



House of Commons
Welsh Affairs Committee

Proposed Legislative Competence Orders relating to Organ Donation and Cycle Paths

Sixth Special Report of Session 2010–11

*Additional written evidence is contained in
Volume II, available on the Committee website
at <http://www.parliament.uk/welshcom>*

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The Welsh Affairs Committee

The Welsh Affairs Committee is appointed by the House of Commons to examine the expenditure, administration, and policy of the Office of the Secretary of State for Wales (including relations with the National Assembly for Wales).

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The Reports and evidence of the Committee are published by The Stationery Office by Order of the House. All publications of the Committee (including press notices) are on the internet at www.parliament.uk/welshcom

The Reports of the Committee, the formal minutes relating to that report, oral evidence taken and some or all written evidence are available in printed volumes.

Additional written evidence may be published on the internet only.

Committee staff

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Legislative Competence Orders

Background

1. The structure and powers of the National Assembly were significantly altered and expanded by the Government of Wales Act 2006, which came into effect with the election of the Third Assembly in May 2007. Part 3 of that Act provided for the Assembly to make “Measures” within the scope of that legislative competence defined by Schedule 5 to the Act. The Act also made provision for that scope to be altered by amendments made to Schedule 5 either by primary legislation (when a bill on an appropriate area is going through Parliament) or secondary legislation (under which the National Assembly can bring forward proposals for Legislative Competence Orders (LCOs) under section 95 of the Government of Wales Act). Since 2007, the Assembly’s legislative competence has been significantly enlarged by these means.

2. Since the introduction of Legislative Competence Orders in Council (LCOs), the Welsh Affairs Committee has published fifteen reports on proposed Legislative Competence Orders.¹ We have also published two reports on the LCO process.² The full background to the LCO process is contained in Annex A to this Report.

3. The 2006 Act also included, at Part 4, arrangements for the transfer of primary legislative competence to the Assembly following a positive vote in a referendum of the Welsh electorate. The scope of that competence was defined (provisionally) by Schedule 7 to the Act. We reported on the scope and effect of Schedule 7 in our First Report of this session.³

4. The *One Wales* agreement between the Labour Party and Plaid Cymru committed the Welsh Assembly Government to hold a referendum on enhanced law making powers for the National Assembly for Wales during the lifetime of the current Assembly. The referendum was held on 3 March 2011 and resulted in a ‘Yes’ vote for enhanced law making powers. The enhanced powers for the National Assembly for Wales will come into effect following the approval of a Commencement Order by the Assembly, to bring into force the “Assembly Act provisions” of the Government of Wales Act. The Commencement Order was due to be debated at a plenary session of the National Assembly for Wales on 29 March. If it is agreed, the Assembly Act provisions come into force on 5 May. Following the coming into effect of Part 4, Legislative Competence Orders will become obsolete.

5. During this calendar year, the Secretary of State for Wales has referred to us two further proposed Legislative Competence Orders for pre-legislative scrutiny: the Proposed

1 Welsh Affairs Committee: Second Report of Session 2007–08, HC 44; Fourth Report of Session 2007–08, HC 257; Fifth Report of Session 2007–08, HC 576; Seventh Report of Session 2007–08, HC 812; Third Report of Session 2008–09, HC 5; Sixth Report of Session 2008–09, HC 306; Ninth Report of Session 2008–09, HC 348; Twelfth Report of Session 2008–09, HC 678; Fourteenth Report of Session 2008–09, HC 778; First Report of Session 2009–10, HC 40; Second Report of Session 2009–10, HC 142; Fourth Report of Session 2009–10, HC 36; Sixth Report of Session 2009–10, HC 186; Seventh Report of Session 2009–10, HC 274; Eighth Report of Session 2009–10, HC 273. See also Fifth Report of Session 2009–10, *Review of the LCO Process*, HC 155.

2 Welsh Affairs Committee: Second Report of Session 2006–07, HC 175; Fifth Report of Session 2009–10, HC 155

3 Welsh Affairs Committee, First Report of Session 2010–11, *The proposed amendment of Schedule 7 to the Government of Wales Act 2006*, HC 603

National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011 relating to organ donation; and the Proposed National Assembly For Wales (Legislative Competence) (Highways and Transport) Order 2011, relating to cycle paths. This Report sets out the details of the Orders and how the result of the Welsh referendum on 3 March affected our scrutiny of them.

The final LCO Proposals

Proposed National Assembly for Wales (Legislative Competence) (Highways and Transport) Order 2011

6. The Proposed National Assembly for Wales (Legislative Competence) (Highways and Transport) Order 2011 was proposed by the National Assembly for Wales's Enterprise and Learning Committee, and was laid before the Assembly on 4 June 2009. The Order would enable the Assembly to consider legislation that could vary the powers and duties of public highway authorities in relation to the provision of routes for use solely or principally by any one or more of the following: pedestrians; cyclists; persons on horseback or leading a horse.

7. This was the first Legislative Competence Order to be proposed by an Assembly Committee and also the first to come directly from the Assembly's petitions process. The Assembly agreed in Plenary in July 2009 that there was no need for detailed consideration of the proposed Order by a Legislation Committee. The LCO was submitted by the Welsh Assembly Government for Whitehall clearance in July 2010.

8. The Secretary of State for Wales invited us to undertake pre-legislative scrutiny of the proposed Order on 3 February 2011. Due to our programme, we were not able to issue a terms of reference before the referendum. On 14 March we received a letter from the Chair of the Enterprise and Learning Committee, National Assembly for Wales, stating the Committee's withdrawal of the Proposed National Assembly for Wales (Legislative Competence) (Highways and Transport) Order 2011. The letter is contained in Appendix A to this report. We therefore have no further comment.

