

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:
Ystafell Bwyllgora 1 – Y Senedd

Dyddiad:
Dydd Mercher, 30 Ionawr 2013

Amser:
09:00

Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales



I gael rhagor o wybodaeth, cysylltwch â:

Polisi: Llinos Dafydd

Deddfwriaeth: Fay Buckle/Sarah Beasley

Clerc y Pwyllgor

029 2089 8403/8041/8032

PwyllgorIGC@cymru.gov.uk

Agenda

1. Cyflwyniad, ymddiheuriadau a dirprwyon

2. Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru): y dull o graffu

(09:00 – 09:15) (Tudalennau 1 – 27)

HSC(4)-04-13 papur 1

3. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn Dystiolaeth 4

(09:15 – 10:00) (Tudalennau 28 – 31)

Arweinydd Clinigol – Rhoi Organau, Bwrdd Iechyd Cwm Taf

Dr Dariusz Tetla, Arweinydd Clinigol – Rhoi Organau, Bwrdd Iechyd Cwm Taf

Yr Athro Vivienne Harpwood, Cadeirydd Pwyllgor Rhoi Organau Cwm Taf

Academi Colegau Brenhinol Cymru

Dr Peter Matthews

4. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn Dystiolaeth 5

(10:00 – 10:45) (Tudalennau 32 – 48)

Yr Awdurdod Meinweoedd Dynol

Alan Clamp, Prif Weithredwr

Cymdeithas Trawsblannu Prydain

Chris Watson

Egwyl (10:45 – 11:00)

5. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn Dystiolaeth 6 (11:00 – 11:45) (Tudalennau 49 – 57) Pwyllgor Moeseg Rhoi Organau y DU

Syr Peter Simpson, Cadeirydd Pwyllgor Moeseg Rhoi Organau y DU

Cyngor Biofoeseg Nuffield

Dr Tim Lewens

6. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – Sesiwn Dystiolaeth 7 (11:45 – 12:30) (Tudalennau 58 – 59) Yr Athro Ceri Phillips

7. Papurau i'w nodi (Tudalen 60)

8. Cynnig o dan Reol Sefydlog 17.42(ix) i benderfynu gwahardd y cyhoedd ar gyfer eitem 1 yn y cyfarfod yr wythnos nesaf (7 Chwefror 2013) (12.30) Eitem 1 (7 Chwefror 2013)

Eitem 2

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Y Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru) – Ystyriaeth Cyfnod 1

At: Y Pwyllgor Iechyd a Gofal Cymdeithasol

Gan: Y Swyddfa Ddeddfwriaeth

Dyddiad y cyfarfod: 30 Ionawr 2013

Diben

1. Amlinellu rôl y Pwyllgor yng Nghyfnod 1.
2. Gwahodd y Pwyllgor i ystyried ei gylch gorchwyl, a chytuno arno, a'i ddull o graffu ar y Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru) ('y Bil') yng Nghyfnod 1.

Cefndir

3. Ar 22 Ionawr, cyfeiriodd y Pwyllgor Busnes y Bil at y Pwyllgor Iechyd a Gofal Cymdeithasol ('y Pwyllgor'), gan nodi bod angen cyflwyno adroddiad arno erbyn 21 Mehefin 2013.
4. Ar 28 Ionawr, bydd Gwenda Thomas AC, y Dirprwy Weinidog Plant a Gwasanaethau Cymdeithasol, yn cyflwyno'r Bil a Memorandwm Esboniadol. Bydd hefyd yn gwneud datganiad yn y Cyfarfod Llawn ar 29 Ionawr.
5. Mae'r Gwasanaeth Ymchwil wedi paratoi papur yn rhoi cefndir y Bil ac mae'r ddogfen hon ar gael ar wahân.

Rôl y Pwyllgor

6. Rôl y Pwyllgor yng Nghyfnod 1 yw 'ystyried egwyddorion cyffredinol y Bil a chyflwyno adroddiad arnynt' (Rheol Sefydlog 26.10)
7. Nid oes gofynion penodol yn y Rheolau Sefydlog sy'n rheoli'r modd y bydd y Pwyllgor yn ymgymryd â'r gwaith craffu hwn. Ar y sail honno, mae cylch

gorchwyl drafft wedi'i amlinellu ym mharagraff 9 y papur hwn ac, ym mharagraffau 10–15, awgrymir sut y gellir ymgymryd â'r gwaith craffu.

8. Ar ôl i'r Pwyllgor gyflwyno adroddiad, bydd dadl Cyfnod 1 yn cael ei chynnal yn y Cyfarfod Llawn. Ar ddiwedd y ddadl hon, gofynnir i'r Cynulliad gytuno ag egwyddorion cyffredinol y Bil. Os caiff yr egwyddorion cyffredinol hyn eu derbyn, bydd y Bil yn symud ymlaen i Gyfnod 2, pan fydd y Pwyllgor yn trafod ac yn gwaredu gwelliannau'r Pwyllgor (ar hyn o bryd, bwriedir cynnal Cyfnod 2 ym mis Medi/Hydref 2013).

Y cylch gorchwyl drafft

9. Wrth graffu ar egwyddorion cyffredinol y Bil yng Nghyfnod 1, awgrymir bod y Pwyllgor yn cytuno ar y cylch gorchwyl a ganlyn:

Ystyried egwyddorion cyffredinol y Bil a'r angen i ddeddfu er mwyn darparu ar gyfer:

- Deddfwriaeth Gymraeg sydd wedi'i chydgrynhoi ac sy'n symleiddio ac yn egluro dyletswyddau, gan gynorthwyo'r broses o ddarparu gwasanethau cymdeithasol a lleihau'r amser a'r adnoddau sydd eu hangen i ddeall y fframwaith cyfreithiol presennol;
- Deddfwriaeth newydd a fyddai'n ailadrodd ymrwymiad Llywodraeth Cymru i wasanaethau cymdeithasol integredig ar gyfer oedolion, plant a'u gofalwyr gyda Chyfarwyddwr Gwasanaethau Cymdeithasol yn gyfrifol amdanynt.
- Hyrwyddo partneriaeth a gweithio agosach a mwy integredig rhwng awdurdodau lleol, a rhwng awdurdodau lleol a chyrff eraill, gan gynnwys darparwyr y GIG;
- Cryfhau'r cyfarwyddyd cenedlaethol a chynyddu cysondeb mynediad at wasanaethau cymdeithasol ledled Cymru tra'n cynnal atebolrwydd lleol am weithredu;
- Datblygu gwell rôl o ran lles ac atal ar gyfer awdurdodau lleol a'u partneriaid er mwyn helpu i osgoi neu ohirio'r angen am ofal a chymorth;

- Hyrwyddo'r broses o ymrymuso defnyddwyr gwasanaethau gan roi llais cryfach iddynt a rhagor o reolaeth dros wasanaethau;
- Cryfhau'r broses o ddiogelu ac amddiffyn oedolion a phlant.

Dull y Pwyllgor o graffu yng Nghyfnod 1

10. Yn unol â'r terfyn amser a bennwyd gan y Pwyllgor Busnes, bydd angen i'r Pwyllgor gwblhau ei waith craffu ar y Bil a chyflwyno adroddiad arno erbyn 21 Mehefin fan bellaf.
11. Mae'r dyddiad cau yn caniatáu 16 wythnos fusnes ar gyfer ymgymryd â'r gwaith hwn, er y bydd yn rhaid ei gyflawni ar yr un pryd â gwaith arall y Pwyllgor o ran polisi a deddfwriaeth. O ystyried pwysau gwaith y Pwyllgor, ar hyn o bryd mae pump sesiwn dystiolaeth wedi'u trefnu gyda thystion allanol a dwy sesiwn gyda'r Dirprwy Weinidog Plant a Gwasanaethau Cymdeithasol.
12. Mae'r Pwyllgor wedi cytuno eisoes ar y dull cyffredinol a ganlyn o graffu ar ddeddfwriaeth yng Nghyfnod 1:—
 - Cais cyffredinol am dystiolaeth
Cyhoeddi cais cyffredinol am dystiolaeth, rhoi gwybod i'r wasg yng Nghymru amdani a'i chyhoeddi ar wefan y Cynulliad.
 - Cais am dystiolaeth ysgrifenedig
Gwahodd sefydliadau ac unigolion dethol i gyflwyno tystiolaeth ysgrifenedig. Ceir rhestr o ymgylgoreion posibl yn Atodiad 1.
 - Tystiolaeth lafar
Gwahodd y prif randdeiliaid i roi tystiolaeth lafar mewn cyfarfodydd yn y dyfodol (a chynnal yr ymgynghoriad yr un pryd). Dull posibl o reoli'r sesiynau tystiolaeth lafar yw trefnu'r pump sesiwn sydd wedi'u trefnu yn ôl themâu i adlewyrchu prif ddarpariaethau'r Bil. Ceir amserlen bosibl yn Atodiad 2.

- **Ymgysylltu ac Allgymorth**

Ceir amlinelliad arfaethedig o'r gwaith ymgysylltu ac allgymorth i gefnogi'r Pwyllgor wrth iddo ymgymryd â'i waith yn Atodiad 3. O gofio'r dyddiadau cau sydd wedi'u pennu, mae rhai opsiynau'n fwy ymarferol nag eraill.

13. Mae'r dyddiad cau ar gyfer cyflwyno adroddiad yn caniatáu cyfnod ymgynghori o 6 wythnos, rhwng 1 Chwefror a 15 Mawrth. Bydd hyn yn golygu bod modd ystyried tystiolaeth ysgrifenedig a'i defnyddio i gynorthwyo'r sesiynau tystiolaeth lafar.
14. Bydd y dystiolaeth ysgrifenedig a llafar a gesglir yn helpu i lywio gwaith y Pwyllgor o drafod y Bil a'i adroddiad dilynol.
15. Er gwybodaeth, mae Rheolau Sefydlog y Cynulliad yn caniatáu i'r Pwyllgor Cyllid a'r Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol gyflwyno adroddiad ar yr agweddau perthnasol ar y Bil.

Cam i'w gymryd

16. Gwahoddir y Pwyllgor i:

- gytuno ar y cylch gorchwyl drafft (fel y'i hamlinellir ym mharagraff 9);
- cytuno ar ei ddull o graffu yng Nghyfnod 1 (fel y'i hamlinellir ym mharagraffau 10 – 15);
- cytuno ar ymgynghoriad chwe wythnos a'r rhestr o ymgynghoreion (Atodiad 1);
- cytuno ar y dull o graffu ar y Bil yn ôl themâu (Atodiad 2); a
- nodi'r gwaith ymgysylltu ac allgymorth arfaethedig i gynorthwyo'r Pwyllgor a gwneud sylwadau ar y gwaith hwnnw (Atodiad 3).

