

Y Pwyllgor Iechyd a Gofal Cymdeithasol

Lleoliad:
Ystafell Bwyllgora 1 – Y Senedd

Dyddiad:
Dydd Iau, 24 Ionawr 2013

Amser:
09:00

Cynulliad
Cenedlaethol
Cymru

National
Assembly for
Wales



I gael rhagor o wybodaeth, cysylltwch â:

Polisi: Llinos Dafydd / Deddfwriaeth: Steve

George/Sarah Beasley

Clerc y Pwyllgor

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Agenda

1. Cyflwyniad, ymddiheuriadau a dirprwyon

2. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru): Cyfnod 1 – sesiwn dystiolaeth 8 (Tudalennau 1 – 3)

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Lesley Griffiths AC, y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Mark Osland, Dirprwy Gyfarwyddwr Cyllid, yr Adran Iechyd a Gwasanaethau
Cymdeithasol
Fiona Davies, Gwasanaethau Cyfreithiol.

3. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru): Cyfnod 1 – sesiwn dystiolaeth 9 (Tudalennau 4 – 8)

Tenovus

Dr Rachel Iredale, Cyfarwyddwr y Tîm Cefnogaeth Canser
Miss Julia Yandle, Rheolwr Gwasanaethau Cyngor

Prifysgol Abertawe, Ganolfan Economeg Iechyd Abertawe, Coleg y Gwyddorau Dynol a Iechyd

Yr Athro Ceri Phillips BSc.(Econ), MSc. (Econ), PhD, Economegydd Iechyd

Bwrdd Iechyd Aneurin Bevan

Glyn Jones, Cyfarwyddwr Cynorthwyol Cyllid (Gweithrediadau)

4. Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y canlynol:

Eitem 5

5. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru): ystyried tystiolaeth yr Aelod sy'n gyfrifol

6. Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru): Cyfnod 1 – sesiwn dystiolaeth 10

Yr Aelod sy'n gyfrifol

Mick Antoniw AC, yr Aelod sy'n gyfrifol am y Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos (Cymru)

Vaughan Gething AC

Paul Davies, Aelod Cyswllt o Athrofa Iechyd a Gofal Cymdeithasol Cymru

Joanest Jackson, Cyngorydd Cyfreithiol

[Bil Adennill Costau Meddygol ar gyfer Clefydau Asbestos \(Cymru\) \(fel y'i cyflwynwyd\)](#)

[Memorandwm Esboniadol](#)

Egwyl (12.00 – 13.00)

7. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – sesiwn dystiolaeth 1 (13.00 – 14.15)

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Lesley Griffiths AC, y Gweinidog Iechyd a Gwasanaethau Cymdeithasol

Pat Vernon, Pennaeth Polisi ar Ddeddfwriaeth Rhoi Organau a Meinweoedd

Dr Grant Duncan, Dirprwy Gyfarwyddwr y Gyfarwyddiaeth Meddygol, Llywodraeth Cymru

Sarah Wakeling, Gwasanaethau Cyfreithiol, Llywodraeth Cymru

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

8. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – sesiwn dystiolaeth 2

(14.15 – 15.00) (Tudalennau 9 – 18)

Sefydliad Aren Cymru

Roy Thomas, Cadeirydd Gweithredol Sefydliad Aren Cymru

9. Bil Trawsblannu Dynol (Cymru): Cyfnod 1 – sesiwn dystiolaeth 3
(15.00 – 15.45) (Tudalennau 19 – 29)

Gwaed a Thrawsblaniadau'r GIG

Sally Johnson, Cyfarwyddwr, Rhoi Organau a Thrawsblannu

10. Papurau i'w nodi

Llythyr gan y Prif Ystadegydd – Cynnwys ac amseru ystadegau swyddogol ynghylch iechyd (Tudalen 30)

Llythyr gan y Gweinidog Iechyd a Gwasanaethau Cymdeithasol – Camau a gododd o'r cyfarfod ar 5 Rhagfyr (Tudalennau 31 – 35)

Eitem 2

Health and Social Care Committee

Recovery of Medical Costs for Asbestos Diseases (Wales) Bill

RMCA14 – Lesley Griffiths AM, Minister for Health and Social Services

Health and Social Care Committee

Stage 1 Consideration of the Recovery of Medical Costs for Asbestos Diseases (Wales) Bill – Mick Antoniw AM – Members Bill

Written Evidence from the Minister for Health and Social Services

Consultation Questions

General

1. Is there a need for a Bill to allow recovery of costs of NHS treatment for asbestos-related diseases in Wales?

The Bill would allow the Welsh Ministers to recover costs incurred by Welsh NHS bodies in providing care and treatment to sufferers of asbestos-related diseases, and provide for funds recovered to be used for the care and treatment of victims. There is currently no other legislative basis on which these costs can be recovered by the Welsh Ministers. I believe it is appropriate for those responsible for the exposure to asbestos to be required to contribute to the care and treatment of victims, instead of the public purse having to bear all these costs, and consider the Bill achieves this in a way which is proportionate and justified

2. Do you think that the Bill, as drafted, delivers the stated objectives as set out in the Explanatory Memorandum?

I am content the Bill as drafted, achieves the main objectives the Member in Charge has set out for it. Of course, I will be interested to hear the views of the Committee and others as to how it might be improved.

3. Are the sections of the Bill appropriate in terms of introducing a regime to allow the recovery of costs of NHS treatment for asbestos-related diseases in Wales. If not, what changes need to be made to the Bill?

The Government is content the sections of the Bill and the powers therein for subordinate legislation, are appropriate to enable the proposed cost recovery scheme to operate. Subject to the Assembly passing the Bill, the Welsh Ministers intend to consult, in due course, on the subordinate legislation required to give effect to a scheme to recover the relevant costs. It will be important to ensure any prospective scheme operates effectively to recoup the costs with a minimum level of administrative outlay.

4. How will the Bill change what organisations do currently and what impact will such changes have, if any?

Broadly speaking, the Bill would extend, in respect of treatment provided by, or on behalf of, the NHS in Wales, provisions similar to those of the Health and Social Care (Community Health and Standards) Act 2003 which apply to personal injury cases, to sufferers from asbestos-related diseases. As such, organisations (in particular, Local Health Boards and NHS Trusts in Wales) have some experience of operating a very

similar scheme to that envisaged by the Bill. The Explanatory Memorandum sets out an assessment of the impact on the various sectors involved.

It is not envisaged significantly new arrangements will be required to be developed and implemented by Local Health Boards and NHS Trusts in order for them to provide information to support the cost recovery scheme. However, there will need to be some transitional development work. This is covered in the Explanatory Memorandum.

5. What are the potential barriers to implementing the provisions of the Bill (if any) and does the Bill take account of them?

Although the Government considers the administrative costs outlined in the Explanatory Memorandum to be an accurate estimate, further work will be required to establish with a degree of certainty the costs associated with administering the scheme. In particular, the Welsh Government will need to enter into detailed discussions with the Compensation Recovery Unit (in the Department for Work and Pensions). Our intention, subject to the will of the Assembly, is a scheme could be implemented from the beginning of the 2014-2015 financial year. This is an ambitious target given the need to consult on, produce and progress through the Assembly, a number of items of subordinate legislation that will support the operation of the cost recovery scheme.

6. Do you have any views on the way in which the Bill falls within the legislative competence of the National Assembly for Wales?

