee was established on 26 November 2008 as one of the Assembly’s legislation committees. Its powers are set out in the National Assembly for Wales’ Standing Orders, particularly Standing Order 10, 22 and 23. These are available at www.assemblywales.org

Committee membership

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* Andrew Davies AM was the permanent substitute for Ann Jones AM for the duration of the Committee’s scrutiny of the proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011.
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The Committee's Recommendations

The Committee’s recommendations to the Welsh Government are listed below, in the order that they appear in this Report. Please refer to the relevant paragraphs of the report to see the supporting evidence and conclusions:

- We agree in principle that legislative competence in the areas identified within the proposed Order should be conferred on the National Assembly.

- We recommend that the Minister develops a public education programme as part of the development of the legislation that will arise from this proposed Order.

- We recommend that the Minister considers whether the term ‘or other authorisation’ should be deleted or replaced by another form of words that more clearly describes the powers that the Welsh Government is seeking to acquire.

- We are content that the scope of the proposed Order should apply only to persons aged 18 and over, and accordingly, we are content with the definition of ‘deceased adult’ used in the proposed Order.

- We are content with definition of ‘relevant material’ used in the proposed Order.

- We are content with the fixed exception relating to coroners’ functions included in the proposed Order.
1. **Introduction**

**Background**

1. On 10 January 2011, the Minister for Health and Social Services ("the Minister") laid the proposed *The National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011* \(^1\) ("the proposed Order") and Explanatory Memorandum\(^2\), in accordance with Standing Orders 22.13 and 22.14. The Minister made a statement in Plenary about the proposed Order on 12 January 2011.\(^3\)

2. On 7 December 2010, the Business Committee agreed to refer the proposed Order to Legislation Committee No.1 for detailed consideration. It subsequently agreed a reporting deadline of 4 February 2011.\(^4\)

**Scope of the Committee's Scrutiny**

3. The Committee agreed the scope of its scrutiny out of Committee on 12 January 2011, as set out below:

   (i) to consider the general principles of the proposed Order and whether legislative competence in the areas identified in Matter 9.3 be conferred on the Assembly; and

   (ii) to consider whether the terms of the proposed Order are too broadly or narrowly defined.

4. We issued a general call for evidence in the form of an online survey and invited organisations with an interest in the subject area to submit written evidence to inform our work. The survey questions and list of consultation responses can be found at the end of this report.

5. We would like to place on record our thanks to all those who took the time to respond to our consultation, particularly in light of the limited time we were able to make available for comments given our reporting deadline.

6. We took oral evidence from the Minister for Health and Social Service at our meeting on 20 January 2011.

\(^1\) [http://www.assemblywales.org/lco-ld8348-e.pdf](http://www.assemblywales.org/lco-ld8348-e.pdf)

\(^2\) [http://www.assemblywales.org/lco-ld8348em-e.pdf](http://www.assemblywales.org/lco-ld8348em-e.pdf)

\(^3\) RoP, 12 January 2011

\(^4\) Business Committee, 11 January 2011
7. Under Standing Order 22.21, in preparing our report we must, so far as is reasonably practicable, take into account any recommendations made on the proposed Order by:

   (i) any other committee of the National Assembly for Wales; and

   (ii) any committee of the House of Commons, the House of Lords or any Joint Committee of both Houses of Parliament.

8. No such recommendations have been made in respect of the proposed Order.

9. The following report represents the conclusions we have reached based on the evidence received during the course of our work.
2. Principle of the proposed Order

Background

10. The purpose of the proposed Order is to amend Part 1 of Schedule 5 to the Government of Wales Act 2006 ("the 2006 Act") to confer legislative competence on the National Assembly by inserting a new Matter, Matter 9.3, into Field 9 (health and health services).

11. The conferral of legislative competence on the National Assembly by the proposed Order will enable the Welsh Assembly Government ("Welsh Government"), Assembly committees or individual Assembly Members to bring forward proposals for legislation, in the form of Assembly Measures, within the scope of Matter 9.3.

12. Matter 9.3 is set out below:

Matter 9.3

Consent or other authorisation for the following activities for the purpose of transplantation to a human body—

(a) storage and use of the body of a deceased adult;

(b) removal, storage and use of any relevant material of which such a body consists or which it contains.

This matter does not include consent or other authorisation for any of the activities mentioned in paragraphs (a) and (b) in the following circumstances without the consent of a coroner.