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

9. The Proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order was announced as part of the Welsh Assembly Government's legislative programme on 13 July 2010. It would confer legislative competence on the Assembly in relation to consent or other authorisation for organ and tissues donation for the purposes of transplantation. This would allow the Welsh Assembly Government to introduce an opt-out system of organ donation, or "presumed consent", for those living and dying in Wales, in addition to continuing to participate in the existing UK-wide opt-in system.

10. The National Assembly for Wales (Legislative Competence) (Local Government) Order 2011 was laid before the National Assembly by the Minister for Health and Social Services, Edwina Hart AM, on 10 January 2011. The proposed Order was referred to the Assembly's Permanent Legislation Committee No. 1. The Committee issued a call for

written evidence and subsequently held an evidence session with the Minister for Health and Social Services and published its report on 4 February.

11. The Secretary of State for Wales laid the proposed Legislative Competence Order before Parliament on 10 January and invited the Committee to undertake pre-legislative scrutiny. We announced our inquiry and issued a call for evidence on 18 January. The terms of reference are contained in Annex B to this report.

12. We received a number of written submissions from organisations and individuals about the proposed LCO. We planned to hold a number of oral evidence sessions. However, before we started this stage of our inquiry, the referendum was held.

13. The Minister for Health and Social Services announced the withdrawal of the proposed Order relating to organ donation on 9 March 2011. In a statement to the plenary of the National Assembly for Wales she commented that it:

. . . must be for the next Assembly Government to bring to fruition my aspirations, and those of many Assembly colleagues, to introduce a Bill, the effect of which will be to increase the number of potential organs available for transplant . . .⁴

On 9 March, the Minister for Health and Social Services wrote to us to inform us of her decision to withdraw the proposed LCO. A copy of the letter is at Appendix B.

14. No purpose would therefore be served by our continuing our inquiry. However, due to the controversial nature of the proposal, we considered it would be valuable for the written evidence submitted to us to be made publicly available. We have therefore published the written evidence together with this Report.⁵ We hope that the National Assembly for Wales will give serious consideration to the evidence and that it will inform continued debate on the subject of presumed consent for organ donation in Wales.

15. We also received advice from two specialist advisers, Professor Keith Patchett, Emeritus Professor of Law, University of Wales, and Alan Trench, Edinburgh University. Their advice to the Committee is published as Annex C to this report.

4 RoP, 9 March 2011, National Assembly for Wales

5 Written evidence is contained in Volume II, available on the Committee website at: <http://www.parliament.uk/welshcom>

Annex A

Background to the Legislative Competence Order Procedure

The Government of Wales Act 2006 introduced a procedure whereby the National Assembly for Wales can bring forward proposals which would extend the Assembly's lawmaking powers by way of Legislative Competence Orders in Council. The Orders do not themselves change the general law for Wales—they pave the way to subsequent 'Measures' to change the law applying to Wales within the devolved areas of legislative competence. They do this by adding new "Matters" to the "Fields" of legislative competence set out in Schedule 5 to the Government of Wales Act 2006.

These proposals for draft Orders may be introduced by the Welsh Assembly Government, by committees of the National Assembly, or by individual Assembly Members (chosen by ballot). They are subject to pre-legislative scrutiny by committees of the Assembly appointed for this purpose and by committees of the House of Commons and the House of Lords. Whitehall agreement ("clearance") is a necessary prerequisite before a proposed Order is referred by the Secretary of State for Wales to each House at the pre-legislative scrutiny stage.

Following the pre-legislative scrutiny stage, the National Assembly may agree an actual draft Order. This may take account of committee recommendations (from either its own committees or Westminster) arising from pre-legislative scrutiny. The draft Order may then be laid before Parliament by the Secretary of State for Wales—and he or she may still decline to do so at this stage. If the draft Order is laid, it is considered by both House of Parliament, and may be debated by them. Draft Orders at this stage are not amendable and can only be approved or rejected. If approved by both House, and once it is given the royal assent in the Privy Council, direct law-making powers are devolved to the Assembly within the scope of the Order in Council. The Assembly can then make laws in the form of Assembly Measures, which need to be passed by the National Assembly but which require no further approval by either Whitehall or Parliament.

Annex B

Terms of Reference of the Committee's inquiry into the Proposed National Assembly for Wales (Legislative Competence)(Health and Health Services) Order 2011

The Committee would welcome comments on the following aspects of the proposed Order—

- Is the LCO request in the spirit and scope of the devolution settlement?
- Is the use of the LCO mechanism in accordance with the Government of Wales Act 2006?
- Does the Order relate to Field 9, Part 1 of Schedule 5 and Subject 9, Schedule 7 of the Government of Wales Act 2006?
- To what extent is there a demand for legislation on the matter(s) in question?
- Are there any cross-border issues relating to the LCO (e. g. financial or policy issues)?
- Are the purpose and scope of the LCO clearly defined, including the terms and definitions used?
- Does the LCO have the potential to increase the regulatory burden on the private or public sector?
- Would the proposed LCO necessitate the formation or abolition of Welsh institutions and structures? If so, where does the legislative competence to exercise such changes lie?
- Is the use of an LCO more appropriate than, for example, the use of framework powers in a Westminster Bill to confer competence on the Assembly?
- Has full use been made of any existing powers to issue statutory guidance and/or secondary legislation in relation to this Matter?
- Does the LCO have the potential to cause confusion regarding legal jurisdiction and the individuals to whom any Measure would apply to?
- What are the implications of Article 8 and Article 9 of the European Convention on Human Rights on any such Measure?