Atodiad 1

Unigolion/sefydliadau posibl y gellir cysylltu â hwy i ofyn am dystiolaeth ysgrifenedig:

*Wedi ymateb i Ymgynghoriad Llywodraeth Cymru

Byrddau Iechyd ac Ymddiriedolaethau'r GIG yng Nghymru
Bwrdd Iechyd Lleol Prifysgol Abertawe Bro Morgannwg
Bwrdd Iechyd Lleol Aneurin Bevan
Bwrdd Iechyd Lleol Prifysgol Betsi Cadwaladr
Bwrdd Iechyd Lleol Prifysgol Caerdydd a'r Fro
Bwrdd Iechyd Lleol Hywel Dda
Bwrdd Iechyd Lleol Cwm Taf
Bwrdd Iechyd Lleol Addysgu Powys
Bwrdd Ymddiriedolaeth GIG Felindre
Ymddiriedolaeth GIG Gwasanaethau Ambiwlans Cymru
Iechyd Cyhoeddus Cymru
Cynghorau Iechyd Cymuned
Bwrdd Cynghorau Iechyd Cymuned yng Nghymru *
Abertawe Bro Morgannwg
Cyngor Iechyd Cymuned Aneurin Bevan (Gwent, Caerffili, Tor-faen, Casnewydd,

Mynwy)
Cyngor Iechyd Cymuned Betsi Cadwaladr (Conwy, Gwynedd, Ynys Môn)
Cyngor Iechyd Cymuned Brycheiniog a Maesyfed
Cyngor Iechyd Cymuned Caerdydd a'r Fro
Cyngor Iechyd Cymuned Cwm Taf
Cyngor Iechyd Cymuned Hywel Dda
Cyngor Iechyd Cymuned Trefaldwyn
Llywodraeth Leol – Prif Weithredwyr Cymdeithas Cyfarwyddwyr Gwasanaethau Cymdeithasol a Chymdeithas Cyfarwyddwyr Addysg Cymru
Cyngor Bwrdeistref Sirol Blaenau Gwent
Cyngor Bwrdeistref Sirol Pen-y-bont ar Ogwr
Cyngor Bwrdeistref Sirol Caerffili
Cyngor Sir Caerdydd
Cyngor Sir Gâr
Cyngor Sir Ceredigion
Dinas a Sir Abertawe
Cyngor Bwrdeistref Sirol Conwy
Cyngor Sir Ddinbych

Cyngor Sir y Fflint
Cyngor Gwynedd
Cyngor Sir Ynys Môn
Cyngor Bwrdeistref Sirol Merthyr Tudful
Cyngor Sir Fynwy
Cyngor Bwrdeistref Sirol Castell-nedd Port Talbot
Cyngor Dinas Casnewydd
Cyngor Sir Penfro
Cyngor Sir Powys
Cyngor Bwrdeistref Sirol Rhondda Cynon Taf
Cyngor Bwrdeistref Sirol Tor-faen
Cyngor Bro Morgannwg
Cyngor Bwrdeistref Sirol Wreccsam
Cymdeithas Llywodraeth Leol Cymru *
Byrddau Diogelu Plant
Cyngor Bwrdeistref Sirol Blaenau Gwent
Cyngor Bwrdeistref Sirol Pen-y-bont ar Ogwr
Cyngor Bwrdeistref Sirol Caerffili

Cyngor Caerdydd
Cyngor Sir Gâr
Cyngor Sir Ceredigion
Cyngor Sir Ddinbych
Cyngor Sir y Fflint
Cyngor Gwynedd
Cyngor Bwrdeistref Sirol Merthyr Tudful
Cyngor Bwrdeistref Sirol Tor-faen
Cyngor Bwrdeistref Sirol Castell-nedd Port Talbot
Cyngor Dinas Casnewydd
Cyngor Sir Penfro
Cyngor Sir Powys
Cyngor Bwrdeistref Sirol Rhondda Cynon Taf
Dinas a Sir Abertawe
Cyngor Bro Morgannwg
Cyngor Bwrdeistref Sirol Wrecsam
Rheolwyr Timau Troseddau Ieuencid Cymru Gyfan
Cyngor Bwrdeistref Sirol Pen-y-bont ar Ogwr

Cyngor Bwrdeistref Sirol Caerffili
Cyngor Caerdydd
Cyngor Sir Gâr
Cyngor Sir Ceredigion
Cyngor Sir Ddinbych
Cyngor Sir y Fflint
Cyngor Gwynedd
Cyngor Bwrdeistref Sirol Merthyr Tudful
Cyngor Sir Fynwy
Cyngor Bwrdeistref Sirol Castell-nedd Port Talbot
Cyngor Dinas Casnewydd
Cyngor Sir Penfro
Cyngor Sir Powys
Cyngor Bwrdeistref Sirol Rhondda Cynon Taf
Dinas a Sir Abertawe
Cyngor Bro Morgannwg
Cyngor Bwrdeistref Sirol Wrecsam
Asiantaethau Swyddogol

CAFCASS Cymru
Arolygiaeth Gofal a Gwasanaethau Cymdeithasol Cymru *
Comisiynydd Plant Cymru *
Y Comisiwn Cydraddoldeb a Hawliau Dynol
Yr Awdurdod Gweithredol Iechyd a Diogelwch
Arolygiaeth Gofal Iechyd Cymru *
Yr Asiantaeth Diogelu Iechyd
Sefydliad Iechyd Gwledig
Gwasanaeth Gwybodeg GIG Cymru
Y Sefydliad Cenedlaethol dros Iechyd a Rhagoriaeth Glinigol
Asiantaeth Genedlaethol Arwain ac Arloesi mewn Gofal Iechyd
Comisiynydd Pobl Hŷn Cymru
Y Sefydliad Gofal Cymdeithasol er Rhagoriaeth *
Asiantaeth Gwella Gwasanaethau Cymdeithasol
Cyrff Proffesiynol
Cymdeithas Cyfarwyddwyr Addysg Cymru
Cymdeithas Cyfarwyddwyr Gwasanaethau Cymdeithasol Cymru
Cymdeithas Cyfarwyddwyr Gwasanaethau Cymdeithasol

Cymdeithas Gweithwyr Cymdeithasol Prydain yng Nghymru
Cymdeithas Cenedlaethol Swyddogion Prawf
Coleg Brenhinol y Ffisigwyr
Conffederasiwn GIG Cymru
Y Sector Gwirfoddol
Action on Hearing Loss Cymru
Gweithredu dros Blant
Adoption UK *
Age Cymru – Prosiect Fy Mywyd Mewn Cartref
Ymddiriedolaeth AIDS Cymru
All Care
Fforwm Rhieni a Gofalwyr Cymru Gyfan
Pobl yn Gyntaf Cymru
Cofrestr Mabwysiadu y DU
Anheddau Cyf
Gofal Arthritis yng Nghymru
Cymdeithas dros Newid Go lawn Cymru
Cymdeithas Spina Bifida a Hydroceffalws yng Nghymru

Ategi Cyf
Awtistiaeth Cymru
Rhwydwaith Sector Gwirfoddol Pobl Dduon Cymru
Canolfan Therapi Plant Bobath Cymru
Cymdeithas Pobl Fyddar Prydain yng Nghymru
Sefydliad Prydeinig y Galon yng Nghymru
Cymdeithas Prydeinig Anableddau Dysgu
Y Groes Goch Brydeinig
Ymddiriedolaeth y Gofalwyr yng Nghymru
Hawliau Anabledd y DU
Gwasanaethau Nyrsio a Gofal Cartref Cerecare
Chwarae Teg
Cynghrair Pensiynwyr y Gwasanaeth Sifil
CLIC Sargent
Cymdeithas Ymarferwyr Cymunedol ac Ymwelwyr Iechyd
Cymdeithas Cludiant Cymunedol
Llais Defnyddwyr Cymru
Contact the Elderly

Croesffyrdd – Gofalu am Ofalwyr
Gofal Galar Cruse Cymru
Cymorth Cymru
Yr Ymddiriedolaeth Ffibrosis Systig
Daybreak (Wales) Ltd. (nid oes cyfeiriad e-bost/rhif ffôn ar gael)
Dementia UK
Cynghrair Iselder
Plant Anabl yn Cyfri
Diabetes Cymru
Epilepsi Cymru
Gingerbread
GISDA, John Edwards, Rheolwr Swyddfa
Cymdeithas y Teidiau a Neiniau
Independent Age
Cymorth Canser Macmillan
Merched y Wawr
Undeb y Mamau yng Nghymru
Rhwydwaith Menywod o Leiafrifoedd Ethnig yng Nghymru
Cymdeithas Iselder Manig – Sefydliad Deubegynol Cymru

Mudiad Ysgolion Meithrin
NACRO Cymru
Cymdeithas Genedlaethol Awtistiaeth Cymru
Ymddiriedolaeth Genedlaethol Geni Plant
Y Gymdeithas Genedlaethol i Blant Byddar yng Nghymru
Ffederasiwn Cenedlaethol Pensiynwyr y Post Brenhinol a BT
Ffederasiwn Cenedlaethol Sefydliadau'r Merched
Cymdeithas Genedlaethol Pensiynwyr Cymru
Y Confensiwn Pensiynwyr Cenedlaethol
New Family Social
NIACE Cymru
Cynghrair Eiriolaeth Pobl Hŷn
Un Llais Cymru
PACT
Y Ffederasiwn Rhieni
Parkinson's UK Cymru *
Cymdeithas y Cleifion
Fforwm Pensiynwyr Cymru
Sense Cymru

RNIB Cymru
Sefydliad Cenedlaethol Brenhinol Pobl Fyddar a Thrwrm eu Clyw Cymru
Y Llang Brydeinig Frenhinol
Achub y Plant
SNAP Cymru
Stonewall Cymru
Cymdeithas Mabwysiadu a Maethu Prydain *
Ymddiriedolaeth Plant a Phobl Ifanc Cymru
The Disability Can Do Organisation
Vision 21 (Cyfle Cymru)
Cynghrair Cynhalwyr Cymru
Gwasnaeth Asesu Gyrru a Symudedd Cymru
Cynghrair Niwrolegol Cymru
Senedd Pobl Hŷn Cymru
Rhwydwaith Gweithwyr Gofalwyr Cymru
Cyngor Cymru i'r Deillion
Cyngor Cymru i Bobl Fyddar
Cynghrair Ailalluogi Cymru
Gwasanaeth Brenhinol Gwirfoddol y Merched

Darparwyr tai, y sector annibynnol a chyrrff cynrychiadol
Cymdeithas Rheolwyr Tai Ymddeol
Centre for Housing and Support
Cymdeithas Plant Dewi Sant *
EroSH (Essential Role of Sheltered Housing)
Y Gydmeithas Gofal Cenedlaethol
Cymdeithas Gofal Gogledd Cymru
Cymdeithas Cartrefi Nyrsio Cofrestredig
Cymdeithas Gofal Cartref y DU
Cartrefi Melin
Cartrefi Abbeyfield
Tai Cymoedd i'r Arfordir
Seren Group
Pennaf Housing Group
Sefydliad Tai Siartredig Cymru
Family Housing Association Cymru
Academia
Athrofa Iechyd a Gofal Cymdeithasol Cymru
Ysgol y Gwyddorau Cymdeithasol, Prifysgol Bangor