The circumstances are those where a person carrying out any activity mentioned in paragraphs (a) and (b) knows, or has reason to believe, that the body of a deceased person, or relevant material which has come from the body of a deceased person, is or may be, required for the purposes of functions of a coroner.

In this matter—

“deceased adult” means a deceased person who had attained the age of 18 before death;
“relevant material” means material that consists of human cells, apart from gametes, embryos, hair and nails.

Explanatory Memorandum

13. In the Explanatory Memorandum accompanying the proposed Order, the Welsh Government states that:

“This legislative competence would enable legislation to be developed to take forward the Welsh Assembly Government’s policy of increasing the number of organs and tissues available for donation, and in particular by introducing a “soft” opt-out system. By “soft” opt-out system we mean doctors can remove organs from every adult who lives and dies in Wales where the law applies, unless a person has registered to opt out; but adopting good practice whereby doctors ask the relatives for their agreement at the time of death. The persons to whom such legislation applies will need to be clearly identified in the legislation.”

14. The Welsh Government also indicates that the introduction of an opt-out system of organ donation would apply to “those living and dying in Wales” and operate in addition to “the existing UK-wide opt-in system.”

15. The Welsh Government also explains that it wants to increase the number of organ and tissue donors in Wales in order “to improve both the health and quality of life of citizens.” It lists the reasons for introducing a “soft” opt-out organ donation system as follows:

- Studies show that the majority of people say that they would be willing to donate their organs for transplantation purposes, but only around a quarter of the population are on the NHS Organ Donation Register [in the UK]

- Given that the majority of people say that they would be willing to donate, presuming consent rather than presuming objection

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1 Explanatory Memorandum, paragraph 31
2 Explanatory Memorandum, paragraph 9
3 Ibid.
4 Ibid.
5 Explanatory Memorandum, paragraph 6
6 The Welsh Government explains that the list was originally produced by the British Medical Association but that it endorses the list.
is more likely to achieve the aim of respecting the wishes of the deceased person.

- Unlike the current system, there would be a clear mechanism for protecting the wishes of those who do not want to become a donor.

- While relatives would still be consulted, they would be relieved of the burden of making the decision in the absence of any indication of the deceased person’s wishes.

- A shift to presumed consent would prompt more discussion with families about organ donation.

- With such a shift, organ donation becomes the default position. This represents a more positive view of organ donation, which is to be encouraged.

- Despite the acknowledged difficulties of obtaining meaningful data about the presumed consent in other countries, the BMA believes that, as one part of a broader strategy, a shift to presumed consent is likely to have a positive effect on donation rates.\(^\text{10}\)

16. The Explanatory Memorandum also refers to the work of the Organ Donation Task Force\(^\text{11}\); the 2008 report of the National Assembly’s Health, Wellbeing and Local Government Committee inquiry into presumed consent for organ donation\(^\text{12}\) and a public debate on presumed consent, initiated by the Welsh Government.\(^\text{13}\)

Evidence from consultees

17. We received eighty responses to our consultation survey and of these, sixty four per cent were in favour of the proposed Order, with thirty six per cent against.

\(^{10}\) Explanatory Memorandum, paragraph 21


\(^{12}\) National Assembly for Wales, Health, Wellbeing and Local Government Committee Inquiry into Presumed Consent for Organ Donation, July 2008

\(^{13}\) A report on the outcome of this debate is contained in the following consultation document: Welsh Government, Options for Changes to the Organ Donation System in Wales, May 2009
18. Many people in favour of the proposed Order felt it would increase the number of organs available for donation and save lives. Diabetes UK Cymru said:

“The need for new organs is vital for a number of conditions and the proposed 'opt out' system would be a great advance for the number of people for whom a new organ could literally be a matter of life and death.”

19. In supporting the proposed legislation, a member of the public said that:

“The ethical concerns which have been raised are valid in many ways, but weighed against the overwhelming evidence that the measure could increase the number of organs available for transplant, thereby saving lives, one must favour changing the system in the way the Heath Minister is suggesting.”

20. In expressing their support for the proposed Order, the British Heart Foundation Cymru said:

“The BHF supports measures to improve the UK’s rate of organ donation. These measures include consistent national promotion coupled with a strong infrastructure of organ retrieval and professional training. Whilst such measures will go a long way to improving donor organ availability, we believe that a soft opt out system where close relatives retain the power of veto should underpin organ transplantation in Wales, and more broadly the UK as a whole. We believe the Assembly should be able therefore to legislate in this area, as detailed in the Order.”

