

## Y Pwyllgor Iechyd a Gofal Cymdeithasol

---

Lleoliad:  
Ystafell Bwyllgora 1 – Y Senedd

---

Dyddiad:  
Dydd Mercher, 20 Chwefror 2013

---

Amser:  
09:00

---

Cynulliad  
Cenedlaethol  
Cymru

National  
Assembly for  
Wales



I gael rhagor o wybodaeth, cysylltwch â:

Steve George  
Clerc y Pwyllgor  
029 2089 8242  
[PwyllgorIGC@cymru.gov.uk](mailto:PwyllgorIGC@cymru.gov.uk)

---

### Agenda

---

#### 1. Cyflwyniad, ymddiheuriadau a dirprwyon

#### 2. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – sesiwn dystiolaeth 11 (09.00 – 10.30)

##### Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Lesley Griffiths AC, y Gweinidog Iechyd a Gwasanaethau Cymdeithasol  
Pat Vernon, Pennaeth Polisi ar Ddeddfwriaeth Rhoi Organau a Meinweoedd  
Dr Grant Duncan, Dirprwy Gyfarwyddwr y Gyfarwyddiaeth Feddygol, Llywodraeth Cymru  
Sarah Wakeling, Gwasanaethau Cyfreithiol, Llywodraeth Cymru

[Bil Trawsblannu Dynol \(Cymru\)](#) a [Memorandwm Esboniadol](#)

#### 3. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – sesiwn dystiolaeth 12 (10.30 – 11.30)

Phil Walton

Rheolwr Tîm (Nyrsys Arbenigol Rhoi Organau De Cymru), Gofal a chydlynu rhoddwyr, Gwaed a Thrawsblannu'r GIG

#### 4. Papurau i'w nodi (Tudalennau 1 – 12)

#### 5. Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y canlynol: Trafod yr Adroddiad Drafft

**(11.30)**

Yn unol â Rheol Sefydlog 17.42(vi), caiff pwyllgor benderfynu gwahardd y cyhoedd o gyfarfod lle mae'n cyd-drafod cynnwys, casgliadau neu argymhellion adroddiad y mae'n bwriadu ei gyhoeddi.

**6. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru):  
Trafod yr Adroddiad Drafft (11.30 – 12.30) (Tudalennau 13 – 23)**

Sesiwn breifat

## Y Pwyllgor Iechyd a Gofal Cymdeithasol

---

Lleoliad: **Ystafell Bwyllgora 3 – Y Senedd**

---

Dyddiad: **Dydd Iau, 7 Chwefror 2013**

---

Amser: **09:01 – 14:20**

---

Cynulliad  
Cenedlaethol  
Cymru

National  
Assembly for  
Wales

Gellir gwyllo'r cyfarfod ar Senedd TV yn:

[http://www.senedd.tv/archiveplayer.jsf?v=cy\\_400000\\_07\\_02\\_2013&t=0&l=cy](http://www.senedd.tv/archiveplayer.jsf?v=cy_400000_07_02_2013&t=0&l=cy)

[http://www.senedd.tv/archiveplayer.jsf?v=cy\\_400002\\_07\\_02\\_2013&t=0&l=cy](http://www.senedd.tv/archiveplayer.jsf?v=cy_400002_07_02_2013&t=0&l=cy)



---

### Cofnodion Cryno:

---

#### Aelodau'r Cynulliad:

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

---

#### Tystion:

**Joyce Robins, Patient Concern**  
**Rev. Aled Edwards,, Cytûn – Eglwysi Ynghyd yng Nghymru**  
**Geraint Hopkins, Cytûn – Eglwysi Ynghyd yng Nghymru**  
**Saleem Kidwai, Cyngor Mwslimiaid Cymru**  
**Y Parch. Carol Wardman, Yr Eglwys yng Nghymru**  
**Stephen Wigley, Yr Eglwys Fethodistaidd yng Nghymru**  
**Yr Athro John Saunders**