Annex C

Advice received from Alan Trench, Europa Institute, Edinburgh University

1. The purpose of this note is to set out what I see as the major constitutional and administrative issues presented by the proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011, on which the Committee has been asked to carry out pre-legislative scrutiny by the Secretary of State.

Background

2. The proposal for the present order was set out in the Assembly Government's legislative programme for 2010–11 (published in July 2010). It did not figure in the 'One Wales' coalition agreement of July 2007. In announcing the intention to bring it forward, the First Minister said:

Some may question taking forward a Legislative Competence Order with the referendum on the horizon. However, while I hope all parties in the Assembly will do all they can to secure a "yes" vote, we cannot take the outcome for granted and as a responsible Government, we are therefore working with the current process until the referendum is held, and won.¹

3. The underlying policy objective is to introduce in Wales what is known as a 'soft opt-out' system for organ donation, with organs taken for transplant unless objections have been set out by the deceased during their lifetime with consultation with the deceased donor's relatives but no right for them to block the collection of organs. There were considerable, unsuccessful, lobbying efforts to secure similar systems when the 2004 Act was being drafted and considered in Parliament, and while the Scottish legislation was being formulated as well. They were also reviewed (and rejected) in 2008 by the UK Department of Health's Organ Donation Taskforce.² They were further recently considered by the House of Lords European Union Committee, in the context of EU legislation (discussed in the next paragraph).³ Such systems appear to operate in a large number of other European countries, however; according to a 2003 European Commission report, 21 member states (including countries awaiting accession in 2004) had some form of such a system.⁴ This number appears to include Spain, Belgium, Austria and Sweden. The transplant rates of these countries vary considerably; there are varying degrees of success in increasing the number of organs available for transplant.

1 Welsh Assembly Government News Release, 13 July 2010, 'Wales will seek further powers to increase organ donation', available at <http://wales.gov.uk/newsroom/healthandsocialcare/2010/100713organ/?lang=en>

2 Organ Donation Taskforce *The potential impact of an opt out system for organ donation in the UK: an independent report from the Organ Donation Taskforce* (London: Department of Health, 2008), available from http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf

3 House of Lords European Union Committee 17th Report of Session 2007–08 *Increasing the supply of donor organs within the European Union* HL Paper 123–I (London: The Stationery Office, 2008).

4 See European Commission Directorate-General Health and Consumer Protection *Human Organ Transplantation in Europe: An Overview*, 2003, available at http://ec.europa.eu/health/ph_threats/human_substance/documents/organ_survey.pdf

4. Varying practices across the European Union—including differing criteria for determining whether organs are appropriate for transplantation into another person—have led to an EU Directive (Directive 2010/45/EU) on standards of quality and safety of human organs intended for transplantation, approved in May 2010, as part of an EU Action Plan on Organ Donation and Transplantation.⁵ This has to be implemented by 27 August 2012, and in particular requires member states to designate a national agency responsible for monitoring the new common standards. It does not seek to alter the power of member states to determine issue about consent by donors.

The existing legal regime for organ donation

5. The present law for organ donation (and related matters) in Wales, and also England and Northern Ireland, is set out in the Human Tissue Act 2004 (henceforth ‘the 2004 Act’). The explanatory notes to the 2004 Act state that ‘the Act has been drafted in liaison and agreement with the Welsh Assembly’.⁶ That was, of course, before the present devolved government took office after the 2007 elections, and also before the Government of Wales Act 2006 was passed, separating the National Assembly and Welsh Assembly Government. The explanatory note describes the 2004 Act as relating to ‘reserved matters’ (a wrong description in relation to Wales). However, this subject is clearly devolved in both Scotland and Northern Ireland. In Scotland, separate legislation—the Human Tissue (Scotland) Act 2006—has been passed. In Northern Ireland, the Westminster legislation remains in force, but it would be open to the Northern Ireland Assembly to pass its own if it wished. (The 2004 Act was passed while the Assembly was suspended.) The only aspect that is expressly ‘reserved’ under the Scottish and Northern Ireland settlements is xenotransplantation.⁷

6. The legal regimes for organ donation therefore already differ across the UK. Both regimes work through UK-wide institutions: the Human Tissue Authority (HTA), as regulator and standard-setter, and what is now NHS Blood & Transplant (NHSBT), as the body that collects and supplies organs for transplant.⁸ Both regimes have in common the requirement for consent to be given for organs to be removed for transplant, from both dead and living donors (as well as a prohibition on payment for donation). The conditions for that vary, however. In Scotland, authorisation may be verbal and if written does not need to be witnessed. In England, Wales and Northern Ireland, appropriate consent must be written and witnessed. (The Scottish regime also has a less strict approach to obtaining consent from those under 18, though as the draft LCO only relates to persons over 18 that has no direct bearing on the present case).

7. An important aspect of both regimes is to ensure that tissue is not removed (whether for transplant or otherwise) when it may be needed for post-mortem examination. They do so in different ways (necessary because the office of coroner does not exist in Scotland).

5 *Official Journal of the European Union* L 207/14, 6.8.2010.

6 Explanatory Notes to Human Tissue Act 2004, paragraph 7.

7 Xenotransplantation is the transplantation into human beings of organs derived from other species. ‘Reservation’ has a different legal meaning in Scotland and Northern Ireland—it would be wholly outwith the jurisdiction of the Scottish Parliament to legislate on this, but the Northern Ireland Assembly could do so with the consent of the Secretary of State.

8 NHS Blood and Transplant organises the practical aspects of organ transplantation though its Directorate of Organ Donation & Transplantation, which was formerly known as UK Transplant. NHSBT is constituted as an NHS Special Authority.