21. They went on to say:

“The current system of organ donation does not adequately reflect the high levels of public support. This support for organ donation remains very high at around 90 per cent, yet the number of people signed up to the Organ Donor Register is...
just 28 per cent. This highlights the need for a system that better captures the intentions of the public.\textsuperscript{17}

22. This view was shared by other consultees. One member of the public felt that an “opt-out system would mean that more people actually get their wishes granted” and that “it would help to eliminate the discrepancy between the number of people who say they want to donate organs and the number actually donated.”\textsuperscript{18} Similar views were expressed by another member of the public:

“It clears up the grey area where people would be happy to donate, but have not got around to letting anyone know. That grey area could save hundreds of lives and bring an immeasurably better quality of life to so many people.”\textsuperscript{19}

23. He added that:

“Sometimes, you have to make radical decisions that make a difference and without doubt, this is one of those times.”\textsuperscript{20}

24. People Like Us Cymru made the following points:

“It has been widely accepted that the majority of people support the idea of organ donation but do not sig[n] up to the register. A soft opt out system will make it easier for people to have their wishes followed after their death.”\textsuperscript{21}

25. They added that:

“People who are not willing to donate can register their wishes by opting out.”\textsuperscript{22}

26. This view, that the emphasis should be on opting-out rather than opting-in, was shared by an anonymous contributor:

“It seems stupid to me to have so many people losing their battle for life when organs would be available. People tend not to take the trouble to register to donate because they are busy doing other things or don't think about it. If someone has

\textsuperscript{17} HHS66
\textsuperscript{18} HHS17
\textsuperscript{19} HHS47
\textsuperscript{20} Ibid.
\textsuperscript{21} HHS57
\textsuperscript{22} Ibid.
strong views against donation they will make sure that they opt out."²³

27. A member of the public suggested that relying on a donor register would not lead to increases in the number of organs available for transplantation.²⁴ He felt that:

“Organ Donor Register promotion creates awareness but does not solve the problem, increasing the number of people on the Organ Donor Register alone is not enough.”²⁵

28. Other consultees felt that acquisition of powers and the use of a “soft” opt-out system would set a precedent for the rest of the UK to follow²⁶, while others felt that a system of presumed consent should be introduced in Wales because it is working well in other countries within the EU.²⁷

29. As indicated above there was however a significant minority of people who were opposed to the National Assembly acquiring powers and the use of a “soft” opt-out system.

30. A number of consultees felt that the introduction of a system of presumed consent would remove the rights of citizens at the expense of the state and that such a system would infringe on the rights of the individual. An anonymous contributor felt that:

“... the proposal for a 'soft opt out' goes too far in assuming that anyone has a right to the body parts of another human being. Our bodies are our own and not the possession of a state to use as it sees fit; this is an unacceptably intrusive proposal on the rights of the individual. If people wish to donate it is their gift and their gift alone. ... If the state wishes to assist in increasing the level of donations then the state has to be more persuasive in achieving increased levels of voluntary donation. I am sympathetic to the needs of those awaiting transplants and some situations can be very difficult but transplantation is an opportunity not a right.”²⁸

²³ HHS3
²⁴ HHS 67
²⁵ Ibid.
²⁶ HHS22, HHS48, HHS53, HHS65, HSS79
²⁷ HHS22, HHS48, HHS67
²⁸ HHS5
31. Another anonymous contributor raised concern about the potential for violating individual human rights and also expressed dissatisfaction with the underlying thinking behind presumed consent:

“I am uncomfortable with the concept that you can assume that ... absence of disagreeing with something implies implicit agreement.”

32. A member of the public felt that:

“To force through an opt-out system as proposed would at a stroke remove this profound compact between citizen and state and effectively leave the state as "owning every person's organs", which are "loaned out" for the duration of life and then returned on death.”

33. He added that:

“Clearly, there is a concern about the low rate of donation and there are many people waiting for an appropriate organ, so the best way is to be more creative and pro-active in how the national agencies encourage citizens to make this important gift for another.”

and promoted the virtue of the current opt-in system:

“The current opt-in system respects the citizen's right to decide to act altruistically by pledging their organs following death for possible use by an anonymous donee. Such a system operates in Ireland which has one of the best rates of donation in the world and where there is a "high-trust" environment, facilitating a greater willingness of citizens to donate.”