The Government concurs with the view put forward in the Member in Charge's Explanatory Memorandum that the provisions of the Bill fall within subject heading 9 (Health and health services) of Part 1 of Schedule 7 to the Government of Wales Act 2006, which in particular includes "organisation and funding of national health service". I was also very pleased to see the Presiding Officer has confirmed her view that the Bill is within the legislative competence of the Assembly.

Powers to make subordinate legislation

7. What are your views on powers in the Bill for Welsh Ministers to make subordinate legislation (i.e. statutory instruments, including regulations, orders and directions)?

We are content the Bill, as drafted, provides powers for the Welsh Ministers to make subordinate legislation only where it is appropriate to do so. This is principally to allow for detailed provision to be made in relation to the operation of the cost recovery scheme. Further, we are content with the proposed Assembly procedure attached to the powers, as these broadly align to the guidelines that the Government follows when drafting provisions.

Financial Implications

8. What are your views on the financial implications of the Bill?

As stated above, further work will be required to establish more detailed costings for the scheme which the Bill envisages. The Bill proposes a tariff-based approach which will enable the Welsh Ministers to implement the scheme in such a way as to keep administrative costs to a minimum, and we will seek to implement the legislation in such a

way as to minimise the costs relative to the costs which we are able to recover. Overall I consider the Bill presents an opportunity to release significant resources which it is intended will be utilised to provide additional services for the benefit of victims of asbestos-related diseases and their families.



Health and Social Care Committee - scrutiny of the Recovery of Medical Costs for Asbestos Diseases (Wales) Bill

Written submission from Tenovus, Wales' largest cancer charity

This paper is Tenovus' written response to the Health and Social Care Committee's call for evidence in relation to Mick Antoniw's Bill for the Recovery of Medical Costs for Asbestos Diseases.

During the initial consultation phase, Tenovus issued a statement fully supporting the general principles of the Bill and highlighting the effects the civil litigation costs reforms, as cited in the Legal Aid, Sentencing and Punishment of Offenders Act 2012 (LASPO), will have on compensation claims for victims of asbestos-related diseases, namely that victims would be required to surrender a quarter of the damages that they have been awarded to pay for legal costs.

On 26 June 2012 Bill Esterson MP (Sefton Central, Labour) stated

"The legislation requires terminally ill asbestos victims who succeed in a claim for compensation against negligent, guilty employers to pay up to 25% of their damages for pain and suffering in legal costs. They are not part of the compensation culture, nor are they legally aided, so to include them in that provision is wholly wrong. Many sufferers are so defeated by their illness that they never make a claim under current circumstances. Victim support groups have been told by victims that the change proposed would be a significant further deterrent to them making a claim at all".

The UK government have subsequently stated that the (LASPO) reforms will not apply to mesothelioma cases and a review of the effects of the reforms on such cases will be implemented in Spring 2013.

In July 2012 the UK government announced new measures to speed up the process of compensating mesothelioma victims. These measures would be introduced as part of a multi-million pound support scheme to help those victims who cannot trace a liable employer or employers' liability insurer.

Some support groups welcomed the scheme as a step in the right direction but criticised its scope and particularly the exclusion of sufferers of other asbestos-related diseases such as lung cancer caused by exposure to asbestos.

A further announcement made by the UK government in December 2012 regarding the plans to speed up the process of compensating mesothelioma victims through the introduction of a pre-action protocol and electronic portal to register claims has also been met with criticism and is viewed by some as a further erosion of victims' access to justice and compensation. Concerns have been raised about making the process automated and not personal and that pay-outs will be significantly smaller as a result. This will have a huge impact on sufferers and their families.

There has been much discussion surrounding the notion of the 'polluter must pay' which is commendable and right; however, there needs to be further thought given to the very real possibility that this Bill will act as a deterrent to would-be claimants who may witness employers and insurers defending claims far more vigorously as they have more to lose where the recovery of medical costs becomes an additional factor.

It is well documented that mesothelioma is an aggressive and terminal disease with an average life expectancy of less than two years from diagnosis. A claim for compensation can take up to two years to settle which means that sufferers often die before their claims are paid out.

At Tenovus, we believe that the starting point should be the victims of asbestos-related diseases themselves and any discussion should surround how they can benefit from any proposed legislation. Victims and support groups should be at the forefront of these discussions and their views given weight above all others with an interest in the process.

With regard to the Bill generally, on 5 December 2012 Mick Antoniw made the following statement:

"The purpose of the Bill is simple. In cases where compensation has been paid in respect of a victim of an asbestos-related disease, with or without an admission of liability, the Welsh Government will be entitled to recover the cost of the medical treatment provided. The Bill does not create any new legal entitlement to compensation. It merely says that where compensation has been paid, the cost of medical treatment can be recovered by the Welsh Government with the intention that the costs recovered will be used to provide additional medical support and assistance to asbestos victims and their families. As Members will see from the Bill and the explanatory memorandum, the Bill could recover costs of just over £2 million each year. It is intended that that would be used, for example, to provide additional nursing and hospice care, support and counselling for families and other medical assistance. In this way, I believe that the Bill can make a real difference to the quality of life of asbestos victims who have been so cruelly smitten by this terrible occupational disease, and also to their families".

Tenovus broadly agrees with the premise that costs recovered will be used to provide additional medical support and assistance to asbestos victims and their families. However, what assurances can be given, and checks and balances put in place, to ensure that all the money recovered will go directly back into funding services for asbestos sufferers and not swallowed up by a cash strapped NHS?

Tenovus also raises the following questions: Will medical support and assistance not be available without this Bill? Will there be cause for concern amongst sufferers that resources are limited and they may not receive the best possible care? We believe that more consideration should also be given to the wider network of support services available to victims from the third sector for example, and whether there would be provision for financially supporting those vital services alongside those provided by the NHS.

Will there also be further provision for victims and their families to be supported through the cost of lengthy legal cases where an employer / insurance company is challenging a claim for compensation? It is noted that much of the delay in these cases is due to defendant tactics and thus the fear is that the added dimension of the recovery of medical costs will compound this.

Tenovus would like to thank the Health and Social Care Committee for the opportunity to respond to the Bill and look forward to viewing its development through the next stage.

For further information contact:

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Ms Julia Yandle, Advice Services Manager, Tenovus. Tel: 029 20768785



Recovery of Medical Costs for Asbestos Diseases (Wales) Bill: personal statement

Introduction

There are four main diseases associated with inhalation of asbestos fibres:

- Mesothelioma - a form of cancer mainly affecting the lining of the lungs
- Asbestos related lung cancer
- Asbestosis - a non-malignant scarring of the lung tissue
- Non-malignant pleural disease

There is no specific Welsh study assessing the costs associated with asbestos related diseases, with the only information available that from a study that estimated that the hospital costs of mesothelioma in UK in 2000 of £16 million¹ - and which would probably equate to £23.3 million at current prices. The study also highlighted that such estimates “are certain to be gross underestimates of the total health service costs of asbestos related illness and treatment,” given that lung cancer cases due to asbestos, other cancers linked to asbestos-exposure and other asbestos-related diseases were not included in the calculations of the cost burden.

