Health and Social Care Committee

Meeting Venue:
Committee Room 1 – Senedd

Meeting date:
20 February 2013

Meeting time:
09:00

For further information please contact:
Policy: Llinos Dafydd / Legislation: Sarah Beasley/Steve George
Committee Clerk
029 2089 8403/8032/8041/8242
HSCCommittee@wales.gov.uk

Agenda

1. Introductions, apologies and substitutions

2. Human Transplantation (Wales) Bill: Stage 1 – Evidence session 11 (09.00 – 10.30)
Minister for Health and Social Services
Lesley Griffiths AM, Minister for Health and Social Services
Pat Vernon, Policy for Organ and Tissue Donation Legislation
Dr Grant Duncan, Deputy Director Medical Directorate, Welsh Government
Sarah Wakeling, Legal Services, Welsh Government

Human Transplantation (Wales) Bill and Explanatory Memorandum

3. Human Transplantation (Wales) Bill: Stage 1 – Evidence session 12 (10.30 – 11.30)
Phil Walton
Team Manager (South Wales SNODs), Donor Care and Co-ordination, NHS Blood and Transplant

4. Papers to note (Pages 1 – 12)

5. Motion under Standing Order 17.42 to resolve to exclude the public from the meeting for the following business: Consideration of the Draft Report (11.30)
In accordance with Standing Order 17.42(vi), a committee may resolve to exclude the public from a meeting where it is deliberating the content, conclusions or recommendations of a report it proposes to publish.

Private session
Health and Social Care Committee

Meeting Venue: Committee Room 3 – Senedd
Meeting date: Thursday, 7 February 2013
Meeting time: 09:01 – 14:20

This meeting can be viewed on Senedd TV at:
http://www.senedd.tv/archiveplayer.jsf?v=en_400000_07_02_2013&t=0&l=en
http://www.senedd.tv/archiveplayer.jsf?v=en_400002_07_02_2013&t=0&l=en

Concise Minutes:

Assembly Members:
Mark Drakeford (Chair)
Mick Antoniw
Rebecca Evans
Vaughan Gething
William Graham
Mike Hedges
Elin Jones
Lynne Neagle
Jenny Rathbone
Lindsay Whittle
Kirsty Williams

Witnesses:
Joyce Robins, Patient Concern
Rev. Aled Edwards, Cytûn – Churches Together in Wales
Geraint Hopkins, Cytûn – Churches Together in Wales
Saleem Kidwai, Muslim Council of Wales
Rev. Carol Wardman, Church in Wales
Stephen Wigley, Methodist Church in Wales
Professor John Saunders

Committee Staff:
Steve George (Clerk)
Olga Lewis (Deputy Clerk)
Sarah Beasley (Clerk)
Sarah Sargent (Deputy Clerk)
Victoria Paris (Researcher)
Joanest Jackson (Legal Advisor)
Robin Wilkinson (Researcher)
Gwyn Griffiths (Legal Advisor)
1. Recovery of Medical Costs for Asbestos Diseases (Wales) Bill: Consideration of Key Issues

1.1 On the basis of the resolution of the Committee passed at the meeting 30 January 2013, in accordance with Standing Order 17.42(ix), the Committee considered this item in private session.

2. Introductions, apologies and substitutions

2.1 Apologies were received from Darren Millar.

3. Human Transplantation (Wales) Bill: Stage 1 – Evidence session 8

3.1 The Committee heard evidence from Joyce Robins, co-founder of Patient Concern.

4. Human Transplantation (Wales) Bill: Stage 1 – Evidence session 9

4.1 The Committee heard evidence from the Reverend Aled Edwards, Chief Executive, Cytûn–Churches Together in Wales and Secretary, Inter–Faith Council for Wales; Geraint Hopkins, Policy Officer, Cytûn–Churches Together in Wales; Saleem Kidwai, Muslim Council of Wales; the Reverend Carol Wardman, Bishops’ Adviser on Church and Society, Church in Wales; and Stephen Wigley, Methodist Church in Wales.