34. Other consultees also expressed support for the current opt-in system. Another member of the public said:

“Organ donation is a sensitive issue for many people in many ways and ... there is nothing wrong with the present method of people wishing to donate organs if they so wish. To make people state if they do not want to donate is fundamentally
wrong, in some way it is shaming people to do something they do not want to do for whatever reason. People should be allowed to make their own decision on this sensitive issue, if people wish to donate then register in the normal way, if people do not wish to donate then do not register… “33

35. The British Transplantation Society questioned "whether 'Opting-Out' is truly consent."34 They added that:

“For those who decide to opt-out it is clear that they are making a positive decision not to consent, but for the majority it is assuming or presuming they consent, when in reality many will not make a conscious decision to do so.”35

36. The British Transplantation Society also felt that:

“It would be better to defer any decision until 2013 as recommended in the second Organ Donation Taskforce report (The potential impact of an opt-out system for organ donation in the UK), by which time the full impact of the recommendations from first report of the ODTF will be known.”36

37. The Donor Family Network also expressed support for “the recommendation of the Organ Donation Task Force not to proceed with a move to a system of presumed consent in the UK” and believed "that if the recommendations of the full task force report are undertaken transplant numbers can be increased within the existing system.”37

38. A number of consultees opposed to the proposed Order felt that decisions should be taken at a UK level38 and that having different practices between Wales and the rest of the UK in relation to organ donation would lead to confusion.39 On this last point and related to

33 HHS38
34 HHS50
35 Ibid.
36 Ibid.
37 HHS58
38 HHS15, HHS33, HHS34, HHS36, HHS46, HHS56, HHS77
39 HHS14, HHS50, HHS52, HHS78
the fact that the proposed system would apply to those who live and die in Wales only, the Human Tissue Authority\(^{40}\) stated that:

“Organ donation teams in Welsh hospitals will need to be trained on both systems and able to identify which group a deceased, or soon to be deceased, person is in. There is a risk that introducing complexity, and potentially confusion, to a clear statutory system could diminish people’s confidence in organ donation and consent more widely.”\(^{41}\)

39. In considering the Welsh Government’s wish to see an increase in the number of organ and tissue donors to improve the health and quality of life of citizens, the Human Tissue Authority said “there is no evidence provided to substantiate the fact that ... a soft opt-out scheme will do this”\(^{42}\) and added:

“If there is to be a move away from the current position of an opt-in system under the Human Tissue Act, with the associated protections given to the individual’s wishes and consistency in consent requirements, it should have a solid evidence base.”\(^{43}\)

40. One of the themes that emerged from the evidence received was the emphasis placed on the need for better public information and education. Both those in favour of the proposed Order and those against highlighted the importance of this issue.

41. In supporting the proposed Order, SNAP Cymru said:

“We understand this to be a very difficult order and strongly recommend high publicity for the opt out opportunity. This publicity should be on going to protect people's rights in decision making.”\(^{44}\)

42. A member of the public said:

“It has always been recognised that should the Assembly receive a[n] LCO ... a lot more work will need to be done to

\(^{40}\) The Human Tissue Authority’s response was provided as an initial consideration given the short consultation period and the authority did not express a view on whether or not it supported the proposed Order.

\(^{41}\) HHS69

\(^{42}\) Ibid.

\(^{43}\) Ibid.

\(^{44}\) HHS30
inform and educate the people of Wales in all matters of the proposed change, especially giving advice and guidance to those people who wish to opt out. In addition, a lot of consideration and deliberation will be needed as to how such a law will work in practice. 

43. The Organ Donation Committee of the Hywel Dda Health Board felt that the introduction of legislation would of itself raise the profile of organ donation:

“The legislation change will certainly generate much needed publicity and debate about organ donation, get families talking about the subject so that they know what each other might want.”

44. Amongst those opposed to the proposed Order, there was a call from a member of the public for more to be done to encourage people to opt in to organ donation under the existing scheme:

“... matters of such ethical sensitivity require better public education and information to enable better informed personal decisions to be made about opting into the donation process.”

45. Another member of the public opposed to the proposed Order called for organ donation issues to be part of the wider health education agenda:

“... this is a very emotive subject, and should be brought into general health education, to encourage people to make informed decisions...”