Comment on costs and benefits appraisal of the options

1. The appraisal is a very detailed consideration of the costs and benefits and is basically technically sound, although the incorporation of variation around the estimates used would have proved to be helpful.
2. The assumption that there will be 80 cases each year for which NHS treatment costs can be recovered fails to take into account the HSE data that shows the increasing trend in mesothelioma cases until at least 2016.
3. The CRU tariffs used are those from April 2010 – as stated these are uplifted each year to reflect inflation – and would therefore increase the gross annual recovery amount.
4. The choice of a 5-year time perspective seems rather limited.
5. One aspect of the rationale for government involvement in the economy is to offset adverse effects on society resulting from what are termed externalities, where the effects of production impact on others not directly involved in that process. The repayment of costs incurred by the NHS resulting from the treatment of asbestos-related diseases – in addition to compensation paid to the sufferers – is intended to fully capture all of the costs associated with the production process.
6. However, the adoption of a societal perspective in the cost-benefit analysis may not be the most appropriate approach in this particular context.
7. The inclusion of the ‘business costs’ into the calculations, and specifically the NHS cost repayment, will make it impossible for the net present values to be positive given that the cost to businesses equates with the benefit to government. The issue in essence here is whether the additional cost borne by private sector organisations, resulting from the

¹ Watterson A, Gorman T, Malcolm C, Robinson A, Beck M. The economic costs of health service treatments for asbestos-related mesothelioma deaths. Ann NY Acad. Sci 2006; 1076: 871-881.

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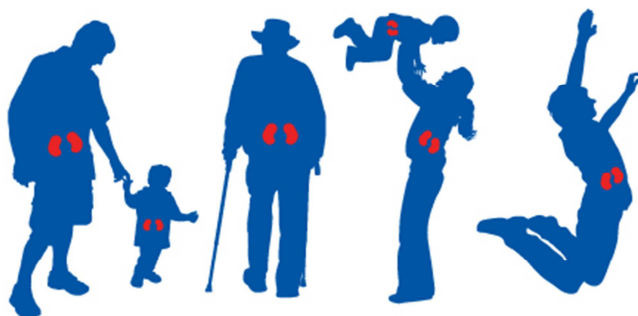
payment of compensation, will adversely affect the decision to continue with production. If there is still a net gain to the organisation from continuing with production there remains a net efficiency gain for society and should therefore be viewed accordingly.

8. However, as indicated in some cases the compensator will be public sector organisations and there will therefore be a negative impact on the Exchequer, which basically becomes a transfer between respective public sector organisations.
9. The perspective employed by NICE, for example, in their appraisal of technologies is that of the National Health Service and personal social services, while other appraisals view the evaluation from the perspective of the public purse.
10. If a partial societal perspective was employed for the cost-benefit analysis – and therefore not including the cost to employers/insurers the resultant net benefit would be positive, with net benefits gained of £7.8 million and NPVs of £6.9 million.

Ceri J. Phillips

January 2013

Eitem 8



Kidney Wales Foundation
Sefydliad Aren Cymru

Charity Number 700396

The Human Transplantation (Wales) Bill

Evidence to the National Assembly for Wales

Health & Social Care Committee

The Kidney Wales Foundation, established in 1967, believes the measures set out in the Human Transplantation (Wales) Bill (“the Bill”) are a progressive proposed change in the law and will be a key component of change in organ donation in the UK. We are supportive of the Bill and provide support of the implementation of the Bill in this evidence to the Health & Social Care Committee of the National Assembly for Wales.

We have been campaigning for the change in the law over many years and we have a determination to see the successful implementation of the law because of the clear effect it will have in changing the cultural approach in Wales and the UK on organ donation and, of course, the lives of so many in the future. It is, however, key that the proposed legislation is implemented with the goodwill of the people of Wales. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The law in proper practice, as evidenced by the Bill, will be essential.

Under the current system of informed-consent, the burden of responsibility for the decision is put heavily on the family, and the task of asking for consent is usually delegated to a transplant coordinator. The freedom given by the new law has as a corollary, the fact there may be more responsibility now put on the doctors. Doctors feel responsible for the patient and the patient's family, and are less directly concerned about the needs of the community. This could explain the reluctance of some, in the UK, less so in Wales, to make use of all the possibilities offered by the law in its current form. In stating this we have seen a majority of doctors in favour of the Bill and those against very much in the minority. It illustrates the difficulty of coping with a situation which is new in medical practice. In the UK the British Medical Association has adopted it as policy for a number of years despite repeated failed challenges by its membership. We hope the profession can adapt as a whole. Implemented properly, Wales will lead the way. We believe other parts of the UK, where increasingly the debate is being brought to the surface, will follow. We will then see the real change for patients, who sadly see themselves on a “death row” and “voiceless” as those, with authority provide and offer, in their eyes, despairing solutions of more education instead of real action and the hope of overcoming such a heavy burden of eventual death.

It is heartening to see the majority of politicians and opinion formers and media galvanised to see proper progressive debate and see the need to provide a better life in our society to those who need to be looked after psychologically as well as physically with their families and communities. We appreciate the role of many who have worked diligently in getting us to this Bill stage particularly Government Ministers, Civil Servants, Assembly Members, Assembly Officials and our Supporters.

Roy J Thomas

21 January 2013

Key Points in Summary for Discussion and in Support of the Bill

1. As demand increases year by year for organ transplants, there is a need for new thinking from all Governments and the Welsh Government and the proposed Bill provides a welcome fresh approach.
2. We believe it is important how the policy is worked up with the law and that care is taken in how the Government communicates the messages to the public; as this is where other countries implementing opt out have failed.
3. We support the “duty” placed on Welsh Ministers in Section 2 to promote transplantation. It is often the case that Westminster has not done so as well as Wales and Scotland which is borne out in the numbers of the population on the Organ Donation Register. In recent times First Ministers, Health Ministers and Cabinet Members together with leading politicians across Wales have taken this duty seriously. We pleased to see it enshrined in the law.
4. We support the definition “deemed consent”. It provides clarification and is preferable to presumed consent which can often be misinterpreted.
5. Communication is a complicated subject but the public have shown they are in favour of the proposals although when we polled the public there was over 70% support for an opt out law change some three years ago; and over 63% in a St David’s Day BBC Poll in 2012; but this slipped to 49% in a Poll by Beaufort for the Welsh Government recently.
6. Government needs to communicate the key issues clearly and it does not seem that due weight has been given to our partners such Diabetes UK; British Heart Foundation; British Lung Foundation and WKPA in the Donate Wales Campaign and Opt For Life Cymru -no mention is made in the Explanatory Memorandum of the efforts made by the third sector. This sector is critical to the success of the Bill. A further example is the one important omission from the Communications Strategy, although rightly included in the continuous communication strategy is the role of students in higher education, who contributed so much to the Donate Wales campaign following approaches from the third sector.
7. One of the lessons from the successful implementation of opt out legislation in Belgium in 1986 was the factual dissemination of the issues and the opposition to those we prayed on human fears of death and human organ retrieval. See Appendix A for a summary of the first ten years of the Belgium experience.
8. Lessons should be learnt from the Belgium experience and as an example instead of traditional “road shows” more creative forms of communication could be undertaken such as working with World re-known *Gunter Von Hagens’* plastination process “*Body Worlds*” which brings an element of educational as well as the dramatic and could tell the story of transplantation - see Appendix B setting out the medical success in these fields. The Exhibition is undertaking a World Tour, and is currently in Cape Town, but an approach to the organisers or similar Exhibition describing outcomes of successful transplantation is far more effective than the usual advertising and pamphlets. Personal stories and the effect of transplants on Welsh people could feature heavily. The experience of those

waiting and the trauma it causes amongst families is often swept under the carpet, as being too difficult to expose emotionally. The reality of the waiting needs exposure especially on those who have no experience of it and find organ donation or this Bill difficult to support for reasons which they sometimes cannot articulate.