Canolfan Heneiddio Arloesol, Prifysgol Abertawe
Canolfan Ymchwil Gwaith a Gofal Cymdeithasol
Sefydliad Ymchwil Meddygaeth a Gofal Cymdeithasol – Canolfan Datblygu Gwasanaethau Dementia Cymru
Prifysgol Caerdydd
Rhwydwaith Ymchwil a Datblygu Pobl Hŷn a Heneiddio
Ysgol y Gyfraith Bangor
Ysgol y Gyfraith Aberystwyth
Ysgol y Gyfraith Abertawe
Ysgol y Gyfraith Morgannwg
Ysgol y Gyfraith Caerdydd
Grŵp Ymchwil Gwasanaethau Cymdeithasol
Partneriaethau Gofal Cymdeithasol Rhanbarthol
De-ddwyrain Cymru
De-orllewin Cymru
Gogledd Cymru
Canolbarth Cymru
Undebau Llafur
UNSAIN
Uno'r Undeb

Cyngres yr Undebau Llafur Cymru
Prif Gwnstabiliaid yr Heddlu
Dyfed Powys
Gwent
Gogledd Cymru
De Cymru
Prif Swyddogion Tân Gwasanaethau Tân ac Achub Cymru
Canolbarth a Gorllewin Cymru, Richard Smith, Prif Swyddog Tân
Gogledd Cymru, Simon A Smith, Cynorthwydd Personol y Prif Swyddog Tân
De Cymru, Huw Jakeway, Prif Swyddog Tân
Arall
Canolfan Cydweithredol Cymru
Sefydliad Cenedlaethol ar gyfer Ymchwil Gofal Cymdeithasol ac Iechyd
Fferylliaeth Gymunedol Cymru

Y rhai sydd wedi ymateb i Ymgynghoriad Llywodraeth Cymru

Y Cyngor Cyfiawnder Gweinyddol a Thriwilysoedd

Materion eiriolaeth

Ar ôl mabwysiadu

Cynghrair Henoed Cymru

Age Connects – Age Cymru

Cymdeithas Alzheimer's

Barnardo's

Black Association of Women Step Out (BAWSO)

British Geriatric Society Wales
Sefydliad Prydeinig yr Ysgyfaint
Bwrdd Cyngorau Iechyd Cymuned yng Nghymru
BUPA
Gofal a Thrwsio
Rhwydwaith Cydgysylltu Gofal Cymru
Care for the Family
Fforwm Gofal Cymru
Cynhalwyr Cymru
Cartrefi Cymru
Cyngor Cefn Gwlad Cymru
Cymdeithas Siartredig Ffisiotherapi
Plant yng Nghymru
Care for the Family
Cyngor ar Bopeth Cymru
Coleg y Therapyddion Galwedigaethol
Cartrefi Cymunedol Cymru
Consortiwm Bywydau Cymunedol
Cyswllt Teulu
Consortiwm Asiantaethau Mabwysiadu Gwirfoddol
Dignified Revolution
Anabledd Cymru
Diverse Cymru
Cymdeithas Gofal Cartref Cymru
Cymdeithas Syndrom Down
FNF Both Parents Matter Cymru
Rhwydwaith Maethu Cymru
GOFAL
GRWP Gwalia
Hafal
Hafod Care
Haven Trust
Swyddfa'r Comisiynydd Gwybodaeth
Sefydliad Joseph Rowntree
Cymdeithas y Cyfreithwyr
Anabledd Dysgu Cymru
Leonard Cheshire Disability

Linc Care
Lles Cymru
Mencap Cymru
Darparwyr Eiriolaeth Iechyd Meddwl
Cymdeithas Clefyd Niwronau Motor
Multiple Sclerosis Society Cymru
Yr Ymddiriedolaeth AIDS Genedlaethol
Gwasaneth Cenedlaethol Rheoli Troseddwyr Cymru
Nationwide Association of Fostering Providers
Gwasanaeth Mabwysiadu Gogledd Cymru
Y Gymdeithas Genedlaethol er Atal Creulondeb i Blant
Christine Rees, Cyfarwyddwr Cynorthwyol Perthyn
Post Adoption Centre
Iechyd Cyhoeddus Cymru
Ombwdsmon Gwasanaethau Cyhoeddus Cymru
Coleg Brenhinol yr Ymarferwyr Cyffredinol Cymru
Coleg Brenhinol y Nyrsys
Grŵp Gofal Gydag Urddas Coleg Brenhinol y Nyrsys (Cymru)
Coleg Brenhinol Pediatreg ac Iechyd Plant
Coleg Brenhinol y Seiciatryddion yng Nghymru
Coleg Brenhinol y Therapyddion Lleferydd ac Iaith
Y Gymdeithas Fferyllol Frenhinol
Scope
Y Gymdeithas Strôc
Tai Pawb
Tros Gynnal Plant
Tunstall Healthcare
Cymdeithas Tai Unedig Cymru
Voices from Care
Swyddfa Archwilio Cymru
Cyngor Gweithredu Gwirfoddol Cymru
Comisiynydd y Gymraeg
Grŵp Cynghorol Arweinwyr Ffisiotherapi Cymru
Cyngor Ffoaduriaid Cymru

Atodiad 2

Themâu posibl i drefnu'r gwaith o graffu ar y Bil

1. Egwyddorion cyffredin y Bil

- Yr angen am statud Cymraeg
- Gwasanaethau integredig i oedolion a phlant a rhagor o gysondeb o ran mynediad
- Pwyslais ar les a dulliau ataliol
- Cyfarwyddyd cenedlaethol cryf ac atebolrwydd lleol am weithredu.
- Hyrwyddo'r broses o ymrymuso defnyddwyr gwasanaethau
- Hyrwyddo partneriaeth a gweithio integredig ar draws gwasanaethau

2. Mynediad gan oedolion, plant a gofalwyr at wasanaethau:

- Dyletswyddau llesiant, gwasanaethau ataliol, gwybodaeth a chynghor
- Asesu oedolion, plant a gofalwyr
- Diwallu anghenion oedolion, plant a gofalwyr, gan gynnwys Taliadau Uniongyrchol
- Codi tâl ac asesiad ariannol

3. Gwasanaethau ar gyfer plant sy'n derbyn gofal/plant sy'n cael eu lletya/plant sydd wedi'u mabwysiadu:

- Plant sy'n derbyn gofal, adolygiad o achosion, gadael gofal
- Plant sy'n cael eu lletya, llety diogel
- Mabwysiadu

4. Diogelu oedolion a phlant

- Trefniadau amddiffyn oedolion
- Bwrdd Diogelu Annibynnol Cenedlaethol
- Byrddau Diogelu ac Amddiffyn

5. Swyddogaethau gwasanaethau cymdeithasol:

- Swyddogaethau gwasanaethau cymdeithasol, Cyfarwyddwyr gwasanaethau cymdeithasol
- Fframwaith canlyniadau cenedlaethol a chodau
- Cydweithredu, integreiddio a phartneriaeth
- Cwynion a chyflwyniadau
- Arall – gan gynnwys preswyliaeth gyffredin, adennill costau ac ati, ymyrraeth gan Lywodraeth y DU

Atodiad 3

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Y Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru)

Gwaith craffu Cyfnod 1 – Cynnig Cyfathrebu

Cyflwyniad

Bydd Pwyllgorau fel arfer yn ymgymryd â gwaith ymgynghori ac ymgysylltu fel rhan o'u gwaith craffu ar Filiau yn ystod Cyfnod 1. Bydd hyn fel arfer yn cynnwys galwad cyffredinol am dystiolaeth, gwahodd cyflwyniadau ysgrifenedig, clywed dystiolaeth lafar mewn pwyllgor a gweithio gyda Thîm Allgymorth y Cynulliad i ymgysylltu â chyfran o'r cyhoedd i gael amcan o farn pobl ar y Bil.

O gofio maint y Bil Gwasanaethau Cymdeithasol a Llesiant (Cymru) a pha mor gymhleth ydyw awgrymir y byddai'r Pwyllgor o bosibl yn dymuno defnyddio ystod ehangach o ddulliau cyfathrebu ac ymgysylltu i'w gynorthwyo gyda'i waith craffu Cyfnod 1.

Mae'r papur hwn yn amlinellu'r dulliau ymgysylltu y gellir eu defnyddio gan Dîm Allgymorth y Cynulliad ac mae'n cynnwys nifer o awgrymiadau ar gyfer ymgynghori â chynulleidfaoedd targed yn seiliedig ar ymgynghoriad cychwynnol â sampl o unigolion a sefydliadau perthnasol.

Unwaith y bydd y Pwyllgor wedi ystyried yr opsiynau hyn ac wedi cytuno ar unrhyw ddulliau ymgysylltu y mae'n dymuno eu defnyddio, bydd y Tîm Allgymorth yn gweithio gyda'r Clercod Deddfwriaeth a'r Gwasanaeth Ymchwil i ddatblygu strwythur ar gyfer cymorth a gweithredu.

Dulliau Posibl o Ymgysylltu

Digwyddiadau

Mae digwyddiadau ac ymweliadau yn gyfle i'r Pwyllgor:

- Hybu'r ymchwiliad;
- Rhoi cyfle i Aelodau'r Cynulliad siarad ag unigolion a grwpiau sydd â diddordeb yn y mater dan sylw;

Bydd nifer o grwpiau yn cynnal digwyddiadau yn y Senedd yn ystod y broses o graffu ar y Bil yn ystod Cyfnod 1, ac efallai y bydd Aelodau'n dymuno cymryd rhan yn y digwyddiadau hyn. Maent yn cynnwys:

Mis Chwefror

- Sefydliad Canser yr Ysgyfaint Roy Castle (4/2/13)
- WGC Homelessness (7/2/13)
- Diverse Cymru (8/2/13)
- Achub y Plant (19/2/13)
- Darlith Prifysgol Morgannwg ar Faterion Cyhoeddus (19/2/13)
- Diwrnod Clefydau Anghyffredin (20/2/13)
- Apêl Cennin Pedr Marie Curie (26/2/13)

Mis Mawrth

- Diwrnod Rhyngwladol y Menywod (8/3/13)
- Ymchwilio i gamdriniaeth (6/3/13)
- Diwrnod Gwaith Cymdeithasol y Byd (20/3/13)
- Cymorth Cymru (21/3/13)

Grŵp Cynghori

Rydym yn ymwybodol bod nifer o sefydliadau allanol wedi dangos diddordeb mewn ymgysylltu'n uniongyrchol âg aelodau'r Pwyllgor, gyda'r bwriad o ddylanwadu ar waith y Pwyllgor o graffu ar y Bil yn ystod Cyfnod 1 a'i gynghori wrth iddo wneud y gwaith hwn.

Ar sail hyn, drwy drafodaethau â chadeirydd y Pwyllgor a thrwy gefnogaeth rhai o aelodau eraill y Pwyllgor, awgrymwyd y dylai'r sefydliadau hyn sefydlu grŵp cynghori i osgoi dyblygu gwaith ymgysylltu wrth ddatblygu gwaith mewn partneriaeth hefyd. Bydd y grŵp yn cael budd o ddod â sefydliadau ynghyd y byddent fel arfer yn ymgysylltu ag Aelodau'r Cynulliad yn unigol. Bydd y Grŵp Cynghori hefyd yn gallu cydgysylltu cyngor penodol o feysydd amrywiol o arbenigedd yr aelodau, sy'n cynnwys ystod o elusennau gweithredol ym maes gofal cymdeithasol.