5. Discussion of Business Committee's letter about committee timetables

5.1 The Committee discussed the letter and agreed to respond to the Business Committee noting that it was not content with the proposal.

6. Papers to note

6.1 The Committee noted the minutes of the previous meetings.

7. Human Transplantation (Wales) Bill: Stage 1 – evidence session 10

7.1 The Committee heard evidence from Professor John Saunders.

TRANSCRIPT
View the meeting transcript.
Health and Social Care Committee

HSC(4)–06–13 paper 1

Health and Social Care Committee Forward Work Programme: February – March 2013

To: Health and Social Care Committee
From: Committee Service
Meeting date: 20 February 2013

Purpose
1. This paper invites Members to note the Health & Social Care Committee timetable attached at Annex A.

Background
2. Attached at Annex A is a copy of the Health & Social Care Committee’s timetable until the Easter recess.

3. It is published as an aid to Assembly Members and any members of the public who may wish to be aware of the Committee’s forward work programme. A document of this kind will be published by the Committee at regular intervals.

4. The timetable is subject to change and may be amended at the Committee’s discretion as and when relevant business arises.

Recommendation
5. The Committee is invited to note the work programme at Annex A.
ANNEX A

WEDNESDAY 20 FEBRUARY 2013

Morning only

Human Transplantation (Wales) Bill
Oral evidence sessions

Recovery of Medical Costs for Asbestos Diseases (Wales) Bill
Consideration of draft report (private)

THURSDAY 28 FEBRUARY 2013

Morning and afternoon

Social Services and Well-being (Wales) Bill
Oral evidence sessions

Human Transplantation (Wales) Bill
Consideration of key issues (private)

[If necessary] Recovery of Medical Costs for Asbestos Diseases (Wales) Bill
Consideration of draft report (private)

Sub-committee on Smoke-free Premises etc (Wales) (Amendment) Regulations

WEDNESDAY 6 MARCH 2013

Morning only

Social Services and Well-being (Wales) Bill
Briefing from Expert Advisers (private)
Roundtable discussion on the Bill’s themes (private)

THURSDAY 14 MARCH 2013

Morning and afternoon

Human Transplantation (Wales) Bill
Consideration of draft report (private)
ANNEX A

Access to medical technologies in Wales
Seminar on scope of inquiry (private)
Sub-committee on Smoke-free Premises etc. (Wales) (Amendment) Regulations

WEDNESDAY 20 MARCH 2013

Human Transplantation (Wales) Bill
Consideration of draft report (private)
Sub-committee on Smoke-free Premises etc. (Wales) (Amendment) Regulations
[If necessary] Social Services and Well-being (Wales) Bill
Oral evidence sessions

Monday 25 March – Sunday 14 April 2013: Easter recess
Evidence to Health and Social Care Committee

Human Transplantation (Wales) Bill

Further suggestions from Professor Vivienne Harpwood

The Bill would benefit from clarification in a number of ways, as the people who will need to interpret and act upon the proposed legislation will be clinicians and families of donors, all of whom have a right to expect that the language used will be accessible. The Welsh public at large, and those who come to live in Wales, some of whom do not have English or Welsh as their first language, will be educated about the important social and practical matters proposed in the Bill, and will need to understand its provisions. Greater clarity of language will facilitate realistic opportunities for publicity and discussion. Some suggestions are outlined below:

Deemed or presumed?
The central focus of the Human Transplant (Wales) Bill is on the provision of a “soft” opt-out system, in which consent is presumed in certain circumstances. However, this is not immediately obvious on the face of the Bill, which uses the word *deemed* – a term that is difficult for non-lawyers to understand. The history of the use of *deemed* indicates that it can be a complex and difficult word even for lawyers.