9. A communications plan does not need to be totally led by Government. NHS Blood and Transplant in England have failed to increase the rate on the Organ Donation Register above 30% of the population. Not so in Wales where the BMA indicated in evidence, that the Tell a Loved One campaign led by charities “there has been a 49% increase in deceased organ donors in Welsh hospitals between 2007/08.” NHS BT failed to work with charity partners in England, Wales and N Ireland preferring to work only with Government or select charities it can control. Sadly, the usual communication was a photo shoot with a Patient and a Minister on Queen Street.

10. Accordingly, we believe the Welsh Government at a minimum should work on a new Organ Donation Transplant Strategy based on:

6.1 Implementing new legislation in Wales for “deemed consent” efficiently by working with partners to deliver a substantial increase in donors and not in isolation-it would be a big step for charities to lead such a campaign but governments are not always best placed to bring consensus due to political allegiances and perceived public opinion on trust in messages;

6.2 Delivering a new dedicated transplant infrastructure for Wales and promoting organ donation coordinators and their work;

6.3 Consulting persons of 16 and older in schools and colleges and working with students in Universities and Colleges;

6.4 Promoting the role of the family in discussing organ donation by communication and campaigns and real meaningful discussions with BME Groups and seeking case studies of donor and recipient families in all cases.

11. The existing Organ Donor Register should be improved and efficiencies eliminated and assurances given that NHS BT will accord with wishes of donors with a proper contact with Welsh Government for services otherwise procured properly. NHS BT have always been against this legislation see evidence to the Welsh Select Committee of the House of Commons in January 2012. We certainly hope NHS BT’s views have changed if they operate the new Register.

12. We support the principle of appointed representatives in Section 7 of the Bill but would like to see the promotion of adopted wording for guidance throughout Wales.

13. We support further organs being made available to the rest of the UK as organs have in the past from Europe especially Spain and the UK to Wales.

14. On equality; in our tradition of democracy all rights are balanced by obligations, those in favour of opt out support a framework of law for social obligation. There is a genuine concern about further rational discussion about principles and practicalities of implementation.

We have consulted various multi faith groups who are in favour of these proposals. For example, the Presbyterian Church of Wales has around 28,000 members in some 650 churches as well as strong links with churches abroad.

We have received support from across Wales and in particular Community Councils .We has consulted with all Town and Community Councils in Wales and do so every year.

The Bench of Bishops of the Church in Wales (not the membership) have been opposed to the Bill but their opposition is based on failure to see where the system works in other places and where the Welsh Government has attempted to perfect matters and listen. Time has stood still for the Bench of Bishops as Government consultation after consultation saw improvement and the wishes of individuals respected. Such opposition is unfortunate, as it is built of the sands that State control persists which is unhelpful at best and misrepresents the legislation at worst. It provides alarm where there should be clarity.

15. We believe NHS BT figures should be more transparent and the public need to be more fully aware of the Welsh figures. Since 1 April 2012 in the UK, 494 people have donated organs and 1,279 people have received transplants. 7,494 people are still waiting for transplants. It is apparent in Wales that the numbers are always around the same figure. It is clear that there are in reality more waiting than on the list. In the case of kidney transplants, it is clinically the case, that the future life of an organ transplant for the individual patient is far more successful if a transplant takes place prior to dialysis.
16. Organ Donation and Transplantation offers excellent results for patients. For those with kidney disease renal transplantation provides the most successful and cost effective treatment for established renal failure as supported by the figures and known for some years. However, in Wales a relatively low number of people have received transplants as a consequence of three inter-related factors:
 - Lack of availability of organs
 - Lack of capacity to undertake transplantation
 - Sub-optimal organisational arrangements.

Up to 10,000 people in Wales have renal disease and it affects all age groups. The incidence of renal disease is rising and seems likely to do so for the foreseeable future. The demand for renal transplantation in Wales is projected to continue rising. In terms of provision there is one transplant unit in Wales based at the University Hospital of Wales in Cardiff which serves South Wales. Patients in North Wales receive their transplants in England which is also where all paediatric transplantation takes place (in Bristol).

17. In the early years we pointed to the evidence of Abadie and Gay of Harvard and Chicago Universities (2005) who conducted a study to examine this across 22 countries who have introduced presumed consent systems over a 10 year period. The study found that presumed consent had a positive and sizeable effect on organ donation rates of some 25%-35% higher on average in presumed consent countries. A number of countries have dramatically increased their donation rates following the introduction of soft opt out systems of organ donation. Belgium, for example, which offers a model which can most easily be compared to Wales and the UK, went from 18.9 per million population to 41.3pmp three years after the introduction of opt out legislation. Countries which have introduced "hard" forms of presumed consent have also seen major changes. Austria went from 4.6 pmp to 27.2pmp after five years of presumed consent and Singapore from 4.7pmp to 31.3pmp three years after its introduction. We note further work has been undertaken to support this study and welcome this insight in the Explanatory Memorandum.
18. We have support these proposals as Kidney Wales proposed that the law on consent for organ donation be changed to allow better lives and a change in doing the same thing - that for purposes of disease treatment Welsh residents are deemed to be organ donors on death unless:

- They have opted out.
 - They cannot be identified.
 - The person's place of residence cannot be identified.
 - The wishes of the deceased can be proven to be contrary after relatives have been contacted.
 - Immediate relatives object.
19. The general organisation of transplantation services in Wales is sub optimal and needs to be improved. In the past NHS Wales has relied on NHS Blood & Transplant (NHSBT) to manage its donor campaigning. NHSBT is based in Bristol with a key role to ensure that donated organs are networked and allocated fairly. NHSBT also manages the National Transplant database and maintains and promotes the National Organ Register. Although the Welsh Government works with NHSBT to identify Welsh specific campaigns Kidney Wales believes that the Donate Wales Campaigns operated with charities were far more successful.
20. Kidney Wales supported the efforts of the Wales Organ Donation Implementation Group (WODIG) who has monitored the implementation in particular of the UK Taskforce recommendations. Following the Clinical Engagement Event in March 2011 Kidney Wales supported the obvious need that all LHBs were asked to revise their specific pledges in respect of donation and transplantation. We agreed that emphasis needed to be placed on the need for each organisation to have an identified Clinical Donation Champion and Donation Committee and to raise awareness, support and commitment to ensure that organ donation should not be an unusual event. However, much more resource is needed and better communication to make this more effective.
21. WODIG states that recruitment is on-going to establish the full team of 266 Donor Transplant Co-ordinations (DTCs) who are employed by NHSBT. We support the fact that 15 embedded specialist nurses for organ donation have been established in Wales and organ donation is included as a module in Year 5 of the medical school curriculum as of September 2011. However despite these developments and objectives, there is a recognition that there is much still to do to increase the number of transplants and further discussion is needed with the voluntary sector.
22. Kidney Wales believes the Welsh Government should consider infrastructure/systems across the world particularly in Europe. For example, Spain, who has the highest donation rates in Europe, has approximately three times as many intensive care beds per million populations as the UK. France who also demonstrates good donation rates of 25.3 pmp have 9.3 Intensive Care beds per 100,000 population (vs. 3.2 in Wales). Wales' donation rate (2009/10) of 13.7 per million population equated to 41 deceased donations.
23. The example of Spain is often discussed. One failure in comparing Spain is the difference in culture –where donation is expected of the deceased. Spain does not have an Opt Out Register. In 2010 Spain saw a decrease in its deceased donation rates and it part this has been attributed to a drop in road traffic deaths so again has developed a strategy to increase donation with actions including:
- Earlier referral of possible donors to the transplant co-ordination teams.
 - Benchmarking project to identify critical success factors in donation after brain death.
 - New family approach and care methods.
 - Development of additional training courses aimed at specific groups of professionals supported by their corresponding societies.
 - Consensus documents to improve knowledge about safety limits for organ donation to minimise inappropriate discarding of organs.