Bydd y Grŵp Cyngori yn rhoi cyngor i aelodau'r Pwyllgor ar faterion allweddol sy'n codi o'r ddeddfwriaeth arfaethedig, gan gynnwys nodi cwestiynau a materion y gall tystion unigol ymdrin â hwy gerbron y Pwyllgor lechyd a Gofal Cymdeithasol yn ystod Cyfnod 1. Bydd y Grŵp Cyngori hefyd yn helpu i nodi rhai o oblygiadau cyfreithiol y newidiadau mewn deddfwriaeth a sut y mae'r rhain yn rhyngweithio â'r newidiadau yn Lloegr a'r dyletswyddau presennol ar asiantaethau statudol yng Nghymru.

Ymweliadau â grwpiau anodd eu cyrraedd a chynnwys y grwpiau hyn

At ddibenion y Bil hwn, mae'n bosibl y bydd aelodau unigol o'r Pwyllgor yn dymuno ymweld â sefydliadau a/neu unigolion perthnasol o fewn eu hetholaethau. Byddai ymweliadau o'r fath yn anffurfiol, heb unrhyw gofnod o'r trafodion, a gellir eu defnyddio er mwyn casglu tystiolaeth gan y rhai yr effeithir arnynt yn uniongyrchol gan y Bil. Er enghraifft, defnyddwyr gwasanaeth y gallai'r gwasanaeth a ddarperir iddynt newid o ganlyniad i'r Bil.

Mae casglu tystiolaeth gan grwpiau anodd eu cyrraedd bob amser yn heriol, ond mae'n bosibl y bydd y Pwyllgor yn teimlo bod casglu tystiolaeth gan y grwpiau hyn yn flaenoriaeth oherwydd natur y Bil hwn. Efallai mai mynd ar ymweliadau fydd y ffordd orau o gynnwys grwpiau o'r fath, oherwydd y mae cyfarfod â hwy o fewn amgylchiadau cyfarwydd yn fwy cynhyrchiol na defnyddio dulliau ffurfiol o gasglu tystiolaeth, sy'n gallu codi ofn.

Byddai angen i waith ymgysylltu o'r fath ddigwydd wyneb yn wyneb fel arfer, a byddai angen ystyried yn ofalus unrhyw dystiolaeth sy'n cael ei chasglu o ran sut y dylid ei rhannu â'r Pwyllgor ehangach neu ei defnyddio i gynorthwyo'r broses graffu.

Yn yr un modd, mae'n bosibl y bydd y Pwyllgor yn dymuno ymgysylltu â darparwyr gwasanaethau yn y manau y maent yn darparu'r gwasanaethau hynny.

Cynghorwyr arbenigol

Yn ystod y cyfarfod ar 5 Rhagfyr 2012, cytunodd y Pwyllgor mewn egwyddor y byddai cymorth gan y maes perthnasol yn ddefnyddiol a'i bod yn werth ymchwilio i'r opsiwn hwn. Cytunodd y Pwyllgor y byddai o bosibl yn fuddiol ystyried ceisio

cyngor nifer o ymgynghorwyr, ac y gallai pob un gynorthwyo â'r gwaith o ystyried materion penodol, yn hytrach na phenodi un cyngorwr arbenigol.

Cofnodwyr/rapporteuriaid

Mae aelodau'n gyfarwydd â defnyddio grwpiau rapporteur ac mae'n bosibl y byddant am ystyried y dull hwn gyda'r Bil. Yn yr un modd, bydd aelodau o bosibl yn dymuno defnyddio cofnodwyr, lle bydd y Pwyllgor yn gofyn i un aelod adrodd yn ôl ar bwnc penodol. Gall defnyddio cofnodwyr o bosibl fod yn fwy 'addas' ar gyfer casglu gwybodaeth fel rhan o'r gwaith o graffu ar y Bil hwn oherwydd sensitifrwydd rhai o'r materion a fydd, o bosibl, yn codi. Er enghraifft, casglodd y Pwyllgor Plant a Phobl Ifanc wybodaeth gan ddarpar rieni a rhieni sy'n mabwysiadu yn yr un modd fel rhan o'r ymchwiliad i fabwysiadu. Cynhyrnodd dull o'r fath wybodaeth na fyddai wedi'i chasglu fel arall drwy'r dulliau mwy ffurfiol neu draddodiadol o ymgysylltu.

Digwyddiad gwibrwydweithio

Mae aelodau'r Pwyllgor wedi cymryd rhan mewn digwyddiadau gwibrwydweithio yn y gorffennol ac wedi'u cael yn ddefnyddiol. Mae'r math hwn o ddigwyddiad yn rhoi llwyfan i Aelodau'r Cynulliad gyfarfod â chynrychiolwyr perthnasol o'r gwasanaethau, a defnyddwyr y gwasanaethau hyn, i ddysgu rhagor am y maes a phwy yw'r prif randdeiliaid. Yn ail, maent yn rhoi llwyfan i'r grwpiau ac unigolion perthnasol gyfarfod ag Aelodau'r Cynulliad i drafod materion, blaenoriaethau ac ymgyrchoedd. Fel rhan o'r broses o gyflwyno'r Grŵp Cyngori i'r Pwyllgor, deallwn ei fod yn cynnig cynnal digwyddiad gwibrwydweithio.

Eitem 3

Dariusz Tetla
Clinical Lead Organ Donation
Cwm Taf LHB
Dariusz.tetla@nhs.wales.uk

15 January 2013

Health and Social Committee

Dear Sir

Re: Consultation on The Human Transplantation (Wales) Bill

After its establishment at the beginning of 2010 The Cwm Taf Organ Donation Committee has began its work on organ donation. The main objective of the Committee was to fully comply with the Organ Donation Taskforce's recommendations and to increase the number of organ donations.

The Committee has implemented Organ Donation Policy across the health board.

Strong links between Committee Chair, SNODS, CLOD and their counterparts on regional levels have been established either through individual contacts or regional working group - initially WODIG and later as Regional Collaborative Group.

To increase the awareness of organ donation between staff, an intensive education across the LHB has taken place including meetings with nursing staff and doctors in ITU and Emergency Department, the regular presentation of data from the Potential Donor Audit, and 'Ground Round' presentations for trainees and senior doctors.

While it was commonly accepted that the donor potential for Cwm Taf LHB may be lower than in large hospitals the main objective was to increase referral rates, and to reassure that no potential donors had been missed.

As a result of that tremendous effort some decent increase in referral rates has been recorded over last 3 years. There were 9 donors in Cwm Taf LHB who donated 16 organs in total.

As a person who is actively involved in organ transplantation and donation issues I strongly support every initiative which would lead to an increase in the number of organ donations.

In relation to the Human Transplantation Bill:

Section 2 - Relating to the promotion of transplantation

Introducing this legislation would allow an increase in awareness of the public and also increase consent rates for donation. Several initiatives to promote transplantation have been undertaken on local level in Cwm Taf LHB including presentations to medical staff and medical students. There are also plans to give presentations in schools. It may be worth the Committee

considering whether the promotion of organ donation should become obligatory part of educational programmes.

Section 3-8 Relating to lawful transplantation activities and consent

It's commonly known and accepted that organ donation is particularly difficult area of clinical practice. While introducing 'soft' opt-out system may result in increased number of transplantations, it will certainly impose additional burden on medical practitioners.

The coexistence of two different systems within the UK will require clear identification who is or who is not permanent resident in Wales, especially if no relatives of a deceased person are available.

In relation to subsection (3)(a) (b) of section 3 - it is important to identify valid consent for removal of the tissue, obtained in the country where the relevant material was imported from, and the evidence exists to prove it.

Over last 3 years emphasis has been put on clinical training to increase consent rates for transplantations, therefore it is of particular importance to create legislation which will be transparent and clear, especially concerning valid consent. Otherwise some clinicians may feel discouraged from obtaining consent for donation. Having said that, my personal opinion is that the proposed legislation would not impose many changes in the process of obtaining consent compared with the current opt in system.

Section 9-11 relating to offences

It is recognised that a person is liable for his /her actions, but that a person should also have confidence of being protected by law when acting rightly , without leaving grey areas for different interpretations.

I hope that the new legislation would strengthen the foundation of organ transplantation in Wales, which was established a few years ago after introduction Organ Donation Taskforce recommendations, and it would allow further increase in organ donation activity. It is also equally important for medical professionals to stay reassured that the law protect them if they do right things in the right way.

Yours sincerely,

Dariusz Tetla

Academy of Royal Colleges Wales response to the consultation by the Health and Social Care Committee of the National Assembly for Wales on the Human Transplantation (Wales) Bill

The Academy of Royal Colleges Wales' membership comprises 15 Medical Royal Colleges and Faculties. The Academy aims to provide expert specialist advice to promote quality in healthcare for the benefit of patients in Wales.

Individual Colleges and Faculties have submitted their own responses to the consultation and draft bill. We would like to submit some generic comments based on responses submitted directly by the following organisations:

Faculty of Intensive Care Medicine
Royal College of GPs
Royal College of Paediatrics and Child Health
Royal College of Physicians

Section 2, relating to the promotion of transplantation

We welcome the inclusion of a section in the bill relating to the promotion of transplantation. It is important that the public is fully informed and aware of how the new system of deemed consent would operate and the implications that this may have.

The system of opting out will need to be carefully promoted to the public of Wales as there could be a considerable lack of understanding about how this will affect individuals. Patients whose first language is not English or Welsh will need special consideration as they may not understand the implications. Consideration also needs to be given to patients not registered to practices and those whose religious or cultural beliefs prevent removal of tissue and organs after death.

Section 3, relating to lawful transplantation activities

No specific comments.

Sections 4-8, relating to consent

The problems of tracking patients who move about is recognised in the Explanatory Memorandum. As throughout this Bill, its success depends on how far practical issues like this are addressed, as opposed to matters of basic principle.

Given that young people have higher rates of road accidents and hence the potential to be a source of organs, the residency assessment of students and the issues around their consent is important. A student who has started a course in September, takes up residence in late September or early October, is back home in England for a week mid-term and has a road accident immediately after a month at home in early February, for example, would be difficult to determine under the rules.

We would welcome further clarity with regard to the definition of 'ordinarily resident in Wales for at least six months'. In some cases such as with English students, many may still be registered with a doctor in England and be on the electoral role in England and their residency status unclear.

Sections 9-11, relating to offences

No specific comments.

Sections 12 -20, which make general provision

No specific comments.

2. Any potential barriers to the implementation of these provisions and whether the Bill takes account of them.

No specific comments.

3. Whether there are any unintended consequences arising from the Bill.

Potential changes, with a move to a system of 'opt out', could have a significant impact on Intensive care medicine resources. The UK has the lowest number of intensive care beds, and fewest intensive care specialists, per 100K population of any developed Western nation.

If deemed consent increases donation rates, it will certainly increase the number of potential donors being referred to intensive care for pre-emptive support until they meet the criteria for brain death or and donation. Whilst we accept that the bill is predicated upon the very reasonable desire to increase donation rates, unless the bed pool is increased even a small rise in occupancy could have quite a profound and adverse impact upon the needs of other patient groups.

Organs retrieved from Wales would not be prioritised to Welsh residents and there is unlikely to be a significant reduction in the Welsh waiting list for organ donation. This would need to be clear to the public.