As the draft LCO expressly preserves the need for a coroner's consent when this may be relevant, this issue does not arise here.

8. These arrangements appear already to involve a degree of complexity for NHSBT, which must use separate forms to establish authorisation in Scotland and appropriate consent elsewhere. It has had to provide tailored training for staff in Scotland as a result. In addition, the Scottish Ministers have only conferred limited functions on the HTA (which discharges those as agent for the Scottish Government—statutory functions are not directly conferred on it by the Scottish legislation). HTA therefore has a different role in Scotland compared to England, Wales and Northern Ireland.

9. There is nothing in the proposed legislative power, or the accompanying Memorandum from the Assembly Government, to enable Wales to opt out of the existing UK 'pool' of organs available for transplant. While the power would enable the National Assembly to legislate so as to increase the number of organs from Wales available for transplant, it would not be possible for the Assembly to legislate to require any preferential use of those organs for potential recipients in Wales.

The legal effect of the proposed Order, and the referendum on the Assembly's legislative powers

10. It is worth noting what will happen if there is a 'Yes' vote in the referendum on the Assembly's legislative powers, on 3 March. The 2006 Act is quite clear; section 106 (1) provides that 'Part 3 ceases to have effect on the day on which the Assembly Act provisions come into force'. Part 3 includes the provision (section 95) under which LCOs are made. The Assembly Act provisions will not come into force immediately after a Yes vote is declared, but the Welsh Ministers have indicated that they intend the Assembly to assume those powers from 5 May 2011. As soon as that happens, the application for an LCO will cease to have any meaning.

11. If the LCO were to have been made before that date, but no Assembly Measure passed using it, the effect would be the same. Schedule 5 will similarly have no effect after the Assembly Act provisions come into force, save to establish whether Assembly Measures were within the Assembly's legislative powers when enacted while Part 3 was in force.

12. It is also worth asking whether an Assembly Act to create an 'opt-in' system of the sort contemplated by the Assembly Government would be within legislative competence once those powers come into effect. The key question here is whether organ donation is included within the Assembly's powers set out in Schedule 7. Subject 9 of Schedule 7 includes:

Prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder. ... Provision of health services, including medical, dental, ophthalmic, pharmaceutical and ancillary services and facilities.⁹

It explicitly excludes a number of matters, including ‘xenotransplantation’, but nothing else relevant here. Clearly transplanting organs into a patient who needs them constitutes treatment or alleviation of a disease or illness. The question is whether the removal and collection of organs falls within that formulation. Clearly this only contributes to the treatment of a disease or illness in the recipient, and not the donor. Are organ removal and collection sufficiently closely connected to the transplant to constitute prevention or treatment? If not, do they fall within the wider formulation of ‘provision of health services’? These are the legal questions that such legislation would face, if proposed as an Assembly Act. The Assembly Government appears to consider that Subject 9 does encompass these powers; ultimately, of course this may be for the courts to determine.

13. How the courts might approach the matter is hard to predict. In the closest parallel case (concerning Scottish legislation: *Martin and Miller v. Lord Advocate*, [2010] UKSC 10) the Supreme Court applied a purposive approach and upheld the legislation—but did so by a 3:2 majority, with the dissenters taking a much more analytical approach. Whether this legal foundation for Assembly legislation on organ donation would survive such an analytical approach in a differently composed court cannot be regarded as certain.

14. Questions about the Assembly’s powers to legislate for the collection and removal of organs, raise significant issues of how extensive the Assembly’s legislative powers actually are, and (if it were accepted that the Assembly should be able to legislate regarding it) whether Schedule 7 might need to be amended to ensure that it can.

Legal issues: power of Ministers of the Crown, and conferring functions on UK public bodies

15. In any event, Assembly legislation about organ donation will require the consent of the Secretary of State, as it affects functions conferred on a minister of the Crown (exercisable by the Secretary of State for Health). Some of the Secretary of State’s powers to make regulations or issue guidance will need to be amended to give effect to an ‘opt-out’ regime in Wales. Some of these powers may need to be exercised jointly by the Secretary of State and Welsh Ministers, as regards Wales; others will, at the very least, require consultation by the Secretary of State with the Welsh Ministers before they can be exercised. This is not, strictly, speaking, an issue relating to the LCO, and it would apply equally whether the legal basis for legislation were the draft LCO or Schedule 7 to the 2006 Act, after a referendum. However, it does illustrate the complexity of the legislative scheme that will be needed should the Assembly legislate on this matter.

16. In addition, National Assembly legislation would also need to affect the functions of the UK public bodies (NHSBT and the Human Tissue Authority) that are involved in organ donation and transplantation. So far, devolved Welsh legislation has not done this, so this will be a legal novelty, and the 2006 Act contains no express power to do so. The power to legislate in such a way would appear to be implicit in the framework of the 2006 Act, however, so long as it relates to matters that are devolved, and the Act also contains (in section 70) a power for Welsh ministers to provide financial assistance to help to secure the attainment of an objective which they aim to attain in the exercise of any of their functions. However, there needs to be greater clarity than is presently in the proposal about whether this would be by way of direct conferral of functions on the UK bodies, or by way of a

wider opt-out followed by establishing agency arrangements, as in Scotland. Each raises different legal issues.