- It is a word that can be used in many different ways, and has different meanings and interpretations according to the context.
- It is a legal expression that has no clear meaning in ordinary discourse, and its use often leaves important details to be worked out by the reader.
- There are many different sorts of deeming – e.g. conferring a discretion; adding in something that is otherwise excluded.
- Deeming clauses are commonly found in technical areas of law such as planning Regulations, and have been under sustained criticism for some time in academic and other discussion fora.
- The current legal language in the Bill is a perpetuation of an opaque and problematic position.
- The word *deemed* is used in the Human Tissue Act 2004, which probably accounts for the decision of those who drafted the Welsh Bill. However, that Act has itself been much criticised for its lack of clarity.
- There may not be an equivalent Welsh term to *deemed*, and it is important that there should be no linguistic disjunction between the terms used in the English and Welsh versions of the Bill.

In my view there is a strong case for grasping the opportunity that we have now in Wales to produce clear legislation which can readily be understood by the majority of the population. We have tabula rasa in this respect, and clarity is particularly important in legislation that directly affects such a deeply personal and sensitive matter as consent in medicine.
Since the use of the word *deemed* in connection with what is generally understood as *presumed* consent, could be seen as a deliberate attempt to obfuscate one of the main objectives of the Bill, why not be honest with the people of Wales? This is a Bill aimed at winning hearts and minds, accompanied by a publicity campaign entitled “Heart to Heart”, encouraging families and friends to express make their wishes about organ donation known to those close to them. This reinforces the argument in favour of clarity. The position is that *consent may be presumed in the absence of compelling evidence to the contrary*, and everyone affected by the legislation needs to know that.

Why not make the most important point in the Bill as close to the start as possible? In the preamble, perhaps, by adding the words “*and for the introduction of the concept of presumed consent in certain circumstances*”.

**Clumsy use of language in parts**

e.g. Clause 1 (e) (i): It is not usual to use “*that*” in connection with “*persons*”. The clumsy use of language in the statement “*persons that do transplantation activities*” is almost ungrammatical. Would not “*persons who carry out transplantation activities*” be preferable? Throughout the Bill, “*carry out*” is clearer than “*do*” in relation to transplant activities.

Clause 8 (2) is ungrammatical. “*P’s consent to the activity is deemed*” does not make sense. Is it meant to read “*P’s consent to the activity is deemed to have been given*”? (but as already indicated, I would favour *presumed to have been given*).

**Clarification of the difference between donation after circulatory death (DCD) and donation after brainstem death (DBD).**

It would be helpful if the expressions *DCD* and *DBD* were defined in the Bill.

Clause 5 refers to *excepted patients* and does not therefore refer to DCD patients. Section 8 does refer to DCD patients, but the distinction is not clear on the face of the Bill. Also, the word *deceased* needs to be removed from Clause 12, as it does not currently take account of DCD patients. The same applies to Clause 6, which is opaque because of the lack of these definitions.

**Donors of tissue who are located in the community**

The Bill appears to assume that all patients from whom material is taken for the purposes of donation will be in hospital. However, tissue (e.g. corneas) is taken from donors at home.

**Conjunction with the Mental Capacity Act 2005**

Where a patient has issued an advance refusal of treatment, that decision needs to be taken into account when considering the various processes that might need to be carried out in relation to DCD patients close to death. Has the relationship between the Bill and the MCA and its Code of Practice been taken into account?
An additional chart would add clarity
Why not add a chart to cover all categories of patients?

Proposed duty on Welsh Ministers to promote organ donation.
At present, donors are being lost because there are insufficient numbers of critical care beds. Will the new duty on Ministers result in an increase in the number of critical care beds as part of the restructuring of healthcare services in Wales? Have the financial implications of this been taken into account?
The Human Transplantation (Wales) Bill
Evidence to the National Assembly for Wales
Health & Social Care Committee
Supplementary Evidence by Kidney Wales Foundation

On European Convention on Human Rights and European Community Law

Following our evidence to the Committee on 21 of January and Oral Evidence on 24th of January we set out below our views on Human Rights and European Community Law.

European Convention on Human Rights

The core European Convention on Human Rights provisions falling for consideration in relation to deemed consent are:

- Articles 8 (right to respect for private life); and
- Article 9 (freedom of religion).