---

#### Staff y Pwyllgor:

**Steve George (Clerc)**  
**Olga Lewis (Dirprwy Clerc)**  
**Sarah Beasley (Clerc)**  
**Sarah Sargent (Dirprwy Clerc)**  
**Victoria Paris (Ymchwilydd)**  
**Joanest Jackson (Cyngorydd Cyfreithiol)**  
**Robin Wilkinson (Ymchwilydd)**  
**Gwyn Griffiths (Cyngorydd Cyfreithiol)**

## **1. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru): Trafod y Prif Faterion**

1.1 Ar sail y penderfyniad a basiwyd gan y Pwyllgor yn y cyfarfod ar 30 Ionawr 2013, ac yn unol â Rheol Sefydlog 17.42(ix), trafododd y Pwyllgor yr eitem hon mewn sesiwn breifat.

## **2. Cyflwyniad, ymddiheuriadau a dirprwyon**

2.1 Cafwyd ymddiheuriadau gan Darren Millar.

## **3. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn dystiolaeth 8**

3.1 Clwydd y Pwyllgor dystiolaeth gan Joyce Robins, cyd-sylfaenydd Patient Concern.

## **4. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn dystiolaeth 9**

4.1 Clywodd y Pwyllgor dystiolaeth gan y Parchedig Aled Edwards, Prif Weithredwr, Cytûn – Eglwysi Ynghyd yng Nghymru ac Ysgrifennydd Cyngor Rhyng-ffydd Cymru; Geraint Hopkins, Swyddog Polisi, Cytûn – Eglwysi Ynghyd yng Nghymru; Saleem Kidwai, Cyngor Mwslimiaid Cymru; y Parchedig Carol Wardman, Cyngorydd Esgobion ar yr Eglwys a Chymdeithas, yr Eglwys yng Nghymru; a Stephen Wigley, yr Eglwys Fethodistaidd yng Nghymru.

## **5. Trafod llythyr y Pwyllgor Busnes ynghylch amserlenni'r pwyllgorau**

5.1 Trafododd y Pwyllgor y llythyr a chytunodd i ymateb i'r Pwyllgor Busnes yn nodi nad oedd yn fodlon â'r cynnig.

## **6. Papurau i'w nodi**

6.1 Nododd y Pwyllgor gofnodion y cyfarfodydd blaenorol.

## **7. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn dystiolaeth 10**

7.1 Clywodd y Pwyllgor dystiolaeth gan yr Athro John Saunders.

### **TRAWSGRIFIAD**

Gweld [trawsgriafiad o'r cyfarfod](#).

# Y Pwyllgor Iechyd a Gofal Cymdeithasol

HSC(4)-06-13 papur 1

Blaenraglen Waith y Pwyllgor Iechyd a Gofal Cymdeithasol: Chwefror –  
Mawrth 2013

**At:** Y Pwyllgor Iechyd a Gofal Cymdeithasol

**Gan:** Gwasanaeth y Pwyllgorau

**Dyddiad y cyfarfod:** 20 Chwefror 2013

## Diben

1. Mae'r papur hwn yn gwahodd yr Aelodau i nodi amserlen y Pwyllgor Iechyd a Gofal Cymdeithasol, sydd wedi'i atodi fel Atodiad A.

## Cefndir

2. Yn Atodiad A, ceir copi o amserlen y Pwyllgor Iechyd a Gofal Cymdeithasol hyd at doriad y Pasg.

3. Fe'i cyhoeddwyd i gynorthwyo Aelodau'r Cynulliad ac unrhyw aelodau o'r cyhoedd a hoffai wybod am flaenraglen waith y Pwyllgor. Bydd y Pwyllgor yn cyhoeddi dogfen o'r fath yn gyson.