- Use of organs from expanded criteria donors under an 'old for old' allocation policy has resulted from adaptation to progressive decline of optimal organs.
- National strategic plans to deal better with organ shortage while respecting ethical standards.

In Spain, promotional campaigns and development of particular tools to facilitate discussion have not, as discussed above, been part of the system. Funding is more frontline. The system is based on two basic principles: organisation and continuous adaptation to change. The 'Spanish Model' was particularly adopted in Tuscany where the donor rate rose to 40pmp and Croatia and Portugal have also adopted some of the approach with national transplant agencies, network of procurement hospitals and in house figure of medical transplant co-ordinator and both increased the numbers of donors.

24. Implementation of the Organ Donation Taskforce's Recommendations seeks to improve the donation rates. In 2010/11 Wales saw an increase to 66 deceased donations which equates to 21.9 per million population. If this improvement is to continue, there will need to be adequate Critical Care capacity, (or a viable alternative) in order to continue to facilitate increased donation rates.
25. A limited Critical Care bed stock influences admission policies to intensive care units, and also end-of-life care policies, both of which can potentially influence organ donation rates. We understand from evidence given to WODIG that the ethical tenets of "autonomy, and justice" (fairness) are considerably harder to balance for admission, discharge, donation and withdrawal of care where bed capacity constraints exist. We agree with Critical Care Network in Wales that a successful increase in organ donation will be reliant on adequate resources and capacity to care for and manage potential donors. As highlighted by the Critical Care Network in Wales to WODIG, Wales is already under resourced with the lowest Critical Care bed stock when compared to the rest of the UK and Europe. Spain, the Netherlands, Sweden and France have 8-9 Critical Care beds per 100,000 population, mostly with higher donation rates than Wales. It is therefore recommended that there is an increase in provision of Critical Care beds across the country to bring Wales in line with European neighbours.
26. The Kidney Wales Foundation has for over 46 years, through a thriving fund raising base, supported many aspects of kidney patient care in Wales including transplantation. In addition Kidney Wales played a major role in getting an organ donor card attached to the new driving licence by lobbying 10 Downing Street through the then Welsh Office and was instrumental in setting up Lifeline Wales – a pioneering computer register of people willing to be organ donors in the event of their death. Our current "People Like Us Cymru" patients group aims to demonstrate the need for improved services for kidney patients in Wales and is championed by those patients themselves. The evidence we present is informed by the experiences and views of those in Wales who live with kidney disease and other organ failure every day and our campaigning, support and research.

Appendix A –the Belgian Experience

Source *JOURNAL OF THE ROYAL SOCIETY OF MEDICINE* Volume 89 December 1996
Presumed consent to organ donation: 10 years' experience in Belgium Paul Michielsen MD
J R Soc Med 1996; 89:663-666

1. After 2 years of passionate and sometimes emotional discussions, widely publicised, the presumed-consent transplantation law was voted through in the Senate and in the House of Representatives by a large majority from all political parties in Belgium in 1986.
2. The law is obviously accepted by most people and its application is no longer a matter of controversy. Less than 2% of the population have registered an objection to organ donation.
3. After the implementation of the transplant law in 1986, the kidney retrieval rate rose in 1987-1988 by 86% to 37.4 per million population per year. This increase in cadaveric donations was sustained.
4. Until 1986 work with teaching hospitals this had only limited results. After 1986 the number of collaborating hospitals with donor activities increased.
5. The Belgian law obviously provided a legal environment favourable to the collaboration of intensive care units in non-university hospitals. In the absence of a registered will of the deceased, the law leaves considerable freedom to the medical profession. As might be expected, the practical application was variable and the group in Antwerp continued to seek explicit permission of the relatives with the active involvement of a transplant coordinator in contact with the family. It is noteworthy that, after the introduction of the new law, the retrieval rate was unchanged in Antwerp—a strong argument against the hypothesis that the increase in the number of donors was due to the publicity.
6. Confronted with the persistent shortage, Antwerp decided to abandon the strict informed-consent practice. Unexpectedly, a group in Brussels that had until then supported and applied the presumed-consent principle changed to informed consent. Although the contrary is explicitly stated in the legislation, the group felt that the provision of the law granting the family the possibility to oppose donation implied the obligation to ask explicitly for permission. In this centre as in Antwerp, enactment of the law had no influence on the number of organs retrieved. There was no clear difference in attitude between the Flemish and French speaking parts of the country. The determinant factor was the stance of the head of the department. It would, however, be wrong to conclude that families are rushed from the death room without an explanation or that they are confronted with a scar they did not expect on the body of their loved one. As a rule when death is notified, the family is informed of the intention to proceed with organ removal, but explicit permission is seldom asked. This information is usually given by the doctor in charge and not by the transplant coordinator, whose role is often limited to technical and administrative support. No information is given when the family shows total lack of interest or when the relatives cannot be contacted in due time.
7. Since many donors come from non-teaching hospitals, there is a wide variation in attitudes and there are no reliable statistical data on the way in which the given to the family or on the number of cases in which the family made use of its right to oppose donation. The main factor in the positive attitude of the medical profession to the law is without doubt the legal security.
8. The doctors responsible for the donor can decide freely how much information is given, how it is given and to whom, without risk of being sued. In retrospect and in comparison with the earlier situation law has resulted in more openness. Being informed of the intention to proceed with organ removal has proved a less traumatic experience for the family than a request for permission to proceed. The absence of "horror stories" in the media indicates that the medical profession has applied the law in a sensible and humane way.

9. It is clear that, among the countries participating in Eurotransplant, the two with a presumed consent law, Austria and Belgium, outperform in number of donors Germany and the Netherlands, where formal permission of the family is required. One must, however, be cautious in drawing conclusions about cause and effect. The organ retrieval rate is the final result of different factors and events.
10. A transplant law provides only a legal environment which can influence the extent to which potential donors can be used. The number of possible donors is determined by, among other things, the density of the population and its age stratification, the number of traffic accidents, the number of intensive care units and the social security system. The law can obviously only modify the motivation of the medical profession and of the public. Although the differences in overall retrieval rate are impressive, the influence of the type of law on number of donors can still be questioned. More convincing is the fact that the proportion of multiorgan donors is also significantly higher in the setting of a presumed consent law. If we consider the mean values of the last five years within Eurotransplant, it can be calculated from the data in that the mean retrieval rate per million inhabitants in the countries with presumed consent legislation was 65% higher for kidneys, 71% for lungs, 100% for pancreases, 110% for livers and 145% for hearts.
11. Legislation apart, Belgium and the Netherlands have in common a high density of population, a well-developed social security system and a large number of hospitals with adequately functioning intensive care units. In both countries transplantation started early. Some have argued that differences in the number of road accidents explain the differences in organ retrieval. The importance of this factor is not as overwhelming as it seems at first sight, because traffic deaths include people who died "on the spot" and who are, as a rule, not available as organ donors. The potential donors are mortally injured, i.e. those who die within the first days after admission to an intensive care unit. From the 171 road deaths per million population in Belgium in 1992, less than 20 per million population were mortally injured. When the transplantation law was enacted in 1986 the number of mortally injured was 40 pmp; it decreased progressively to 20 pmp in 1992, while the number of organ donors doubled. According to the 1994 Eurotransplant annual report, the cause of donor death was an accident in only 43.7% of the Belgian donors, against 42% for Eurotransplant and 36.9% for the Netherlands. This marginally higher number of accidental deaths among the donors is insufficient to explain the difference in retrieval rate between the two countries.
12. Another interesting point in the comparison between the two countries is the finding that, until 1986, the retrieval rate was nearly identical although informed consent was the rule in the Netherlands and presumed consent was practised in Belgium but not law. This indicates that there is much more in the presumed-consent law than the possibility of retrieving organs without explicit permission from the relatives. Important is the absolute legal security and the official statement that donation is the rule, with some exceptions. The opportunity for the doctors in charge of the donor to decide if, how and to whom the information is given has also been a major factor in the development of decentralised organ retrieval. The importance of this factor is confirmed by experience in Austria; where in 1981 a presumed-consent law was passed, confirming the practice based on the stricter tradition of presumed consent.