**Evidence from the Minister for Health and Social Services**

46. The Minister explained the purpose of the proposed Order:

“The outcome that we are looking for is an increase in the number of organs for donation, and more people receiving organ transplants. We recognise that it will benefit some Welsh patients, but it will benefit patients throughout the United Kingdom. I hope that, if this practice comes in in Wales, others...”
will seek to do the same elsewhere, in order to increase the number of organs that are available for transplant ... We are not doing it to be different; we are doing it for the right reason, which is to increase the number of organs that are available.”

47. She also said that:

“If you speak to individuals and look at public opinion, everyone says that they think that donation is a good thing. However, when you then look at the number of people who donate, only about a quarter of people actually register. So, for me, it was an issue of ensuring that what people really feel becomes a reality.”

48. The Minister also explained that acquiring legislative powers was part of “a dual process”, which to date has involved better public awareness and looking at health infrastructure. In particular, she noted that:

“... in the discussions that we have had, particularly with the British Medical Association and the voluntary sector, we have been told that there is one more thing to do and that is to have legislation within this area.”

49. The Medical Director of NHS Wales, who accompanied the Minister, also highlighted that the proposed legislation was part of a series of measures aimed at increasing organ donation:

“The key issue at stake is the massive impact on survival and quality of life that transplant surgery can bring for so many patients. Clearly, to enable a full programme of transplant surgery and to avoid people waiting inordinately long times and even dying on transplant waiting lists, one needs to increase the rate of organ donation. This is all about increasing the rate of organ donation. It is about seeking to change to a system of presumed consent as part of a wide range of other

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49 RoP, paragraph 78, 20 January 2011, Legislation Committee No. 1
50 RoP, paragraph 8, 20 January 2011, Legislation Committee No. 1
51 RoP, paragraph 11, 20 January 2011, Legislation Committee No. 1
52 Ibid.
measures and issues, all designed to increase the rate of availability of organs for transplant surgery.”

50. The Medical Director also explained that despite increases in the number of registered organ donors:

“... there still remains a persistent disparity between the registered organ donors and the need for transplants. That is the problem. In Wales, we have nearly 300 people awaiting transplants at present. We undertook only 160 transplants last year, and 37 people died on the transplant waiting list last year. So, there is a gap that needs to be filled.”

51. He also explained how the proposed legislation would ultimately increase organ donation rates:

“We would expect the change to raise public awareness and enable a cultural change, so that, for society in Wales, the default position would be that you are an organ donor. At present, because only 30 per cent of people are registered and 70 per cent are not, when we approach the families, the default position, namely that you are out, is reflected, and around 40 per cent of those families say ‘no’. With presumed consent, we would hope, given the survey results that indicate that perhaps 90 per cent of people would be in, that that would be the default position. We would expect that families, who would still have a say in the matter, would tend to defer to that default position. So, there would be those two things: the increase in the number of people who are, essentially, organ donors; and the cultural change regarding the default position, which will increase the rate of availability of organs.”

52. The Minister and the Medical Director also clarified how the system proposed for Wales would operate alongside the existing UK system of organ donation. She said:

“We do not think that there will be any difficulty at all. We will have our system in Wales and ... we will be a part of the wider

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53 RoP, paragraph 9, 20 January 2011, Legislation Committee No. 1
54 RoP, paragraph 75, 20 January 2011, Legislation Committee No. 1
55 RoP, paragraph 79, 20 January 2011, Legislation Committee No. 1
UK system and, of course, there are other issues within Europe. We do not see this being a problem at all."\(^{56}\)

53. She clarified that the legislation “applies only to adults who live and die in Wales”\(^{57}\) and indicated that organs will then become available for anyone in the UK and under existing agreements, European nationals.\(^{58}\) In explaining this position, she noted that:

“Wales as a nation is being altruistic in what it wants to undertake, because these organs cannot be guaranteed to people in Wales. They will form part and parcel of the national list for the appropriate matches to be made.”\(^{59}\)

54. The Medical Director considered that:

“Without being able to speculate about the operational details of this system, we would hope that what we propose in Wales will support the systems that exist in England.”\(^{60}\)

55. He went on to say:

“We respect entirely the organ donation register, and we would seek to strengthen that. The proposal also does not make any difference to the way in which organs are allocated to recipients. This proposed legislation should strengthen the all-UK arrangements.”\(^{61}\)

56. When questioned about a recommendation of the 2008 report of the National Assembly’s Health, Wellbeing and Local Government Committee (that powers to introduce presumed consent should not be sought at that time), the Minister stated:

“Even though I respect the committee’s report and all of the background work involved, I still feel, on behalf of the Government, that it was right to legislate to increase the numbers of organs that are available for transplant.”\(^{62}\)
57. She also noted that:

"... when the committee reported, it did look at the wider issues of what you need to do to encourage organ donation. It was also looking at the system, and we have made improvements in the system."63

58. The Minister also indicated that she was content that the powers being sought through the proposed Order relate to a field in Schedule 5 to the Government of Wales Act 2006.64

59. The Minister emphasised also that:

"The LCO is the start of the process rather than its end, and in terms of developing the future Measure, some of the questions that have already come from committee colleagues indicate the wide range of issues that we will have to engage with the public on. There will be an opportunity to do that if and when the proposed LCO goes through."65

60. The Minister went on to add:

"If we are successful with the proposed LCO, we will consult further on the format and shape of the proposed Measure, and we will be getting various groups together to discuss the issues."66

61. The Minister also acknowledged the need for further work to be undertaken on the interaction between the Welsh and UK systems prior to the introduction of any future proposed Measure.67 She said:

"... my wish is that there would be discussions on a Measure about all of these issues prior to anything being subject to legislation by the National Assembly for Wales."68

62. The Medical Director highlighted the importance of the need for better public awareness which he felt the introduction of this legislation may bring about. He said:

63 RoP, paragraph 12, 20 January 2011, Legislation Committee No. 1
64 RoP, paragraphs 89-90, 20 January 2011, Legislation Committee No. 1
65 RoP, paragraph 56, 20 January 2011, Legislation Committee No. 1
66 RoP, paragraph 85, 20 January 2011, Legislation Committee No. 1
67 RoP, paragraph 22, 20 January 2011, Legislation Committee No. 1
68 Ibid.
“We do recognise that there is a need to raise public awareness to encourage conversations about organ donation as a healthy, normal part of the process of death, and one that can actually bring comfort to families. We think that introducing this sort of change will actually raise public awareness considerably of the issues.”

63. He added that:

“There will be a need for a prolonged public awareness campaign, probably over two years, to ensure that people are aware of the choices available to them.”

Our view

64. We note the views of the Minister and also those of the organisations and individuals who responded to our on-line consultation survey.

65. While there was a majority of consultees in favour of the National Assembly acquiring the powers to legislate in this area, we note that there was a significant proportion against.

66. In particular, we note the views of consultees who expressed concerns that decisions relating to organ donation should be undertaken at a UK level and that having a different practice between Wales and the rest of the UK would lead to confusion. We do not share these concerns. We note that the introduction of a “soft” opt-out system would sit alongside the existing system of organ donation and that, in the view of the Minister and the Medical Director of the NHS Wales, the system proposed should support and strengthen the existing UK arrangements. In reaching this view, we acknowledge that the details of how this will operate in practice will need to be considered carefully and accordingly, we welcome the commitment of the Minister to consult fully prior to the introduction of the proposed Measure.

67. We have considered two relevant recommendations of the 2008 report by the Health, Wellbeing and Local Government Committee on presumed consent for organ donation, which recommended that the National Assembly should not acquire legislative powers in this area at

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69 RoP, paragraph 69, 20 January 2011, Legislation Committee No. 1
70 RoP, paragraph 71, 20 January 2011, Legislation Committee No. 1
that time and that any future system of presumed consent, introduced by legislation, should be a “soft” system.

68. We note the Minister’s evidence that since publication of that report, the Welsh Government has sought to raise public awareness about organ donation and looked to develop relevant health infrastructure. In light of this, and given that over two years has elapsed since the publication of the Health, Wellbeing and Local Government Committee’s report, we consider that now is an appropriate time to acquire the powers contained in the proposed Order, particularly given the lengthy consideration that may be needed to draw up an appropriate proposed Measure.

69. Accordingly, we agree in principle that legislative competence in the areas identified within the proposed Order should be conferred on the National Assembly.

70. We agree with consultees who have highlighted the importance and need for on-going public education and awareness raising around the issues highlighted by this proposed Order. Given the emotive and sensitive nature of presuming consent for organ donation this is vital. Therefore, we recommend that the Minister develops a public education programme as part of the development of the legislation that will arise from this proposed Order. This programme should address the concerns that have been raised by many consultees about introducing a “soft” opt-out system of presumed consent for the purposes of transplantation.