17. Scottish parallels are of some use here. The Attorney General has given an opinion that it was within the Scottish Parliament's legislative competence to legislate so as to confer functions on a UK public body (or remove them), provided those functions relate to devolved matters. This position is publicly recorded, in Devolution Guidance Note 15.¹⁰ DGN 15 further sets out procedures for consultation where the Scottish Parliaments proposes to legislate in this way. The Human Tissue (Scotland) Act 2006 confers most of its duties on the Scottish Ministers, but authorises them to provide assistance and support (including financial support) to persons providing services relating to transplantation, and to make arrangements with public authorities for the discharge of their functions (sections 2 and 54 respectively). The Scottish approach therefore involves an agency arrangement for certain services relating to donation and transplantation, so that the same institutions are able to provide the service across the UK while being subject to different legal regimes. This approach parallels ones adopted in other areas (e. g. the Food Standards Agency), and has much to commend it.

18. Matters are further complicated by the UK Government's plans to abolish the Human Tissue Authority at some point in the present Parliament. (The Authority is not one of those scheduled for abolition under the Public Bodies bill presently before Parliament). The proposal appears to be that the Care Quality Commission would take over its regulatory functions, which are those of concern here.

19. However, the implications of that clearly need investigating, to establish how workable the scheme envisaged by the Assembly is. That would suggest a need to take evidence from the Assembly Government, the HTA and NHSBT about their plans and concerns. The HTA and NHSBT have some relevant experience about such matters from their experience in dealing with the Scottish organ donation regime.

Human rights issues

20. The letter from the Secretary of State to the Committee's chairman asks the Committee to consider whether the proposed LCO would be compliant with Convention rights protected under the Human Rights Act 1998, and specifically Article 8 (Right to respect for private and family life) and Article 9 (Freedom of thought, conscience and religion). The likely concerns of a number of religious groups have already been noted. Comment in the press suggests that these are particularly matters of concern for the Attorney General, though without a clearer indication of the nature of the Attorney's concerns it is hard to know what to make of them. Certainly, there is scope for these articles to apply to an 'opt-out' system for organ donation. However, neither article is unconditional, and in particular each permits interference with those rights where it is necessary in a democratic society for the protection of health or for the protection of the rights and freedoms of others. In applying the Convention, and such permitted exceptions, the European Court of Human Rights applies a 'margin of appreciation'. As other European countries have adopted 'opt-out' systems without legal problem, it is hard to

¹⁰ Available at <http://www.justice.gov.uk/guidance/docs/dgn15.pdf>

regard such concerns as overwhelming objections.¹¹ They may, however, justify further investigation and inquiry.

21. The idea of an ‘opt-out’ scheme is likely to provoke opposition from those opposed on religious or ethical grounds to the removal of organs from the body. Religious groups with objections may include Muslims, Orthodox Jews and Jehovah’s Witnesses. The Committee can expect to hear their concerns expressed in any evidence it takes (and that may call for careful handling).

22. This would also present a difficult constitutional issue. If the Committee were to accept the need to ensure that there are effective safeguards for those holding such objections, should those be incorporated into an LCO and so circumscribe the legislative powers of the National Assembly? Should they, instead, be left to the National Assembly itself to determine in its legislation, subject to external constraints (including, notably, human rights protected by the European Convention on Human Rights)? It may be more straightforward, and legally equally effective, to leave this to be dealt with by the requirements on the National Assembly and Assembly Government to comply with the requirements of the ECHR under section 94 (or section 108, if the Assembly Act provisions are in force) of the 2006 Act.

23. In any event, a distinction must be drawn between Parliament conferring on the National Assembly legislative powers which could be used in a manner that contravenes Convention rights (which may be the Secretary of State’s concern), and Assembly legislation which actually contravenes those rights. There is no need for Parliament to concern itself with whether powers might breach Convention rights if used in particular ways when it is considering an LCO; the 2006 Act clearly provides that such a use of its powers by the National Assembly would be unlawful, and any legislation that breached Convention rights would be invalid as a result.

Conclusion

24. This is a constitutionally difficult LCO. While some of the issues that the Secretary of State has drawn to the Committee’s attention—notably ECHR ones—appear to have little weight, an ‘opt-out’ system in Wales would present significant practical problems for the bodies involved in organ transplant. These are not wholly novel, given the Scottish situation, but are certainly substantial. Given the looming referendum on the Assembly’s powers and the impact of that, the Committee is unlikely to need to determine these issues under the present system of devolved powers. As any Assembly legislation in this area would have an impact both on ministers of the Crown and UK public bodies, however, the Committee is likely to have an interest in Assembly legislation on this matter assuming that is presented after the May elections.

11 In addition, there are comments by Baroness Hale sitting in the Judicial Committee of the Privy Council on a Scottish devolution issue, to the effect that the UK’s courts should not impose their standard of compliance with ECHR in addition to those adopted by European Court of Human Rights, and competent legislatures. See *DS v.HM Advocate* [2007] UKPC 36 at paras.89–92, 96.

Advice received from Professor Keith Patchett, Emeritus Professor of Law, University of Wales

1. These observations are concerned with the proposed Legislative Competence Order relating to consent in respect of organ donations for the purposes of human transplantation that was submitted by the Secretary of State for Wales to Parliament for pre-legislative scrutiny on 10 January 2011.¹ The instrument has now had endorsement by the Assembly's Legislation Committee No. 1.² The observations in this submission are confined principally to legal matters and to issues of form and drafting. Other advisers may be concerned with substantive issues, which were examined in the Assembly Committee Report.

Overview

2. This instrument adds Matter 9. 3 to Field 9 in Schedule 5 (Health and Health Services) of the Government of Wales Act 2006 ("GOWA"). It focuses on a single issue—the grant to the National Assembly of competence to legislate in respect of:

consent and authorisation for:

- the storage and use of bodies of deceased adults; and
- the removal, storage and use of materials coming from such bodies,

for the purposes of transplantation to human bodies.

It does not give competence to alter the existing law governing organ donation or transplantation in any other respect.