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Appendix B – History of Transplantation of Human Organs and Tissue

Timeline of successful transplants

1905: First successful cornea transplant by Eduard Zirm [Czech Republic]
1954: First successful kidney transplant by J. Hartwell Harrison and Joseph Murray (Boston, U.S.A.)
1966: First successful pancreas transplant by Richard Lillehei and William Kelly (Minnesota, U.S.A.)
1967: First successful liver transplant by Thomas Starzl (Denver, U.S.A.)
1967: First successful heart transplant by Christian Barnard (Cape Town, South Africa)
1981: First successful heart/lung transplant by Bruce Reitz (Stanford, U.S.A.)
1983: First successful lung lobe transplant by Joel Cooper (Toronto, Canada)
1984: First successful double organ transplant by Thomas Starzl and Henry T. Bahnson (Pittsburgh, U.S.A.)
1986: First successful double-lung transplant (Ann Harrison) by Joel Cooper (Toronto, Canada)
1995: First successful laparoscopic live-donor nephrectomy by Lloyd Ratner and Louis Kavoussi (Baltimore, U.S.A.)
1997: First successful allogeneic vascularized transplantation of a fresh and perfused human knee joint by Gunther O. Hofmann
1998: First successful live-donor partial pancreas transplant by David Sutherland (Minnesota, U.S.A.)
1998: First successful hand transplant by Dr. Jean-Michel Dubernard (Lyon, France)
1999: First successful Tissue Engineered Bladder transplanted by Anthony Atala (Boston Children's Hospital, U.S.A.)
2005: First successful ovarian transplant by Dr P N Mhatre (wadia hospital Mumbai, India)
2005: First successful partial face transplant (France)
2006: First jaw transplant to combine donor jaw with bone marrow from the patient, by Eric M. Genden Mount Sinai Hospital, New York
2006: First successful human penis transplant [reversed after 15 days due to 44 year old recipient's wife's physiological rejection] (Guangzhou, China) [7] [8]
2008: First successful complete full double arm transplant by Edgar Biemer, Christoph Höhnke and Manfred Stangl (Technical University of Munich, Germany)
2008: First baby born from transplanted ovary by James Randerson
2008: First transplant of a Vertebrate trachea|human windpipe using a patient's own stem cells, by Paolo Macchiarini (Barcelona, Spain)
2008: First successful transplantation of near total area (80%) of face, (including palate, nose, cheeks, and eyelid) by Maria Siemionow (Cleveland, USA)
2010: First full facial transplant, by Dr Joan Pere Barret and team (Hospital Universitari Vall d'Hebron on July 26, 2010 in Barcelona, Spain.)
2011: First double leg transplant, by Dr Cavadas and team (Valencia's Hospital La Fe, Spain)

- The first human organ transplant occurred on June 17, 1950, at the Little Company of Mary Hospital in Evergreen Park, Illinois. The suburban Chicago hospital, better known as the "baby hospital" for the high number of births there each year, was an unlikely place for this landmark in medical history. And the doctors who took part in the transplant tried to keep the highly experimental procedure quiet. The subject was a 44-year-old woman who suffered from polycystic kidney disease. She received a donor organ, a kidney, from a cadaver, making the procedure even more controversial

for the Catholic hospital. (At the time, the church was opposed to the idea that tissue could be taken from a dead person and put into a living person, and that the tissue would then come to life again.) But the three doctors who performed the procedure had the confidence and trust of the sisters running the hospital. Doctors James W. West, Richard H. Lawler, and Raymond P. Murphy were surgeons on the faculty at Loyola's Stricht School of Medicine and the Cook County Hospital but also practiced at Little Company of Mary. The operation was the last resort for the patient, who had seen her mother, sister, and uncle die from the same disease. Word leaked about the operation, and several days after the procedure, when the patient was doing well, the hospital and doctors went public with their breakthrough, making headlines around the world. The transplanted kidney functioned in the patient for about six weeks-enough time for her other kidney to begin working again; she lived another five years before finally succumbing to the disease.

- On December 23, 1954, Harvard University physicians led by surgeon Joseph E. Murray (1919-) performed the world's first successful transplant from a living donor, the patient's identical twin brother. The operation took place at Peter Bent Brigham Hospital (now Brigham and Women's Hospital). Since the patient and the donor had the same genetic makeup, organ rejection was not an issue. The procedure saved the patient's life, and the well-publicized breakthrough immediately opened up the possibility for similar transplants (between identical twins) as well as for the transplantation of other organs. Dr. Murray and other Harvard researchers continued working on the problem of rejection, eventually developing new drugs that reduce the possibility that a recipient would reject an organ from a non-relative. In 1990 Murray was awarded the Nobel prize for his pioneering work. He shared the prize with his friend and colleague E. Donnall Thomas (1920-), an innovator in bone marrow transplant.

Eitem 9

NHS Blood and Transplant response to the consultation by the Health and Social Care Committee of the National assembly for Wales on the Human Transplantation (Wales) Bill

These comments should be read along side our response to the consultation on the draft bill submitted in September 2012.

NHSBT will respond to the specific points identified in the letter inviting responses to the consultation issued on 6th December 2012.

1. The individual provisions set out in the Bill—

Section 2, relating to the promotion of transplantation,

Section 2 of the Bill places Welsh Ministers not only under a general duty to promote transplantation in order to improve the health of the people of Wales, but also under a more specific duty to ensure people are aware of the arrangements for deemed consent.

Transplantation is a medical procedure and we do not believe it is the intention of the Bill to promote one treatment over another, we therefore believe both the Bill and the explanatory memorandum should be amended so that the duty is to promote “organ donation for the purposes of transplantation.”

Section 3, relating to lawful transplantation activities,

NHSBT has no comments on Section 3.

Sections 4-8, relating to consent,

Paragraph 30 of the Explanatory Memorandum states that if an appointed representative, appointed under section 7, is not contactable then no further attempt will be made to secure consent.

Under the Human Tissue Act 2004 if an appointed person is unable to give consent then the power to make that decision can devolve down the list of qualifying relationships. We would favour this situation being maintained.

Additionally it is not clear from the bill or the explanatory notes how the decision to appoint a representative would be recorded.

We would favour regulations made under section 8(2)(b) being published to coincide with the provisions of the bill coming in to force.

Sections 9-11, relating to offences,

NHSBT has no comments on Section 12.

Sections 12-20, which make general provision.

Inclusion of the word ‘deceased’ in 12(1) marks a significant change from the equivalent section of the Human Tissue Act 2004 (Section 43). It is possible that the addition of the word ‘deceased’ in that section would result in a reduction in donations as preservation activity could only be undertaken once a donor was deceased, this would hit numbers of DCD donors, and would likely prevent hospitals from engaging in pre-mortem optimisation. We believe that for the

avoidance of confusion the word 'deceased' should be removed from that section.