4. Gall yr amserlen newid a gellir ei diwygio yn ôl disgrisiwn y Pwyllgor pan fydd busnes perthnasol yn codi.

## Argymhelliad

5. Gwahoddir y Pwyllgor i nodi'r rhaglen waith yn Atodiad A.

## ATODIAD A

DYDD MERCHER 20 CHWEFROR 2013

*Bore yn unig*

Bil Trawsblannu Dynol (Cymru)

Sesiynau tystiolaeth lafar

Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru)

Ystyried adroddiad drafft (preifat)

DYDD IAU 28 CHWEFROR 2013

*Bore a phrynhawn*

Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru)

Sesiynau tystiolaeth lafar

Bil Trawsblannu Dynol (Cymru)

Ystyried y materion allweddol (preifat)

[Os oes angen] Bil Adennill Costau Meddygol ar gyfer Clefydau  
Asbestos (Cymru)

Ystyried adroddiad drafft (preifat)

Is-bwyllgor ar Reoliadau Mangreoedd etc. Di-fwg (Cymru) (Diwygio)  
2012

DYDD MERCHER 6 MAWRTH 2013

*Bore yn unig*

Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru)

Sesiwn friffio gyda Chynghorwyr Arbenigol (preifat)

Trafodaeth ar themâu'r Bill (preifat)

DYDD IAU 14 MAWRTH 2013

*Bore a phrynhawn*

Bil Trawsblannu Dynol (Cymru)

Ystyried adroddiad drafft (preifat)

## ATODIAD A

Mynediad at dechnolegau meddygol yng Nghymru  
Seminar ar gwmpas yr ymchwiliad (preifat)  
Is-bwyllgor ar Reoliadau Mangreoedd etc. Di-fwg (Cymru) (Diwygio)  
2012

## DYDD MERCHER 20 MAWRTH 2013

Bil Trawsblannu Dynol (Cymru)  
Ystyried adroddiad drafft (preifat)  
Is-bwyllgor ar Reoliadau Mangreoedd etc. Di-fwg (Cymru) (Diwygio)  
2012  
[Os oes angen] Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru)  
Sesiynau tystiolaeth lafar

---

Dydd Llun 25 Mawrth – Dydd Sul 14 Ebrill 2013: Toriad y Pasg

---

## 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*

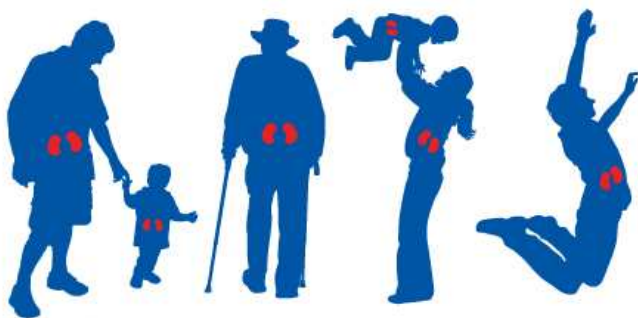
Where a patient has issued an advance refusal of treatment, that decision needs to be taken into account when considering the various processes that might need to be carried out in relation to DCD patients close to death. Has the relationship between the Bill and the MCA and its Code of Practice been 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?



Kidney Wales Foundation  
Sefydliad Aren Cymru

Charity Number 700396

---

# **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 24<sup>th</sup> 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.

We hold the view contained in the 17 November 2008 Independent Report by “*Organ Donation Taskforce*” entitled “*The Potential Impact of An Opt Out System for Organ Donation in the UK*”.

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<sup>1</sup>;
- (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)<sup>2</sup> 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);

---

<sup>1</sup> Spain, Austria and Belgium are the most prominent examples but they are not alone: see e.g. S Gevers, A Janssen and R Friele "Consent Systems for Post Mortem Organ Donation in Europe" *European Journal of Health Law* 11 (2004) 176-177; *New York Times* 23 April 2010; Impact of presumed consent for organ donation on donation rates: a systematic review *BMJ* 2009 338: a3162; The Impact of Presumed Consent Legislation on Cadaveric Organ Donation: A Cross Country Study (December 2005) – Alberto Abadie & Sebastian Gaye.

<sup>2</sup> 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 Farrell, 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 Farrell 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).

**Roy J Thomas**

**14 February 2013**

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon



Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon

Yn rhinwedd paragraff(au) vi o Reol Sefydlog 17.42

Mae cyfyngiadau ar y ddogfen hon