4. The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact Assessment), which estimates the costs and benefits of implementation of the Bill).

We would be concerned about the emphasis on opt out process occurring at registration with a GP and the potential increase in additional work out with general medical service provision. There would likely be a considerable burden on GPs to ensure that the details of individuals were recorded accurately at the time of registration and for individuals to be made aware and to be informed about consent. We welcome the recognition of additional costs (included in RIA Appendix 1 of the Explanatory Memorandum) which relate to training requirements for staff to ensure they are competent to take such consent.

5. The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in Part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation).

No specific comments.

Introduction

1. The Human Tissue Authority (HTA) welcomes the opportunity to respond to the Health and Social Care Committee's consultation on the Draft Human Transplantation (Wales) Bill (the Bill).
2. As the statutory regulator responsible for the consent provisions within the Human Tissue Act 2004 (HT Act), the HTA is charged with ensuring that appropriate and valid consent is in place when organs and tissue are donated from deceased and living people for the purpose of transplantation.
3. The HT Act covers England, Wales and Northern Ireland and requires consent for a number of activities, including organ donation, to be an active and positive act.
4. There are similar provisions in Scotland under the Human Tissue (Scotland) Act 2006 (HT (Scotland) Act), and while the word "authorisation" is used in place of "consent", there is a requirement that this is a positive act and the principle is the same.
5. This response is in regard to the Welsh Government's proposal to introduce an opt-out system for organ donation in Wales. The essence of the proposal is that, for people who both live and die in Wales and who did not make a decision in life on organ donation, the presumption will be that they wished to donate their organs and tissue after death.
6. The HTA has responded to previous consultations on the introduction of an opt-out system for organ donation. These responses can be found [here](#).

The proposal

7. It is of value to set out the main features of the Welsh Government's proposals in order to place this response in context.
8. The Bill introduces the concepts of deemed and express consent. Express consent is identical to the active consent requirement of the HT Act. It is, in the first instance, the consent of the person themselves in life. If that does not exist, the consent of an appointed representative, and, if there is not a representative, then the consent of a person in a qualifying relationship to the donor.
9. Under the Bill express consent will be required for:
 - a. Living organ donation
 - b. Deceased organ donations from children
 - c. Deceased organ donations from adults who lack the capacity to consent
 - d. Deceased donations from people who live and die in Wales but have not been resident for six months or more
 - e. Deceased organ donations from people who die in Wales but who are not resident in Wales
 - f. Deceased organ donations from Welsh residents who die somewhere else in the UK
10. Under the Bill, when an adult Welsh resident who had the capacity to consent dies in Wales, and had registered either a wish to be considered as an organ donor, or their wish not to be an organ donor, this will be acted upon, if possible.
11. If such a person has not registered either a yes or a no, then their consent will be deemed. This means that the starting point of the conversations which will be held with the potential donor's family and friends is that they wished to donate. At present, when there is no recorded wish the family are approached to ask whether they are aware of the wishes of the deceased.
12. The fact that the family will still be involved in the process under the Welsh Government's proposals means that this key safeguard remains in place. Although the family will not have the right to veto the donation if a recorded yes is in place or consent is deemed, if they are able to provide evidence that would satisfy a reasonable person that the deceased did not wish to be a donor this will be accepted.

13. If a person has recorded a no, their family will be informed of this. If a document signed by the deceased, and which post-dates the recorded decision to opt-out, is presented by the family, then donation might be considered.
14. It should be noted that the current legislation (the HT Act) does not give families a veto over the deceased's recorded wishes. When a person has registered on the Organ Donor Register (ODR), and subsequently dies, the role of the family is to let the Specialist Nurse for Organ Donation (SNOD) know whether they had changed their mind, and to provide the medical and lifestyle information necessary to carry out the risk assessment which is required for a decision to be made on whether donation should go ahead. The existing legislation does not make provision for a family to stop a donation because they do not want it to go ahead.
15. In reality, however, the duty of care the surgical and medical teams have to the family of the deceased means that a donation will not usually proceed without their support. This matter is coming to the fore in discussions on deceased donation rates across the UK. The HTA has engaged and will continue to follow with interest these discussions.
16. The HTA believes that there are areas which require further consideration prior to the implementation of the proposed system. However, the operational process as laid out in the explanatory memorandum does not differ significantly from that which operates at present, in the sense that the register will be consulted and a conversation will then be held with the family.
17. What will change is that there will be a new register which will record both wishes to donate and wishes not to donate, and that where the deceased had not made a decision in life, their family will be approached on the basis that he/she wished to be a donor.

The role of the HTA

18. As a statutory regulator, it is not the role of the HTA to either support or object to the proposals of the Welsh Government, which is constituted of the elected representatives of the Welsh people.
19. It is the role of the HTA to provide advice and guidance as required, and this document seeks to provide a detailed response to the areas highlighted in the Committee's letter of 6 December 2012 and other issues for consideration by the Committee. This advice and guidance is based on the experience the HTA has gained since it was established in 2005, and on the provisions of the HT Act as it currently stands.
20. The HTA notes the ethical discussions on the Welsh Government's proposals. However, as a statutory regulator it is outside the remit of the HTA itself to participate directly in such discussions.

Response to terms of reference of the inquiry

21. In its letter of 6 December 2012 the Committee outlined the terms of reference for the inquiry and the HTA has addressed those within its remit below.

The individual provisions set out in the Bill:

Section 2, relating to the promotion of transplantation

22. The HTA has no comments in regard to section 2 of the Bill.

Section 3, relating to lawful transplantation activities

Licensing

23. Under the HT Act a licence is required for two of the activities listed in section 3. These both relate to storage and are included at s.3(2)(a) and (c) of the Bill.

24. The HT Act requires consent (as laid out in section one of the HT Act) for each of these storage activities and as such a licensed establishment must demonstrate that consent is in place as part of the HTA's licensing requirements.

25. Under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 a licence is required for the removal or implantation of an organ. A licence granted by the HTA under these Regulations also requires that HT Act consent is in place.

26. The Welsh Government and the Department of Health will need to ensure that between the three pieces of legislation the licensing requirements for these activities are unaffected by the move to deemed consent in Wales.

Relevant material

27. There is value in noting that section 3 of the Bill refers to "relevant material" rather than just organs. Relevant material is defined at section 16 of the Bill and means "material, other than gametes, which consists of or includes human cells". Relevant material does not include "embryos outside the human body" or "hair and nails from the body of a living person".

28. At present the Welsh Government's plans in regard to deemed consent only address solid organs. However, the Bill provides scope for the transplantation of any relevant material to be lawful with deemed consent. This means that there would be no need for the legislative process to be undertaken to introduce deemed consent to the transplantation of other relevant material.

Import and export

29. Under section 41 of the HT Act the following definitions for import and export are provided:

- a. "Import" means import into England, Wales or Northern Ireland from a place outside England, Wales or Northern Ireland.
- b. "Export" means export from England, Wales or Northern Ireland to a place outside England, Wales or Northern Ireland.

30. Section 3 of the Bill suggests that it is the intention of the Welsh Government that the definitions at section 41 of the HT Act will no longer remain, and in fact, relevant material of the kind mentioned in s.3(2)(c) or (d) will be considered imported if it originates from any jurisdiction outside Wales.

31. If this is the intention, it will be of vital importance for the Welsh Government and NHS Blood and Transplant (NHSBT) to work together to remedy any impact this would have on the allocation and use of deceased donor organs across the UK.

32. Amendments may be required to the HT Act to ensure consistency between this and the Welsh legislation.

33. It will also be important that there is clear and timely communication that the consent requirements of the HT Act in regard to removal of material for the purpose of transplantation remain in place in England and Northern Ireland, and likewise for the HT (Scotland) Act in Scotland.

Section 4-8, relating to consent

Registration of wishes

34. The HTA notes the information provided in the Explanatory Memorandum and Privacy Impact Assessment on the proposed system by which Welsh residents will be able to register their wishes.

35. The HTA further notes that specifying such a system in primary legislation would restrict any changes or amendments that are required to the system in the future. However, without firm assurances as to the system which will be introduced to allow Welsh residents to register their wishes. It is difficult to assess how the process of establishing or seeking consent will differ from that which currently exists.
36. Establishing whether consent is in place and seeking of consent are complex matters and involve communication with people in a period of high emotion. It will be key that any move to a system of deemed consent does not add further complexity and that everyone involved in the process, including clinicians and the family, are informed fully of their role and responsibilities.
37. The HTA believes that the Welsh Government's proposal of a register which allows Welsh residents to both opt-in and opt-out of organ donation is fundamental to guarantee that the wishes of the deceased in life remain paramount. This must be both easy to access and readily available.
38. Such a register would allow the HTA to have greater confidence when drafting a Code of Practice including guidance on deemed consent in Wales, as the practical issues could be clearly addressed and advice provided on what steps should be taken in given circumstances.
39. The absence of such a register could, in the view of the HTA, increase confusion and uncertainty on the proposed system, and could lead to the provision of advice and guidance by any organisation (including the HTA) being unclear and unhelpful.

Living organ donation

40. Under the provisions of the Bill, consent for living organ donation remains "express", in that it is the consent of the individual. In practice it is difficult to imagine when consent to living organ donation could ever be anything other than express, although it should be noted that provision is made in both the Regulations¹ supporting the HT Act and the Bill for living donors who are children or adults who lack the capacity to consent.
41. It is unclear to the HTA why living organ donation is included in the Bill, and on the face of it this inclusion adds complexity and confusion to no identifiable end.

¹ <http://www.legislation.gov.uk/ukxi/2006/1659/contents/made>

Section 9-11, relating to offences

42. Under section 11, consideration should be given to being specific as to who should make a referral to the Director of Public Prosecutions.
43. From the HTA's experience there is merit in policies and procedures being in place from an early stage in order that all involved understand their responsibilities when an offence may have been committed. The Welsh Government may choose not to include this level of detail in the primary legislation; however, it should be available in good time for the proposed 2015 launch date.

Sections 12-20, which make general provision

44. Section 15(6)(b) of the Bill reads "after subsection (6) insert -", the HTA believes this should read "after subsection (5) insert-".

Any potential barriers to the implementation of these provisions and whether the Bills takes account of them

45. Once it becomes law, the Bill will place a number of explicit and implied duties on the Human Tissue Authority. In addition to the requirement to produce a Code of Practice, the HTA is also placed under a duty to superintend the Act. We understand this to mean the provision of advice and guidance on how the legislation should be interpreted.
46. While the HTA has not yet had the opportunity to undertake a full analysis of the impact of the Bill, an initial assessment has identified a number of possible risks to the implementation of the provisions from a regulatory perspective. These relate to our role in advising on the practical circumstances under which consent can be deemed.
47. The HTA currently provides advice on the conditions which need to be fulfilled for consent to be valid. One of these conditions, that consent should be active, will be removed, under certain circumstances, in Wales as a result of the Bill.
48. A further condition is that consent should be informed. It appears to us that for deemed consent to have legitimacy; people affected by it must clearly understand the circumstances under which their consent will be deemed. The explanatory memorandum sets out the communication activity that will support the policy and we provide more detailed views on this in paragraphs 63 to 69. It is the Authority's view that widespread understanding among

people living in Wales, over time, is a pre-requisite to being able to advise on specific circumstances under which consent can be deemed. By extension, any reduction in this understanding may limit our ability to provide such advice.