71. Our consideration of the terms of Matter 9.3 is set out in Chapter 3.
3. Scope of the proposed Order

Evidence from consultees – general comments

72. Some consultees commented in general terms about the wording of Matter 9.3.

73. The Donor Family Network stated:

“The wording is unclear and does not detail the consent issue particularly with respect to non Welsh donors. It is also not clear that this would be a 'soft' option.”

74. A member of the public asked:

“Are the wishes of the next-of-kin considered relevant or proposed for inclusion in the Matter?”

Evidence from consultees – the meaning of “or other authorisation”

75. The Human Tissue Authority indicated that they were uncertain of the meaning of “or other authorisation”:

“The proposed LCO seeks to make consent or any other authorisation a matter for the Welsh Assembly Government. There is no definition of “any other authorisation” given in either the Order itself or the memorandum which accompanies it. We assume that this is to allow the introduction of the soft opt-out system detailed, however it is important that the precise intention of this form of words is shared as a matter of priority, to ensure that pre-legislative scrutiny is as robust as possible.”

Evidence from consultees – the meaning of “relevant material”

76. A few consultees queried the use of the term “relevant material”. In particular, one member of the public felt that:

“I would have thought it more satisfactory and clear for the organs proposed for transplantation to be contained in a definitive list (which could be subsequently amended if the
need arose) rather than the term 'relevant material' as used and subsequently defined."

77. Another member of the public said that:

"... it would be more acceptable to the public if only parts/organs are specified [and] taken (at this stage), rather than a carte-blanche approach, where seemingly anything can be done/taken. 'Relevant material' may not be publicly acceptable..."

Evidence from consultees – application of the proposed Order to children

78. A member of the public queried the application of the proposed Order to children:

"...the donation of organs from deceased children does not appear to be mentioned. This should be with the consent of the parents."

79. Another member of the public was opposed to the proposed Order applying to children.

Evidence from consultees – use of organs for research

80. The Human Tissue Authority made the following observation:

"It should also be noted that at present when consent is sought for organ donation, it is normally also sought for research. As research would remain a Human Tissue Act regulated activity in Wales the family would be required to actively consent to this, potentially introducing confusion at an emotional time."

81. In their evidence in support of the proposed Order, the Pontypool Pacers Health Support Club also referred to the use of organs for medical research.
Evidence from consultees – umbilical cord blood and tissues

82. Anthony Nolan suggested that the proposed Order be amended as follows:

“… we are seeking amendments to the Legislative Competence Order that include umbilical cord blood and tissues as a separate class of tissues for which the Welsh Government may legislate to determine the consent for donation. Furthermore, Matter 9.3 should be amended to reflect that in the class of tissues in which umbilical cords would be included, the donors are by definition without capacity and powers should not be excluded on that basis.”

Evidence from the Minister for Health and Social Services

83. The proposed Order would provide the National Assembly with the competence to legislate in relation to “consent or other authorisation” for certain specified activities for the purpose of transplantation. When questioned about what is meant by “or other authorisation”, the Minister’s legal adviser said that the phrase was chosen:

“… because ‘consent’ alone might give the impression that we were referring only to positive consent. In a system of presumed consent, there may not actually have been a conscious consent or written consent, or any other kind of consent. ‘Other authorisation’ allows us to authorise the use of organs through the provision in the Measure itself. It is about getting rid of the fiction around the term ‘presumed consent’ by saying that it is either ‘consent’ or ‘other authorisation’ by the systems that would be created in the Measure.”

84. We also questioned the Minister on whether the definition of “deceased adult” should refer to persons aged 16 years rather than 18 years (given that those aged 16 years and above are able to consent to medical treatment), and related to this, whether the scope of the proposed Order should be widened to include children.

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80 HHS74
81 RoP, paragraph 112, 20 January 2011, Legislation Committee No. 1
85. In response, the Minister said that:

“We stuck at 18 because this is the cleanest way of dealing with the fact that you are adult at the age of 18.”

86. The Medical Director of NHS Wales highlighted the distinction that was being drawn by the proposed Order:

“The matter of a 17-year-old giving consent for something is different from presuming consent.”

87. On the specific issues of extending the scope of the proposed Order to children, the Minister said:

“You can exempt yourself from presumed consent; you can decide not be part and parcel of it. Therefore, you would make the decision as an adult, and that is the rationale behind our approach.”