3. Part 1 of the Human Tissue Act 2004 stipulates consent for organ donation as a central requirement of the scheme governing body and organ donation currently operating in England and Wales. Provision is made as to consent where the body of the deceased is that of a child or an adult,³ for the appointment of representatives who may consent after the death,⁴ for specified circumstances involving adults who lack capacity to consent⁵ and for exceptional cases where the need for consent can be dispensed with.⁶ In all cases where consent is needed, it must be given explicitly; the donation scheme therefore requires an "opt-in", whether by advance declaration or, where permissible, by others on the occasion of the death.

4. The proposed Order authorises the Assembly to make fresh and therefore potentially different provision with respect to consents. As the Explanatory Memorandum makes

1 Cm 7992.

2 National Assembly for Wales Committee Report, 4 February 2011.

3 Human Tissue Act 2004, Ss.2 & 3.

4 *Ibid*, S.4.

5 *Ibid*, S.6.

6 *Ibid*, S.7.

clear,⁷ its principal aim is to enable the introduction of a mechanism under which consent to organ donation is “presumed” to be in effect in the absence of positive indication (e. g. by registration) that consent is withheld but after the involvement of the deceased’s family concerning the deceased’s wishes—referred to as “a soft opt-out”. (A “hard opt-out” scheme is taken to mean one in which consent is presumed in the absence of an opt-out but evidence from the deceased’s family about the deceased’s wishes is not sought.)

5. However, as drafted, the proposed Order may not be confined to this feature. If, as seems to be the intention,⁸ the existing opt-in scheme under the Human Tissue Act is to continue in Wales as an alternative to the new scheme, the terms of the draft Order appear to allow the Assembly to legislate to alter those provisions of that Act, at least in so far as they are concerned with consent in respect of activities involving material taken from deceased adults for the purpose of transplantation.

Does Matter 9. 3 relate to Field 9 in GOWA Schedule 5?

6. Matter 9. 3 is to be added to the field entitled “Health and Health Services”. To be a valid addition, it must “relate to one or more” of the Schedule 5 fields.⁹ Little guidance is to be obtained from the present entries in this or other fields as to its scope. However, the equivalent Heading 9 in Schedule 7 lists as one of the included subjects “prevention, treatment and alleviation of disease, illness, injury, disability and mental disorder”.¹⁰ It also designates “provision of health services... including ancillary services and facilities”.¹¹ It may reasonably be concluded that the Schedule 5 field should be construed as capable of providing for matters relating to those subjects.

7. On that assumption, a strong case can be made for treating transplantation as relating to “the treatment and alleviation of disease and illness”, and donation of bodies and body materials as an important factor in enabling transplantations to be undertaken. Arguably, arrangements for donation and for the removal, storage and use of human organs and tissue can be brought within the scope of “ancillary services and facilities” that are provided by “health services” in Wales.

8. However, for the purposes of this instrument, the immediate issue is not whether such topics are within Field 9, but whether consent and other authorisation of the specified activities for the purposes of transplantation to humans are within its scope. In this respect, it can be argued that the matter of consent is integral to all organ donation schemes in the United Kingdom, as it is in relation to medical procedures generally. Consent to intrusion into the physical integrity of individuals is a longstanding legal requirement. It is difficult to conceive of the regulation of donation schemes without that matter being addressed, and appropriately dealt with, by the law.

7 Paras. 8 & 9.

8 Explanatory Memorandum, para.9.

9 GOWA, s.95(1).

10 The subjects listed under this heading will govern the Assembly’s legislative competence if the forthcoming referendum produces an affirmative result.

11 Exceptions under this Head include “human genetics, human fertilisation, human embryology” and xenotransplantation (transplants of animal matter into human bodies), but not activities concerned with human tissues regulated by the HTA.

9. Accordingly, if removal, storage and use of human organs and tissue for the purposes of transplantation to humans are considered to be within the scope of “Health and Health Services”, it seems unavoidable that consent and authorisation for those activities should also be treated as a matter that relates to this field. It seems self-evident that competence can be conferred on the Assembly with respect to a pivotal element of an existing scheme authorising transplantation, although competence has not been sought with respect to such schemes themselves.

Scope of the proposed Order

10. The proposed Order makes clear that the consent or authorisation for the specified activities is “for the purposes of transplantation to a human body”. The Human Tissue Act, which will continue to regulate authorised activities, states the purposes for which “removal, storage and use” of relevant materials may be undertaken under that Act. These purposes, set out in Schedule 1, stipulate “transplantation” as just one of several purposes. It follows that the opt-out scheme will not extend to consent for activities undertaken for any of the other purposes. Evidence submitted to the Assembly Committee from the Human Tissue Authority asserted that there could be a potential cause of confusion as explicit consent would still be required for the use of donor organs for research, which is commonly sought from potential donors at the same time as consent for organ donation.¹²

11. Section 1 of the Human Tissue Act includes references to activities when the body material to be used for an authorised purpose (including for transplantation) is not confined to such material taken from human bodies after death.¹³ Clearly activities involving use of such material taken otherwise than from a deceased adult would be outside the proposed Order, and such use in Wales would require explicit consent.

12. These limits set by the proposed Order exclude from the ambit of any opt-out scheme consent for a range of activities regulated by the Human Tissue Act. In those cases, presumed consent will not suffice. The requirements under that Act will continue to govern giving of consent. It may be argued that complexity may arise if removal, storage and use of organs for any of the purposes in the Human Tissue Act, other than organs from deceased adults used for transplantation, must be covered by explicit consent, when in the latter case presumed consent is effective.