Section 17(6) states that references to transplantation shall include transfusion. While this is identical to Section 54(3) of the Human Tissues Act 2004 we believe that the reference to transfusion in the 2004 act was intended to ensure that blood products, transplantation and transfusion are included in the criminal offence of commercial dealings in Section 32 of the Act, as section 15(5) of the act specifically excludes blood and blood products from the regulatory remit of the Human Tissue Authority. As the Human Transplantation (Wales) Bill does not address the criminal offence of commercial dealings, we believe that for the sake of clarity it is important to add; blood, blood products, blood components and stem cells to the list of exceptions contained in Section 16(2) of the bill.

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

The new UK wide register which will be developed as a consequence of this bill needs to retain the confidence of the general public as well as the medical community. Care will have to be taken while developing the new register to ensure it retains its existing role as a register of people's wishes and at the same time develops a new legal role as a register of people who have opted-out.

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

While the primary focus of this bill is to introduce a system of deemed consent in Wales we are worried that including references to living donation could lead to misunderstanding. We would favour references to living donation being removed from the bill and the Human Tissue Act 2004 remain the legal basis of living donation in Wales.

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 welcome the verbal commitment from the Welsh Government regarding funding for the redevelopment of the register and the implementation of the system, we look forward to this being confirmed in writing.

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).

NHSBT has no comments on powers in the Bill for Welsh Ministers to make subordinate legislation.

Draft Human Transplantation (Wales) Bill and Explanatory Memorandum:

Consent to organ and tissue donation in Wales

Consultation response form

Name:	Sally Johnson
E-mail:	sally.johnson@nhsbt.nhs.uk
Telephone number:	07733111312
Address:	Oak House
	Reeds Crescent
Town:	Watford
Postcode:	WD24 4QN
Organisation (if applicable):	NHS Blood and Transplant

Are you responding as a (please tick one):

Health- related organisation	<input checked="" type="checkbox"/>
Individual with a health interest (e.g. working in the NHS)	<input type="checkbox"/>
Political Interest e.g. town council, MP	<input type="checkbox"/>
Religious, humanist or ethical organisation	<input type="checkbox"/>
Voluntary sector organisation	<input type="checkbox"/>
Academic bodies	<input type="checkbox"/>
Statutory Commissioner	<input type="checkbox"/>
Member of the public	<input type="checkbox"/>
Other	<input type="checkbox"/>

Returning this form

The closing date for replies is **10 SEPTEMBER 2012**

Please send this completed form to us by post to the Organ Donation Legislation Team, Medical Directorate, 4th Floor, Cathays Park Cardiff, CF10 3NQ or email to organdonation@wales.gsi.gov.uk

If you are sending your response by email, please mark the subject of your email:
Consultation on the Draft Human Transplantation (Wales) Bill

Alternatively, the consultation responses form is available for completion at www.wales.gov.uk/consultations/healthsocialcare/organbill/?lang=en

Consultation questions

Question 1

Have the concepts of deemed consent and express consent been explained clearly enough?

Yes No

With reference to paragraph 30 of the explanatory memorandum - Where a person who has been appointed to deal with the issue of consent to organ donation and is unable to give consent, paragraph 30 states that no further effort will be made to seek consent. Under the current law if an appointed person is unable to give consent then the power to make that decision can devolve down the list of qualifying relationships. We would favour this situation being maintained.

We believe the bill should set out clearly whether deemed consent will allow pre-mortem interventions to support organ donation which might otherwise be considered in the patient's best interest where there is express consent. This would enable more organs to be preserved for transplantation. . Section 13 of the draft bill 'Preservation for transplantation' is copied directly from the Human Tissue Act and makes it clear that the preservation of a body which may be of use for transplantation is allowable until it has been established that consent for organ donation has not been given or will not be given. It would be helpful if the draft bill could make it clear that deemed consent is sufficient to authorise pre mortem interventions that preserve the potential for donation, possibly by adding a line to section 17 of the bill saying ""consent" means deemed consent or express consent which has the same meaning as in Sections 4, 5, 6, 7 and 8 of this Act".

Question 2

Is the role of the family clear?

Yes No

With reference to paragraph 44 of the explanatory memorandum - we believe that Scenario A needs to set out more clearly how a reasonable person will determine whether the evidence presented is enough to convince them that organ donation should not proceed. This should include what would constitute evidence in law and if there is any time limit on how long ago that information can have been presented to the person making the objection, for example would a half remembered conversation 15years ago be sufficient evidence. The bill needs to minimise any room for doubt in order to support clinicians who will have to make such judgements about what a 'reasonable person' would think in the midst of what is usually a highly emotional situation. Clarity will also help avoid any unreasonable delay and unnecessary intervention to preserve organs until the situation can be established either for or against donation. We think it is unlikely that a family would have written evidence to hand at the time of the donation conversation.

We believe that Scenario B should be more explicit about the need to honour the legally expressed wish of the deceased to be a donor and state that families will be

asked to help make their relative's wish a reality by providing information about the donor's social and medical history to enable donation to go ahead safely. We support the suggestion that where, in an exceptional case the family refuses to honour their relatives wishes, they should be asked to sign a declaration indicating that they take responsibility for overruling their relative's will in this matter.

Question 3

Are the arrangements for the registration of wishes clear Yes No

Comments-

We support the view that one single register will minimise the risk of incorrect decisions being made.

There are risks with relying on an NHS number as a unique identifier. Ten per cent of the people on the ODR do not have an NHS number. There are cases of a single person having more than one NHS number, and NHS numbers have in the past been duplicated between the four UK health departments. This could lead to any records based on that number carrying conflicting information, being incomplete or out of date.

When a new registration to the organ donor register is received by NHSBT we currently cross reference each registration with the National Clinical Spine, a dataset maintained by NHS Connecting for Health (the same national system as GPs use to record new patients). That person can then be identified as an organ donor and any changes in their address or name recorded by their GP are fed back to the ODR so the record can be updated. This process will need to be carried out simultaneously to ensure that clinicians can be confident they are following the last known wishes of the deceased.

We are also concerned that, if an NHS number is necessary to join the new register then people will find it difficult to opt out or opt in as they struggle to remember or locate their NHS Number. Will it be possible to register if you do not know your NHS number?

Although the proposed approach is to have one register in Wales it will mean that there are two registers in the UK with specialist nurses in England, Northern Ireland and Scotland needing to check two registers to be sure a potential donor has not lived in Wales for six months or more when aged over 18. This may not present much of a problem shortly after the legislation is introduced but the risks will grow with each passing year. To illustrate the problem consider a woman who lives in Wales until her early 20s and opts out of organ donation. If she moves to another part of the UK, marries and changes her name then her opt out on the Welsh register is a valid decision about organ donation under the Human Tissue Act 2004 and the Human Tissue (Scotland) Act 2006, unless she later changes her mind and opts in to the NHS ODR. Specialist nurses will need to establish whether any potential donor throughout the UK might have lived in Wales and opted out in the past. This will be time consuming and could lead to unacceptable operational risks if there is any delay

Annexe

in updating either register. It also presents a risk of misidentification if the individual has used different names, addresses etc to register on each database.

The only way to ensure that someone's last recorded wish is captured and retrieved accurately and is available for SNODs is to have a single register across the UK capable of recording the wishes required by the relevant administration. We will assess the resource implications and discuss the options with the four health departments.

The list given under paragraph 59 of the explanatory memorandum should be amended to include 'accessible to appropriate authorised personnel'.