88. The Minister’s legal adviser added the following comments:

“The policy concern was not to overcomplicate what we were doing. If you tried to apply the presumed consent system to children, there would be complicated processes to deal with.”

89. He added:

“So, the idea is that the existing system would continue to be in place for children and young people, and that the new system would only be for adults.”

90. As regards the inclusion of a fixed exception relating to coroners, the Minister’s legal adviser said:

“Under the existing law, if a medical professional who wishes to remove organs from a body is clear that there is appropriate consent for that to happen, but he or she knows or has reason to believe that there are circumstances around the death of that person that would engage the functions of the coroner, nothing can be done in relation to that body unless the coroner

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82 RoP, paragraph 124, 20 January 2011, Legislation Committee No. 1
83 RoP, paragraph 125, 20 January 2011, Legislation Committee No. 1
84 RoP, paragraph 127, 20 January 2011, Legislation Committee No. 1
85 RoP, paragraph 128, 20 January 2011, Legislation Committee No. 1
86 RoP, paragraph 130, 20 January 2011, Legislation Committee No. 1
consents. That is part of the existing law. The exceptions make it clear that there is no intention here to unpick the general role of coroners in similar circumstances. So, it would allow the Assembly by Measure to make the same kind of provision that currently applies in relation to the existing system under a system of presumed consent.”

Our view

91. We note the view of the Minister’s legal adviser regarding the meaning of ‘or other authorisation’ in Matter 9.3. We further note that the Human Tissue Act 2004 uses the term ‘appropriate consent’ in all cases where consent is required under the Act. In our view, the term ‘or other authorisation’ lacks clarity. Therefore, we recommend that the Minister considers whether the term ‘or other authorisation’ should be deleted or replaced by another form of words that more clearly describes the powers that the Welsh Government is seeking to acquire.

92. We note the explanations of the Minister and her officials for not extending the scope of the proposed Order to children. We agree that such an approach would raise potentially difficult and complex issues, which could detract from the overall benefits that the proposed legislation is trying to implement.

93. Related to this point, we have nevertheless considered whether the definition of ‘deceased adult’ within the proposed Order should make reference to persons aged 16 years rather than 18 years. Having considered the views of the Minister on this issue, we are satisfied that for persons aged 16 and 17, the ability to donate organs through the existing opt-in arrangements represents a more appropriate option.

94. In light of the views we express in paragraphs 92 and 93, we are content that the scope of the proposed Order should apply only to persons aged 18 and over, and accordingly, we are content with the definition of ‘deceased adult’ used in the proposed Order.

95. We note the views of some consultees that it would be more appropriate to include a list of organs to which the proposed Order should apply, rather than include the term “relevant material”. However, in our view this would narrow the scope of the proposed

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87 RoP, paragraph 137, 20 January 2011, Legislation Committee No. 1
88 http://www.legislation.gov.uk/ukpga/2004/30/contents
Order unnecessarily; in our view should it be necessary to apply this legislation to certain organs, this would be better achieved through the proposed Measure. Accordingly, we are content with definition of 'relevant material’ used in the proposed Order.

96. Following the explanation provided by the Minister’s legal adviser, we are content with the fixed exception relating to coroners’ functions included in the proposed Order.

97. There were two issues, raised by consultees, which we did not have the opportunity to consider in any detail or question the Minister on, namely the scope of the proposed Order as it relates to consent for the use of donor organs for research, and the collection of umbilical cord blood and tissues. Accordingly, we make no make comment on these particular issues but wish to draw them to the attention of the Minister so that she may consider the issues raised further.
Witnesses

The following witnesses provided oral evidence to the Committee on the dates noted below. Transcripts of all oral evidence sessions can be viewed in full at: http://www.assemblywales.org/bus-home/bus-committees/bus-committees-perm-leg/bus-committees-third-lc1-agendas.htm.

20 January 2011

Edwina Hart AM Minister for Health and Social Services
Dr Chris Jones Medical Director for NHS Wales and Deputy Chief Medical Officer
Huw Davies Office of the Welsh Legislative Council
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Caroline Jones  
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Roy J Thomas  
Emma Bourton  
Craig Muir - Human Tissue Authority  
Peter Vaughan - Chief Police Officers in Wales  
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Member of the public  
Anthony Nolan  
Dr Patrick Cadigan – Royal College of Physicians  
Anonymous  
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