49. Considering the specific provisions of the Bill, section 4 sets out consent provisions for adults. It states that consent can be deemed where express consent is not present. One of the tests for express consent is “the person has died, and a decision of the person to consent or not to consent to the activity was in force immediately before his or her death”.
50. The explanatory memoranda make clear that the intention is to have a register in Wales which records wishes to opt-in or opt-out. While we believe this is necessary, it will not necessarily be sufficient as a basis for establishing the wishes of the individual in life. That is to say that the register will not, in law, be the sole mechanism by which wishes could be registered. A person could opt-out orally or in writing in a variety of ways. For example, registering a desire to opt-out in a will appears to us to be legitimate. Alternatively, if the family said that the deceased had orally expressed the desire not to donate, this also seems to us legitimate.
51. While express consent to donate might not be identified under the current system (resulting in no donation going ahead), the consequences of failing to identify an express wish not to donate under a system of deemed consent (and the donation proceeding) seem to be of a different magnitude ethically and legally. As a result we would expect to take a range of stakeholder views on the appropriate checks to undertake in order to reflect these in a Code of Practice.
52. While our experience (in partnership with NHS Blood and Transplant) will allow us to develop a Code of Practice, a system so designed may pose a number of operational challenges. We are working with officials in Wales and colleagues in NHSBT to address these issues.

Whether there are any unintended consequences arising from the Bill

53. The HTA has sought to address potential unintended consequences in relation to the sections of the Bill above.
54. In particular, please note paragraphs 23 to 26 above on licensing.
55. More generally, the HTA would further advise that agreed review periods are built into the post-launch programme to allow an assessment of the impact of

the legislation. If the impact is a drop in the number of organs being donated, steps should be taken rapidly to understand the root causes.

56. Negative coverage of deemed consent in Wales could lead to mistrust in other parts of the UK, and it will be vital that this change does not adversely impact organ donation.

The financial implications of the Bill (as set out in Part 2 of the Explanatory Memorandum (the Regulatory Impact assessment), which estimates the costs and benefits of the implementation of the Bill)

57. The table of fixed costs associated with the adoption of the opt-out system on page 45 of the Explanatory Memorandum details that spending on communications will fall in the period 2017-22 to £50k per annum, from a high of £1.453m in 2015-16.
58. The HTA believes that communication will be vital in ensuring the legitimacy of a system of deemed consent, in the sense that without it Welsh residents will not know what action they are required to take in order not have their consent deemed, and would caution that £50k per annum appears to be a low spend for such a vital issue.
59. As noted in previous HTA response documents on this matter, a new group of people will be impacted by the system year-on-year and while steps should have been taken during the implementation and launch phases to raise general awareness, campaigns will be required every year. It is true that in order to maintain the legitimacy of a system of deemed consent there will need to be a continuous communication programme, so those that have made a decision in the past are able to revisit it if they wish.
60. The HTA also questions whether an overall communications spend of £2.9m over ten years is adequate for such a significant legislative and operational change on a sensitive and complex issue.

The appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation (as set out in part 1, paragraph 90 of the Explanatory Memorandum, which contains a table summarising the powers for Welsh Ministers to make subordinate legislation)

61. The HTA is not in a position to comment on the appropriateness of the powers in the Bill for Welsh Ministers to make subordinate legislation.

Areas for further consideration

62. The HTA would highlight the following three areas as those which require further consideration and development, and which will be key to the effective implementation and operation of the proposed system.

Communications

63. The commitment made in the Explanatory Memorandum to an effective and sustained communications campaign is noted by the HTA. Communication will be vital in ensuring that every person living in Wales and the bordering counties is aware of the proposed system and how it will affect them. In order for the individual's decision to remain paramount they must be aware of the action they are required to take, if any, to make their views known.

64. Communication with all Welsh residents and those living in the border counties will be important, and attention should be given specifically to those groups who are regarded as being hard to reach. These include those people whose first language is not English or Welsh, and also those living in deprived areas.

65. It will be important to develop a communications plan which ensures people who move to Wales are made aware of the system soon after they become resident, in order to allow them sufficient time to make a decision and, if necessary, record their wishes.

66. The HTA considers that the planned communication with every Welsh resident six months prior to their eighteenth birthday will be important to ensure that there is time for these young people to make an active decision prior to deemed consent applying to them.

67. Any risk of a particular group or groups of Welsh residents being left behind on this matter due to poor communication must be actively addressed by the Welsh Government. Without an effective, comprehensive, targeted and continued communications campaign the proposed system cannot be said to hold the decision of the individual in life as a core principle. Indeed, without proper communication an individual may not be in receipt of the information they require to know what their silence on the matter of organ donation after their death will be considered to mean.

68. In previous responses to the Welsh Government's consultations on an opt-out system for organ donation, the HTA has stressed the importance of a continuous communications campaign. Such a campaign will be critical in ensuring that every Welsh resident remains aware of whether or not the system affects them, and what action they need to take. If the focus on this continuous communications campaign is lost, then there is a significant risk that people will not be properly informed, leading to the whole system being undermined.
69. The HTA intends to continue to work with the Welsh Government to provide input on the communications activity for the proposed system.

Cross-border issues

70. The HTA believes that there is still work to be done on the cross-border issues which arise from the proposed system.
71. The introduction of a register for Welsh residents which records both wishes to donate, and wishes not to donate, would mean that there would be two different registers operating across the UK. In Wales it is envisaged that an individual will be able to record a yes to all organs, a yes to some organs, or an outright no. In the rest of the UK an individual will be able to record a yes to all organs or a yes to some organs. They will not be able to register a no.
72. Operationally this poses challenges as, under the HT Act, it is the wishes of the individual immediately before they died which are held as primary. Therefore if these wishes are recorded on the Welsh register they should be acted on, no matter where the individual dies. This means that, for Welsh residents who die outside Wales, the SNOD will be required to check any Welsh register which exists and act on the recorded wishes, if there are any. In fact, it would be prudent that any Welsh register is checked for every donor, as it may not be clear if they had ever been resident in Wales. By checking both registers the risk that the "wrong" information is relied upon is limited. Therefore, all SNODs must have access to any Welsh register and the Organ Donor Register and be in a position to easily establish whether a person is on either or both registers, and which record is most recent. This information will need to be quickly ascertained, most often in the middle of the night, and its accuracy must be guaranteed.
73. If individuals are able to record their wishes on the new Welsh register prior to implementation of the opt-out system, then this recording will in effect form the

last recorded wishes of the individual. It is vital that these are made available to SNODS in order to ensure compliance with the HT Act.

Post-implementation review

74. The consultation document commits to a thorough and on-going post implementation review and the HTA suggests that this seeks to highlight both successes and challenges. The HTA notes that both the Scottish Government and Northern Ireland Assembly² have expressed interest in the Welsh Government's proposals, and as such the post implementation review may form part of the basis of policy decisions in other parts of the UK. This unique opportunity to share the experience of one country of the UK with others should not be lost, and investigation of the true outcomes for all involved from donor families, to recipients and clinical staff will be key to the wider understanding of how such a system operates.

² <http://www.eveningtimes.co.uk/news/bid-to-change-opt-out-laws-a-step-closer-112363n.19888806>
and <http://www.bbc.co.uk/news/uk-northern-ireland-17089597>

Summary

75. Since the Welsh Government announced their intention to introduce a system of deemed consent for organ and tissue donation in Wales, the HTA has been involved, to a varying degree, in the development of the Welsh Government's proposals which have resulted in the Bill which is the focus of this consultation.
76. The HTA is aware of the wide-range of views which exist on this matter, and as a statutory regulator has sought to provide advice and guidance on matters within its remit and on those areas in which the organisation has gained experience during the past eight years.
77. As detailed above, there are parts of the Bill which the HTA believes require further consideration and exploration.
78. However, it is those areas which are not specified in the Bill, for example the introduction of a Welsh register of people's wishes, the communications strategy and post-implementation review where assurances are needed to give confidence to all involved in the proposal.

Response of the British Transplantation Society

Thank you for asking the British Transplantation Society (BTS) to contribute to contribute to the consultation on the Human Transplantation (Wales) Bill.

1. Individual Provisions set out in the Bill

(a). Section 2, the Promotion of transplantation.

The BTS is delighted to see the inclusion of a section mandating the Welsh Ministers to promote transplantation, provide information and increase awareness about transplantation, and inform the public of the circumstances in which consent will be deemed to have been given. Whether or not one supports “Opting out”, there is no doubt that increased public awareness is vitally important as is government support for transplantation. There is a similar requirement in the Human Tissue (Scotland) Act 2006 to “promote, support and develop programmes of transplantation” as well as to “promote information and awareness about the donation for transplantation of parts of a human body”, and the public awareness campaigns in Scotland have resulted in high rates of registration on the Organ Donor Register and a higher rate of consent to organ donation.

This section of the Welsh Bill and Scottish Act is sadly missing from the Human Tissue Act (2004) that currently applies to the rest of the UK.

(b) Section 3, relating to lawful transplantation activities,

The paragraph relating to storing the deceased person presumably relates to tissue and corneal donation. This seems reasonable. As it reads, the bill might support the removal of organs and tissues for transplantation with “deemed” consent, and these would include the more unusual and emotive forms of transplantation such as hand/arm and face transplants.

(c) Sections 4-8, relating to consent,

Section 4 paragraphs 1 to 3 are not contentious. Paragraph 4 essentially says that the Welsh system will be a soft opt-out, where relatives may oppose organ donation. If opting out legislation is to be introduced then such “soft” opt-out is the type that is favoured by the transplantation profession in the UK.

Section 5 (Consent: excepted adults) is important. In order to ensure a new resident to Wales becomes aware of the legislation within his/her first six months of residence it will be important to continue a programme of public awareness of the legislation at intervals no less than 6 months. The absence of such an undertaking would be a significant cause for concern.

(d) Sections 9-11, relating to offences,

No comments on this section

(e) Sections 12-20, which make general provision.

Section 12a states that it is “lawful (a) to take steps for the purpose of preserving the part for transplantation”. As transplantation advances, all opportunities to recover transplantable organs are being explored. One such relates to potential donors being admitted to an emergency department either dead or in the process of attempted cardiopulmonary resuscitation that then fails. In order to *optimally* preserve organs for transplantation it may be

necessary to administer drugs to the potential donor while maintaining an artificial circulation by cardiac massage, or establishing an extracorporeal circulation of blood to perfuse the organs. Such is the practice in parts of Spain and is also the subject of a pilot in Scotland. The wording of this section would seem to support such interventions in Wales, which go beyond the “minimal steps” permissible under the Human Tissue Act (2004). However the Bill then goes on to say that none of these steps to preserve organs can proceed without prior approval from a coroner (whose jurisdiction will apply to cases of sudden death such as those brought to the emergency department). A requirement for *a priori* approval of a coroner before undertaking “steps for the purpose of preserving the part for transplantation” would effectively prevent such steps from being undertaken in the timely manner that would be required were such donation practices to be explored in Wales.