13. The Assembly Committee discussed the term “deceased adult”, which is used in order to confine the application of Matter 9. 3 to persons aged 18 before their death. This is in contrast with the Human Tissue Act, which provides with respect to appropriate consent for activities involving the bodies of children.¹⁴ The Committee, having noted potential problems with respect to arrangements for opt-outs by or in respect of children (even those old enough at 16 and 17 to consent to medical procedures)¹⁵ accepted the limitation to

12 Evidence of HTA, Assembly Committee Report, para.80. The issue was not examined by the Assembly Committee as there had been no opportunity to raise it with the Minister.

13 HTA, ss.1(1)(d) & 1(1)(f). The regulated uses are listed in Sched.1, Part 1.

14 Human Tissue Act, S.2.

15 RoP, paras. 84–89, 4 February 2011, Legislation Committee No.1

adults in the proposed definition.¹⁶ Accordingly, it appears that children will continue to be provided for under the existing opt-in scheme. The operation in Wales of two schemes dependent on age differences inevitably adds to the complexity in explaining the donation arrangements.

Application of the proposed Order

14. Other than confining the legislative power to consents affecting adults, the proposed Order is silent as to those persons who are to be within the ambit of the implementing legislation. In so far as the existing scheme continues to have effect in Wales, those who opt-in or have opted-in under current arrangements would remain subject to the existing consent procedures without any requirement for a link specifically with Wales. However, to comply with the geographical limitation on the Assembly's competence, any different arrangements with respect to consents must be made applicable in relation to Wales only.¹⁷ The proposed Order contains no provision in this regard. The Explanatory Memorandum states the intention that the scheme is to apply to every adult who lives and dies in Wales.¹⁸ It explains too that the implementing Measure will spell out the criteria that must be met in determining whether these links exist.¹⁹

15. The opt-out scheme calls for a physical link with Wales, prior to his or her death, by the person whose consent is presumed. Provision must be made to enable such persons to become conversant with the scheme, to exercise the right to opt-out if they wish and to change their minds subsequently. This almost certainly will require a registration system for opt-outs, necessitating some form of settled residential connection with Wales. The proposed scheme is also to require that the death must occur in Wales where the decision as to donation will be need to be made. This will enable a check to be made, in accordance with the new statutory scheme, as to the existence of an opt-out, and the duty to involve the family to be fulfilled, by those concerned with arranging the donation.

16. It follows therefore that neither the mere presence of an adult in Wales at the time of death nor the death outside Wales of an adult who otherwise fulfils the residential requirements of the scheme are to be cases covered by the implementing Measure, despite the Welsh connections. The practical requirements of an opt-out scheme are likely to dictate the exclusion of these cases. It is evident too that the precise links with Wales call for detailed elaboration inappropriate in a grant of legislative power.

17. However, It might be argued that how the scheme "relates" to Wales is an important element of the scheme and that its geographical limits should be outlined in the instrument conferring competence. Clarification of the limits might be achieved by including (e. g. in Part 2 of Schedule 5) exceptions having the effect that the implementing legislation

16 *Ibid*, paras. 92–94.

17 GOWA, s.94(5).

18 Explanatory Memorandum, paras. 31 & 36.

19 *Ibid*, paras. 32–35.

cannot apply in the cases of the bodies of those who die outside Wales or of those not living in Wales at the time of death.²⁰

18. It is possible to envisage circumstances where relevant material taken from the body of a person who has been living in Wales and who died there is needed for transplantation in England. The proposed Order can only be concerned with consent and authorisation as they apply to storage and use of body parts in Wales. In so far as England is concerned, the Human Tissue Act prohibits such storage and use without the required authorisation in the form prescribed by that Act.²¹ Consent or authorisation under the implementing Measure cannot alter the consent requirement of that Act as it applies to storage and use in England. Legislative action to that end is outside the competence of the Assembly.²² Nonetheless, it may be necessary to ensure that body parts donated in Wales in accordance with the opt-out provisions of the implementing Measure do not breach that Act if stored or used for transplantation in England.

To what extent does the European Convention on Human Rights affect the proposed Order?

19. Under Article 8 (the right to respect for private and family life) and Article 9 (the right to freedom of thought, conscience and religion) of the Convention when applied to invasions of the human person, non-voluntary compulsion is seen as a violation of individual autonomy and an outrage against informed consent. Further, some faith groups have significant doubts or outright opposition to a system of presumed consent, seeing it as a contradictory to their religious beliefs.²³ A mandatory hard opt-out scheme for organ donation is almost certainly open to challenge as incompatible with the Convention. In those circumstances, the grant of legislative competence explicitly to enact a scheme that dispensed with consent would be in breach of those Articles. However, as other European countries have concluded,²⁴ a soft opt-out scheme can be introduced compatibly with the Convention if there are adequate safeguards in respect of consent and family involvement to ensure actual wishes and beliefs are respected.

20. The Legal Working Group of the Organ Donation Task Force asserted that, to be compatible with the Convention, statutory provisions relating to an opt-out scheme should be made with respect to such matters as:

- a sufficiently low threshold for overriding to the presumption of consent;
- arrangements regarding consents relating to organs of children;

20 The Explanatory Memorandum, paras. 33 & 34, refers to the need for clarity concerning the term “residence”. Any term used in the proposed LCO for this purpose could be elaborated in the implementing Measure.

21 HTA, s.5.

22 HTA, s.42 empowers the Human Tissue Authority to assist other public authorities in the United Kingdom for the purpose of the exercise of its functions. A similar provision is contained in Human Tissue (Scotland) Act 2006, s.54.

23 House of Lords Select Committee on the European Union, Seventeenth Report of Session 2007–08, *Increasing the supply of donor organs within the European Union*, c.10.