We have focused on the principles that would need to underpin any deemed consent system as outlined in the Bill following our analysis and advice taken over time.


The Report summarised its views in the following way: “a system that was based on a presumption of consent or authorisation that allowed adequate provisions for a person to opt out would be compatible with the ECHR. Such a system would need to allow a person to indicate their wishes (such as on a register) during their lifetime and also to allow for evidence from family members about the person’s wishes and beliefs after their death. Particular consideration would be needed for some groups of people, in particular children, people who lack the mental capacity to make a decision to opt out and those whose identity was unknown at the time of their death.”
Annex C to that report contained a careful analysis of the potential Convention issues arising in respect of any opt out system adopted focusing, in particular, on the concept of presumed consent. The analysis was prepared by the Legal Working Group to the Taskforce.

The Working Group’s most important conclusion was that there was no necessary incompatibility problem with a deemed consent system such as to make any assertion of legislative competence illegitimate.

We agree with this view and have taken Counsel Opinion and believe it is further justified by the following considerations:

(a) Opt out systems operate in a substantial number of European Union and Council of Europe countries and they have never, so far as I am aware, led to any challenge before the European Court of Human Rights;

(b) The Additional Protocol to the Council of Europe’s European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin (ETS No. 186) provides at least some insight into the core standards which the European Court might expect to be respected in this field. It includes the following key provisions, none of which preclude the existence of an opt out system:

- Signatory States must have a clear legally recognised system specifying the conditions under which removal of organs or tissues is authorised (Article 17);

- The only absolute bar to organ and tissue removal concerning a deceased person is presented if that person had objected to it (Article 17);

- The human body must be treated with respect and all reasonable measures must be taken to preserve the appearance of the donor corpse (Article 18);

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2 Although the United Kingdom has not signed or ratified this Convention it has been ratified by 12 member States of the Council of Europe. The Convention has only been referred to in the case law of the European Court of Human Rights in an unrelated context (see e.g. SH & Others v Austria Application No. 57813/00 1 April 2010 relating to the availability of fertility treatments).
- Signatory States are obliged to take “all appropriate measures to promote the donation of organs and tissues” (Article 19);

- The Convention requires adequate measures for the protection of the confidentiality of any donor (Article 23).

(c) There is no indication in the approach of the European Commission of the European Community to the issue of transplantation that it considers that such a system would be incompatible with fundamental rights. This is of at least some significance, even having regard to limitations on European Union competence in this area, (see further below).

13. In view of the care of the analysis set out, and to avoid unnecessary repetition, we strongly urge you to bring a copy of the Working Group’s report dated 11 April 2008 and published as Annex C into your evidence.

European Community Law

14. A helpful summary of recent developments in European Union governance over organ donation and transplantation, focusing on the Commission’s action plan and the Organs Directive (subsequently Directive 2010/45/EU 7 July 2010) is set out in the article “Adding Value? EU Governance of Organ Donation and Transplantation” Ann Maree Farell, EJHL 17 (2010) 51-79. This article makes the following important points each of which support our views that a deemed consent system would be compatible with European Community law:

(a) The Commission and the Directive allow for flexibility on the part of Member States in relation to the meeting of obligations with respect to e.g. donor consent (see paragraph 4.3 & Directive Article 14);

(b) As Farell explains “in relation to regulatory requirements covering consent to organ donation, the EU’s competence to act on this issue is circumscribed by Article 168(7) TFEU which states that national provisions regarding the donation or medical use of organs shall not be affected by the adoption of minimum harmonisation measures under Article 168(4)(a) TFEU” (p. 73);
(c) The Commission has expressly acknowledged that there is a “degree of variation as between Member States in relation to the consent regimes that have been adopted in relation to deceased organ donation, reflecting the national specificities of historical, socio cultural protection and political flexibility” (p. 73 citing Commission Impact Assessment accompanying Communication 30.5.02007 SEC (207) 704 at 24-27).
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