2. Barriers to implementation

The BTS can see difficulties in ensuring that newcomers who come to live in Wales are provided with the necessary information explained deemed consent. This is not so much a barrier, but a challenge to implementation of the Bill.

3. Unintended consequences of the Bill

Adverse publicity is the major concern of the BTS. If a family were not present at death, but subsequently come forward to say that the deceased did not agree to donation, and that his wishes had been overlooked or that the database recording his wishes (the ODR) was inaccurate (which has happened with the ODR), there would be significant adverse publicity which would damage transplantation not only in Wales, but also the rest of the United Kingdom. The BTS would be reassured to know that contingencies for such an eventuality have been considered and will be in place ahead of such an event.

4. The financial implications of the Bill

The Organ Donor Taskforce report “*The potential impact of an opt-out system for organ donation in the UK*” discussed opt-out legislation in general. One of the considerations during the Taskforce’s deliberations was balancing the high predicted costs of implementation of opting out compared to the lesser costs of a programme of public awareness campaigns, of the sort conducted in Scotland. The predicted costs of introducing opt-out in Wales are, we believe, significantly less than those predicted by the ODTF in their deliberations.

There is no doubt that renal transplantation is a cheaper form of treatment for a patient in renal failure than dialysis, and savings will be made as more patients are removed from the dialysis programmes in Wales. At the moment this is a function of the organ donation activity throughout the United Kingdom, rather than in Wales specifically, since organs are, and will continue to be, exchanged on a National basis to optimise matching and outcomes.

5. The appropriateness of the powers in the Bill for Welsh Ministers

No comment.

Additional comments

It appears that, through this bill, Wales will introduce opt-out legislation, and as such will be the first nation in the UK so to do. The BTS would strongly encourage every effort be made to record the process carefully, detailing the costs and the final outcome, so that the other home nations can learn and assess whether it is something they wish to do. It would be tempting for the government to audit the process itself, but it might be better received externally were some independent assessment be included in the process and we would like to encourage this.

The BTS would like to see provision in new transplant legislation such as this for pharmacological interventions in potential organ donors, particular those potentially donating after circulatory death (DCD). Currently heparin cannot be given pre-mortem to such donors, even if the blood pressure is terminally falling and has fallen below 50mmHg. DCD donors now form a third of all deceased organ donors in the UK and an intervention such as this may make a significant difference to the outcome of transplants. It is permitted in parts of North America.



Ms Sarah Sargent
Dirprwy Glerc / Deputy Clerk
Swyddfa Ddeddfwriaeth / Legislation Office
Cynulliad Cenedlaethol Cymru /
National Assembly for Wales

10, Dallington Street
London EC1V 0DB

Date: 10 January 2013

Dear Ms Sargent,

Consultation on the Human Transplantation (Wales) Bill : written evidence from the UK Donor Ethics Committee (UKDEC)

Thank you for your letter of 6 December 2012, inviting UKDEC to submit written evidence to the inquiry. I am responding as Chairman on behalf of the Committee.

UKDEC was established in 2010 following a recommendation of the Organ Donation Taskforce (ODTF). It is independent, hosted by the Academy of Medical Royal Colleges (with funding from the UK Health Departments). Its purpose is to address the ethical questions that arise in organ donation, in order to remove barriers to effective decision-making in donation and transplantation. It promotes ethical practice and does not seek to increase the number of donations per se. Further information can be found at www.aomrc.org.uk/donations-ethics-committee.html. Membership includes clinicians, ethicists and lay members.

Our submission therefore focuses on the ethical issues relating to the provisions set out in the Bill, including practical issues that have a bearing on good ethical practice. We also have some concerns about potential unintended consequences which are included in the submission.

Individual provisions set out in the Bill

Sections 4-8 : consent

UKDEC sees no fundamental ethical objection to a system of deemed consent or “opt out”, but we do have concerns about the practicalities involved in ensuring consent under such a scheme is valid and will remain so as time moves on. We also have reservations about the impact on the relationship between professionals and donor families, and on the confidence of professionals to explore new and ethically challenging techniques aimed at increasing the number of successful donations. These issues are dealt with in more detail below, where potential barriers and unintended consequences are discussed.

On the specific provisions, we do have concerns about the provisions in relation to adults lacking capacity. The Bill rightly recognises the need to protect people lacking the capacity to understand the notion of opting out. However the proposals for identifying such people do not seem very robust. The criterion of lacking capacity for a “significant period” before death is vague, and the reliance on discussion with families after death might lead to some very subjective assessments

being made. Further work on how these decisions will be made in practice, and what support will be available for professionals and families, would be helpful.

A particular issue arises in the context of donation after circulatory death (DCD), which accounts for nearly 40% of solid organ donations. The decision-making about donation for a DCD donor happens while the donor is still alive, but lacking capacity. Such decisions are therefore covered by the Mental Capacity Act, and in order for donation to proceed it has to be established that activities to facilitate donation are in the patient's best interests. The potential for a move to deemed consent to undermine DCD schemes is discussed further under "unintended consequences", but on a practical and legislative level the Bill needs to be clear on the consent status of a potential DCD donor who may not have opted out, but is still alive and lacking capacity at the time of decision-making about donation.

Potential barriers to implementation

The Bill, and its associated Explanatory memorandum, acknowledges the communications and educational challenges inherent in a switch to a system of deemed consent. From an ethical perspective, clear information about the system and the implications of opting out or not, is clearly a vital component of an ethically acceptable system. Training and support for professionals will also be a key element in ensuring trust in the new system – if the new system is perceived as too complicated this could undermine trust in both professionals and the public.

Others will be better placed to comment on the financial costs, but we do wonder whether the impact on professionals of setting up and maintaining the new system in parallel with a different system in the rest of the UK has been fully recognised. Sections 45 to 54 of the Explanatory Memorandum set out the vision of how the scheme will work in various scenarios, for example should a person have lived in Wales but die elsewhere, or opt-out when they lived in Wales but then move elsewhere. The Bill appears to place a lot of additional burdens on staff across the UK relating to deciding about ordinary residence in Wales, checking different registers etc. Section 52 says "NHS staff across the UK will need to be aware of the law in Wales and the process will need to have a check built in to ask whether the person had ever lived in Wales, and therefore look for any recorded decision made whilst the person lived in Wales". Implementation needs to ensure all staff are fully trained and supported to help families through the process.

A key assumption is that the switch to deemed consent will lead to an increase in donations. Whilst UKDEC recognises the political imperative for introducing deemed consent in Wales, there are doubts about the evidence. Overall systems in different countries vary, and it is not necessarily possible to compare one opt-out system with another. The evidence linking opt-out systems with increased donation is equivocal or at best weakly in favour of opt-out having an effect. In order for confidence in the system to be upheld, those tasked with implementing it will need to be convinced that the time and resources involved could not be better deployed elsewhere.

We note that families will continue to be involved in decision-making under the proposals, albeit on the basis that in the absence of an opt-out, consent will be deemed, unless the family has evidence that the person really did not want to be a donor. Whilst the surveys carried out in Wales show general support for an opt-out scheme, it remains to be seen whether in practice families accept the absence of objection as consent to donation, and what the impact will be on family satisfaction with

the process. We would recommend that implementation be accompanied by well executed social scientific research to provide an evidence base.

Unintended Consequences

The inevitable upward trend in the demand for organs for transplantation means that clinical practice in transplantation needs to constantly evolve and find new and better ways of delivering successful donations. Donation after circulatory death (DCD) is an important potential source of increasing the organs available for transplantation, particularly hearts.

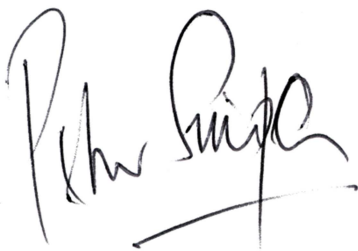
As I mentioned earlier, decisions about DCD donations need to be made whilst the potential donor is still alive. These decisions can be ethically challenging, since there are a range of interventions that might be carried out on a dying patient that will optimise the condition of organs, but have no benefit to the patient other than fulfilling his or her wish to be a donor.

Therefore the justification for intervening, and the balance of benefits and burdens that need to be weighed up in deciding whether an intervention is in the patient's best interests, relies heavily on the strength of evidence that the patient wants to be an organ donor.

UKDEC recognises that there will still be an "opt in" register under the proposals, but we are concerned that a shift towards reliance on the absence of opting out as the basis of consent to donation could shift the delicate balance and undermine professionals' confidence to develop the innovative schemes that have the potential to increase the number of organs for transplantation.

Were this to happen and the unintended consequence limited new opportunities for increasing available organs, this would work against the overall aim of the Bill. We would recommend further work be undertaken on the potential impact on clinical practice in this area.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Peter Simpson', with a long horizontal stroke extending from the bottom of the name.

Sir Peter Simpson

Chair, UK Donor Ethics Committee

16 January 2013

Health and Social Care Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA.

Dear Sir / Madam

Health and Social Care Committee Consultation on the Draft Human Transplantation (Wales) Bill

I am pleased to enclose a submission from the Nuffield Council on Bioethics, an independent body that examines and reports on ethical issues in biology and medicine.

In October 2011, the Council published a report, *Human bodies: donation for medicine and research*, which considers the ethical and social issues that arise when people are asked to donate bodily material and sets out an ethical framework to help policy makers consider the acceptability of various ways of encouraging people to donate (see Chapter 5 of the full report).

More information about the inquiry and the resulting report can be found at: www.nuffieldbioethics.org/donation

Our response to the Welsh Government Consultation on Proposals for Legislation on Organ and Tissue Donation on 31 January 2012 is available at:

http://nuffieldbioethics.org/sites/default/files/files/Welsh_opt-out_consultation_Jan_2012.pdf

Our subsequent response to the Welsh Government Consultation on the Draft Human Transplantation (Wales) Bill on 10 September 2012, is available at http://www.nuffieldbioethics.org/sites/default/files/files/Welsh_opt-

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Professor Jonathan Montgomery

Deputy Chair
Professor Ottoline Leyser CBE FRS

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Professor Michael Moran FBA
Professor Alison Murdoch FRCOG
Dr Bronwyn Parry
Professor Nikolas Rose
Dr Geoff Watts FMedSci
Professor Jonathan Wolff

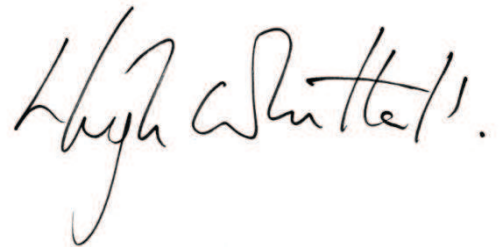
Director
Hugh Whittall

Assistant Directors
Dr Peter Mills
Katharine Wright

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Please do not hesitate to contact me if you would like further information or assistance.

Yours sincerely

A handwritten signature in black ink that reads "Hugh Whittall". The signature is written in a cursive style with a large initial 'H' and a long, sweeping tail on the 'l'.