24 A number of States subject to the Convention have introduced donation schemes adopting differing forms of consent, e.g. Belgium and Spain. With respect to Member States of the EU, the EU Commission’s position is that the process by which consent is managed is a matter to be determined by each Member State. See House of Lords Select Committee on the European Union, 17th Report, above.

- the involvement of families to provide evidence as to the deceased's wishes;
- arrangements for those lacking capacity to express their wishes or whose identity is unknown;
- the ability of those who have expressed their wishes to change their minds;
- a sufficient period of publicity to enable opt-outs to be made and for adjustment before the legislation takes effect.²⁵

21. It seems reasonable to conclude that a soft opt-out scheme can be devised that is compliant with the Convention. The proposed Order is not concerned with the content of any opt-out scheme; it deals only with the power to regulate consent with respect to the specified activities for the purposes of human transplantation. It is difficult to see why, if the power can be used to produce a compatible consent scheme, the mere grant to the Assembly of that power in itself could amount to contravention of the Convention. On the other hand, the form that the legislated consent provisions ultimately take can give rise to issues of compatibility with the Convention. The Independent Organ Donation Task Force in discussing the content of such provisions considered that the legislative provisions must be designed so as to be compliant with the Convention under the terms of the Human Rights Act 1998.²⁶

22. It follows therefore that the question of compatibility of Measure provisions with the Convention provisions is one that has to be addressed by the Assembly, which must ensure that, in exercising the power afforded by this LCO, its formulation of new consent provisions complies with the Convention. Measure provisions are outside the Assembly's competence if they are incompatible with the Convention Rights guaranteed by the Human Rights Act.²⁷ Compliance with that statutory restriction on the Assembly's competence, in the last analysis, is for the courts to determine.

Drafting considerations

23. The terminology of the proposed Order is in the main straightforward, being largely dictated by the terms of the Human Tissue Act. However, the Assembly Committee raised two issues. The first concerning the definition of "deceased adult" has been referred to earlier.²⁸ Secondly, having noted that, unlike that Act, the proposed order refers to "authorisation" as well as to "consent",²⁹ the Committee considered that the former term lacks clarity and that it should either be deleted or replaced by words that more clearly describe the powers being sought.³⁰ Introduction of the term was considered to be necessary as "consent" is typically seen as requiring positive action, and therefore is not a term that is fully appropriate to cover opt-out cases where consent is presumed.

25 Organ Donation Taskforce ("ODTF"), *The potential impact of an opt out system for organ donation in the UK*, 17 November 2008, Annex C: Legal Working Group Report, para. 37.

26 *Ibid*, Section 6.

27 GOWA, s.94(6)(c).

28 Para.13, above.

29 HTA uses the fuller term "appropriate consent".

30 RoP, para 91, 4 February 2011, Legislation Committee No.1.

However, “presumed consent” appears to have been considered unsuitable as amounting to a fiction,³¹ as active consent is not involved. The use of “authorisation” may have been suggested by the term “presumed authorisation”, the preferred terminology of the Legal Working Group of the Organ Donation Task Force.³² Arguably, that formulation or an explicit reference to “presumed consent” would more satisfactorily indicate the principal purpose of the proposed Order.

24. The definition of “relevant material” follows the meaning of the same term in section 53 of the Human Tissue Act. A submission to the Assembly Committee proposed an addition to the definition to enable the collection of umbilical cord blood and tissues.³³ However, such material is typically taken from living persons.³⁴ Accordingly, this proposal appears to be inconsistent with the intended limitation to material taken from the bodies of deceased persons and may be thought to be beyond the scope of the proposed Order.

25. The proposed Order determines the circumstances that require the consent of a coroner before consent or authorisation is effective. These follow the language of section 11(2) of the Human Tissue Act.

31 *Ibid*, para.81

32 E.g. ODTF Report, 2008, Legal Working Group report, Annex C, para. 37. The Task Force itself preferred “opt-out”:
Report, para. 5.2

33 RoP, para 82, 4 February 2011, Legislation Committee No.1. The issue was not examined by the Assembly Committee as there had been no opportunity to raise it with the Minister.

34 It is also a nice question whether the material is being collected from the child as well as the mother, again taking the case outside the scope of the proposed Order.

Appendix A

Letter to the Chair of the Welsh Affairs Committee, House of Commons, from the Chair of the Enterprise and Learning Committee, National Assembly for Wales

Dear David

Enterprise and Learning Committee proposed (Legislative Competence) (Highways and Transport) Order 2011

I am writing to inform you that I am withdrawing my Committee's proposed Legislative Competence Order on Highways and Transport as legislative competence has been achieved by the Referendum.

The Committee is disappointed that we have not been able to secure legislative competence sufficiently quickly to bring forward a Measure in relation to developing and maintaining a network of routes for pedestrians and cyclists during the life of this Assembly. In our Legacy Report to the Fourth Assembly we shall be recommending that a future Committee of the National Assembly for Wales should consider bringing forward an Assembly Bill on this issue early in the term.

I wish to thank you and your officials for the interest you have shown.

Yours sincerely

Gareth Jones AM
Committee Chair

14 March 2011

Appendix B

Letter to the Chair of the Welsh Affairs Committee, House of Commons, from Edwina Hart AM, Minister for Health and Social Services, Welsh Assembly Government

Dear David,

In light of the successful referendum result on 3 March, I am today withdrawing the proposed Legislative Competence Order (“LCO”) in respect of organ and tissue donation.

Under the circumstances, I will not be accepting your invitation to attend the Welsh Affairs Committee on Tuesday 29 March, to give evidence in relation to the proposed LCO.

Edwina Hart AM
Minister for Health and Social Services

9 March 2011

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