Hugh Whittall
Director

Response from the Nuffield Council on Bioethics to the Health and Social Care Committee Consultation on the Draft Human Transplantation (Wales) Bill

With reference to our response to the Welsh Government Consultation on Proposals for Legislation on Organ and Tissue Donation on 31 January 2012 and the Welsh Government Consultation on the Draft Human Transplantation (Wales) Bill on 10 September 2012, we reiterate the following:

Key points:

- Decisions about deceased donation should be based on the known wishes of the donor, so far as these can be discovered.
- We would not oppose on ethical grounds a soft opt-out system, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views. We do, however, note some practical difficulties in implementation, and some doubts as to the impact of such a change.
- It is important that loss of trust in the system is minimised, for example by ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.
- **If an opt-out system is introduced in Wales this should be accompanied by robust research, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change has had on the numbers of organs donated.**
- The possibility of donating material for research use should be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death.

Introduction

- 1 The Nuffield Council on Bioethics is an independent body that examines and reports on ethical issues raised by new developments in biology and medicine. It is funded jointly by the Nuffield Foundation, the Wellcome Trust and the Medical Research Council.
- 2 In October 2011, the Council published a report, *Human bodies: donation for medicine and research*¹, which considers how far society should go in encouraging people to donate their bodily material. The report was the result of a two-year independent inquiry led by Professor Dame Marilyn Strathern. In coming to its conclusions, the Working Party held an open consultation to which members of the public as well as academics and professionals involved in transplantation services were encouraged to respond. A deliberative workshop was also held with members of the public recruited to represent a cross-section of the UK community.² More information about the inquiry, method of working and resulting report can be found at: www.nuffieldbioethics.org/donation

¹ Nuffield Council on Bioethics (2011). *Human bodies: donation for medicine and research* (London: Nuffield Council on Bioethics). Available at: www.nuffieldbioethics.org/donation

² Opinion Leader (2010) Nuffield Council on Bioethics: *human bodies in medicine and research - report of deliberative workshop on ethical issues raised by the donation of bodily material* (London: Opinion Leader). Available at: [www.nuffieldbioethics.org/donation-externalconsultation](http://www.nuffieldbioethics.org/donation/donation-externalconsultation)

Ethical considerations

- 3 We believe that **decisions about deceased donation should be based on the known wishes of the donor**, so far as these can be discovered. Such information should, ideally, derive from the person's own expression of these wishes before death (see paragraphs 5.57-5.61 of the full report).
- 4 In the absence of a record of the deceased's wishes (including the absence of any evidence of objection), information as to their likely wishes should be sought from those close to the deceased person, who are usually best placed to know the deceased person's wishes, and who themselves, in their bereavement, have a stake in how their deceased relative's body is treated.
- 5 We take this overall view on the basis that there is sufficient evidence that, for many people, the disposal of their bodily material is a matter of significant personal concern, and that to take material without some evidence that this is in accordance with the person's wishes risks treating the person's body as a means to others' ends.
- 6 Clearly not everyone regards their bodily material – during life or during death – in such a way, but the entrenched and opposing views on proposals for an 'opt-out' approach to deceased organ donation highlight the fundamental lack of consensus on this issue within the UK. However, we make a distinction between what is required for valid consent to an intervention during one's lifetime, and what should be required for valid consent in respect of a deceased person's bodily material. In particular, we suggest that the degree of detail required when providing information about the proposed procedure will differ significantly, and that it should be possible for a person to provide legal authority for donation after death on the basis of quite minimal information, if this is sufficient for them to be clear about their own wishes.
- 7 Finally, we emphasise the importance of consent in creating and maintaining trust in health professionals and the health care system as a whole. We note that where 'medical mistrust', or mistrust of the system, is cited as a reason for people to hold back from donating bodily material, this may be associated with concerns about consent: both that the terms of the consent may be abused (for example by using the donated material in a different way from that envisaged in the consent) and that additional material may be taken without explicit consent. This is a factor that must be taken into account when considering any changes to approaches to consent.

Research on effectiveness of opt-out systems

- 8 We are aware of the ongoing discussions in the research literature as to whether increases in organ donation in countries such as Spain that have introduced opt-out legislation can be ascribed to the legislative framework, or whether other systemic factors in the way organ procurement is managed are the main contributing factor to the increase. A systematic review of studies comparing 'before and after' donation rates after legislative change in a number of countries,

published in 2009, concluded that changing to an opt-out system of consent alone was unlikely to explain the variation in organ donation rates between countries, with many other factors identified as relevant. These included both factors affecting the total number of potential donors available (for example rates of motor accidents, the population's age distribution, and the country's definition of death), and factors affecting how many of those potential donors in fact went on to donate (for example the organisation and infrastructure of the transplant system, wealth and investment in health care, and underlying public attitudes and awareness).³

- 9 Another study, published subsequently, concluded by contrast that opt-out systems *are* associated with relatively higher rates of deceased donation – but also with relatively lower rates of living donation.⁴ We are also aware of research modelling the possible effects on organ supply of an opt-out system, based on differing levels of individual and family opt-out.⁵ We note that, while such models demonstrate a potential increase in the number of available organs (and hence lives saved) on the basis of particular assumptions about numbers opting out, such assumptions clearly remain to be tested.

Our recommendations

- 10 In our opinion, **the importance to be attached to the person's own wishes rules out absolutely any consideration of introducing a 'hard' opt-out approach to deceased organ donation**, given the impossibility of ensuring that everyone would be sufficiently well-informed to have the opportunity of opting out during their lifetime.
- 11 However, **we would not oppose on ethical grounds a soft opt-out system**, in which families had the opportunity (without pressure) of contributing their knowledge of the person's own views and, where appropriate, of determining that the person would not have wished to become a donor, or indeed that donation would cause the family significant distress. We do, however, note some practical difficulties.
- 12 First we suggest that **initial assumptions as to the numbers of additional organs that might be obtained in such a way should be modest**, if families do indeed continue to feel genuinely free to express any objections they feel. It does not automatically follow that families who currently refuse consent to the use of their deceased relative's organs would take a different view under such a system. Indeed, if families in such cases felt coerced in any way, then this would potentially render their role meaningless. On the other hand, if the effect of any policy change were to change attitudes so that donation were seen as 'natural' or 'normal', hence increasing the likelihood that families would conclude that donation would be in line with their deceased relative's wishes, this would be

³ Rithalia A, McDaid C, Suekarran S, Myers L, and Sowden A (2009) Impact of presumed consent for organ donation on donation rates: a systematic review BMJ 338.

⁴ Horvat LD, Cuerden MS, Kim SJ et al. (2010) Informing the debate: rates of kidney transplantation in nations with presumed consent Annals of Internal Medicine 153: 64

⁵ Bird SM, and Harris J (2010) Time to move to presumed consent for organ donation BMJ 340: c2188.

ethically unproblematic. Similarly, if families felt relieved from the requirement actively to make the decision, this too might lead to fewer refusals.

- 13 Second, given the strong opposition in some quarters to the notion of any form of opt-out scheme, and the associated concerns that the state (acting through health professionals and the health care system) would be intervening to 'take' organs rather than facilitating their being 'given', there is at least a risk that some degree of trust in the system could be lost. In such circumstances, **it would be particularly important that systems should be designed in such a way as to minimise such loss of trust**, for example by ensuring that those seeking family views are not themselves subject to targets that might be seen as leading to pressure on families.
- 14 As we have already shown, there may be a significant difference between how people think or say they will act in particular theoretical situations, and what they actually do if that situation arises (see paragraph 6.19 of the full report). We are therefore hesitant to rely on research reporting on how people say they would respond to the introduction of a soft opt-out system including all the protections described above. **If an opt-out system is introduced in Wales we recommend that this is accompanied by robust research**, both on the role of relatives in determining whether organs may be donated, and on the effect that the legislative change (as opposed to any confounding factors such as system changes) has had on the numbers of organs donated. Such research would provide a clear evidence base for any proposals for change elsewhere in the UK, or indeed further afield.

Donation of organs and tissue for research

- 15 We note again that current proposals in Wales will apply to the donation of organs and tissues for the purposes of transplantation only, and not include the donation of organs and tissues for other purposes, such as research, display or commercial use.
- 16 We consider that it is crucial that any change in the systems used to obtain consent should take fully into account the implications for the donation of organs and tissue for research purposes. In the context of the current 'opt-in' system to organ and tissue donation, our report recommends that **the possibility of donating material for research use should be routinely raised with the person's family when authorisation for the removal and use of organs or tissue is sought after death**. We also suggested that routine information about the Organ Donor Register should include explicit reference to the potential research uses of organs and tissue, and that potential donors should have the option of authorising such uses in advance.

Eitem 6

Human Transplantation (Wales) Bill: personal statement

1. My comments relate primarily to the cost-benefit analysis contained within the Regulatory Impact Assessment.
2. The current supply of organs available for transplant is roughly 41 short of current levels of demand – based on numbers of patients who died while waiting for transplant. It is estimated that the new legislation would result in 15 more donors per year – an increase of 25% and an additional supply of 45 organs available for use in transplantation.
3. The cost-benefit assessment of the soft opt-out system indicated that the predicted increase in donor organs would not incur additional costs in terms of impact on critical care, surgical services including theatre time. However, hospitals are currently operating at capacity levels that allow for no additional procedures given the demands on staff time and the system in general. It is difficult to predict when the potential donors would become available with consequential problems in planning when the relevant procedures would be taking place. It is therefore possible to envisage a situation where it would not be possible to undertake the procedure and the potential donor organ might not materialise and the potential beneficiary not receive the benefits which the policy and the bill is seeking to ensure. Alternatively, the procedure will take place but at the cost of other procedures being cancelled and patients having to face the prospect of additional delays in their waits for surgery.
4. It is not clear whether the policy – if successful - will result in the need for additional staff resources or additional training requirements across Wales.
5. The situation whereby the level of supply of organs exceeds levels of demand in Wales need to be factored into the cost-benefit analysis – the system of charging other systems for transport etc. of donor organs, for example, to increase their respective levels of transplantation warrant consideration.
6. The administration costs of the soft opt-out system need to be considered relative to the current system of organ donation, while the additional costs resulting from an increased number of transplants would be managed by the Health Boards – additional pressure on already stretched resources possibly! However, it has to be recognised that there will be health benefits that emerge as a result of the policy which is the primary goal of the NHS – that is to enhance health status as opposed to ‘making money’!
7. The costs of transplantation, those that are incurred to minimise risk of rejection and on-going treatment costs need to be compared with the costs offset as a result of the transplant e.g dialysis and on-going patient management costs. This is done in the cost-benefit analysis of the soft opt-out scheme using Department of Health data – but which seemed somewhat dated (2005/06 prices). A more recent analysis using Welsh data might be an advantage.
8. The benefits of transplants were translated into Quality Adjusted Life Years (QALYs) – which is the accepted currency for assessing health gain – although the valuation of £60,000 for each QALY gained (again based on Department of Health estimates) does seem excessive when compared with the NICE QALY threshold of £20,000 - with increased valuations for end-of-life therapies.

9. It is important to state however that the economic issues are but one feature that need to be taken into consideration in assessing this particular policy initiative – and economic appraisal cannot do justice to all of the factors that need to be included in any evaluation of this policy.

Professor Ceri J. Phillips

January 2013

Eitem 7

CommitteeName

Meeting Venue: **MeetingLocation**

Meeting date: **MeetingDate**

Meeting time: **MeetingActualTimeRange**

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