With reference to paragraph 65 - it needs to be clear whether the details identified as a 'minimum' will be a mandatory part of the new register.

A specification for a register needs to be developed which will cover the following points: how will the register be populated and by whom, implementation of safeguards to ensure only those people eligible to register are able to do so; defining the relationship with the existing NHS ODR (for example will it be a replacement with Welsh records migrating, on which organs and tissues will people be able to record a decision, will the two registers be linked and aligned or will they be totally separate); authorising access to the register; clarifying whether the register will be bilingual or available in other community languages. Agreement will also need to be reached on whether the register covers Wales only or whether it could be scaled up to include other nations if desired.

We also believe that the new register should capture information about tissue donation if deemed consent also applies to tissues. The Welsh Government will need to consider whether information should be general or specific. Currently the tissues which can be donated are:

Bone (normally long bones from the leg but also pelvis and humerus occasionally)

Skin

Tendons (Achilles, Semi-tendinosis, Patella, Tibialis Anterior (there is a small demand from surgeons for peroneous longus))

Meniscus

Heart Valves and vessels

Eyes

Infrequently - trachea

Under the new legislation, we think it should be made clear that deemed consent applies only to those organs and tissues listed on the register. Consideration should be given to whether/how the list should be amended when new forms of organ and tissue transplantation become routine. We think it would be helpful to clarify how novel forms of transplantation will be handled. For example people should know that novel forms of transplantation, e.g. face and limbs are excluded and their family will be asked to take this decision on their behalf.

The inclusion of tissues in the Bill may give rise to expectations about tissue donation that would not be fulfilled. NHSBT collects tissue only in North Wales and

currently has an adequate supply. Other organisations collect eyes and heart valves only in South Wales.

Question 4

Are the arrangements for establishing residency clear? Yes No

In determining whether a person has met the residency requirements NHSBT will rely on the family or next of kin to help establish the relevant information including whether the deceased is resident in Wales and for what period of time.

It is proposed that an address will be treated as being in Wales if it falls into the local 'gazetteer' of a local authority in Wales as postcodes are unreliable on the Welsh/English border. It would be helpful if the legislation could clarify whether the Gazetteer should be checked at the point of donation or will the clinicians talking to the family rely on them to establish Welsh residency.

While it will in most cases be simple for NHSBT staff to establish residency, deciding whether or not someone has had "an opportunity to opt-out if that is their wish" is far more subjective and not a judgement NHSBT staff will be able to make. It would be helpful if the legislation could establish clearly a time period after which everyone would be assumed to have had the opportunity to opt-out and deemed consent would apply. This will be particularly important as people approach their 18th birthday so they know whether they need to make their opt out decision before or after this date.

Paragraph 26 and paragraph 40 of the explanatory memorandum need to be consistent. Paragraph 26 says the arrangements will include people studying in Wales, where as Paragraph 40 says people who are working or studying in Wales during the week but returning to a permanent home at weekends will not be. Clarification is needed on this point.

Paragraph 25 states that if a person's address is in Wales, if they generally live at that address, and they have lived at that address or another address in Wales for more then six months they can be considered to live in Wales, however a person living in Wales during the week and returning to a permanent home in England at weekends could fulfil the three requirements yet paragraph 40 states they would not be covered.

Question 5

Does the Equality Impact Assessment properly set out how legislation will affect different sections of society, including children and people who lack capacity? Yes No

The Bill and the explanatory memorandum need to provide sufficient clarity on who will make a decision as regards to capacity and how that capacity will be assessed.

Although the issue of capacity may emerge during the donation conversation, it needs to be clear whether the Specialist Nurse should formally ask the family about their relative's mental capacity and whether it is legally acceptable to rely on their response.

Question 6

The outline for the communication plan is shown in the Explanatory Memorandum. Do you feel reassured that the Welsh Government is planning the public information campaign thoroughly?

Yes No

While we are confident that the extensive communications plan that the Welsh Government has put in place will be effective, it is still possible that there will be some people who are not aware of the new arrangements. We would appreciate guidance on what to do in a situation where a family claim ignorance of the new law even after the publicity and engagement campaign which the Welsh Government has planned.

Who will be responsible for writing to someone who is approaching their 18th birthday and what database will be used? Any data protection and medical confidentiality concerns regarding sharing of information between, for example, NHSBT and a local authority or two NHS bodies will need to be addressed

Paragraph 35 of the explanatory notes goes on to say that 18 year olds will be given 'enough time' to decide whether they will opt in or out. It needs to be clear what is meant by 'enough time'. Will it be the case that, in effect, no one under the age for 18 years and 6 months will be subject to deemed consent?

Question 7

We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Reference to Transfusion

Section 17(3) of the draft bill states "In this Act, references to transplantation are to transplantation to a human body and include transfusion.". For the sake of clarity we believe it is important to add: blood, blood products, blood components and stem cells to the list of exceptions contained in Section 16(2) of the draft bill.

Duty to Promote Transplantation

Section 2 of the Bill places Welsh Ministers not only under a general duty to promote transplantation in order to improve the health of the people of Wales, but also under a more specific duty to ensure people are aware of the arrangements for deemed consent.

Transplantation is a medical procedure and we do not believe it is the intention of the Bill to promote one treatment over another, we therefore believe both the Bill and the explanatory memorandum should be amended so that the duty is to promote "organ donation for the purposes of transplantation."

Living Donation

It is clear that the primary focus of the Bill is to change the system consent for deceased organ donation to an “opt-out” system. We believe reference to living donation could cause confusion.

Tissues

The inclusion of tissues in the Bill may give rise to expectations about tissue donation that would not be fulfilled. NHSBT collects tissue only in North Wales and currently has an adequate supply. Other organisations collect eyes and heart valves only in South Wales.

List of Organs and Tissues

Paragraph 20 of the explanatory notes provides a list of organs covered by the soft opt-out legislation. Tissues are not mentioned and the legislation should be clear about whether all or specific tissues are covered. It will also be important to clarify the position with regard to novel forms of organ and tissue transplantation e.g. face, limbs, uterus, and larynx.

Paragraph 54 of the Explanatory Memorandum

This should be amended to reflect the wording of Section 15(1)(b) of the draft Bill. We would propose changing the wording to “Section 15(1)(b) of the Bill allows for organs donated in Wales under deemed consent to be lawfully used for transplants undertaken outside Wales.”

Partnerships

NHSBT’s partnerships with Boots and the DVLA have proved very successful and result in a significant number of additions to the ODR. While the mechanism for registering through the DVLA is currently available in English and Welsh, this is the only partnership that provides a bilingual service.

Paragraph 66 of the explanatory notes states that ‘all registration mechanisms will be available bilingually and in a variety of other languages’. We are concerned that requiring our existing partners to provide services in a variety of languages could make them less inclined to work with us and result in a drop off in registrations from those sources.

Confidentiality

Responses to consultations may be made public – on the internet or in a report. Normally the name and address (or part of the address) of its author are published along with the response, as this helps to show the consultation exercise was carried out properly.

If you would prefer your name and address to be kept confidential, please tick here:

If you would prefer your response to be kept confidential, please tick here:



Mark Drakeford AC
Cadeirydd
Y Pwyllgor Iechyd a Gofal Cymdeithasol
Cynulliad Cenedlaethol Cymru
Bae Caerdydd
CF99 1NA

Annwyl Mr. Drakeford

Mae'r Gweinidog Iechyd a Gwasanaethau Cymdeithasol wedi cyfeirio'ch llythyr, dyddiedig 5 Rhagfyr 2012, ynghylch cynnwys ac amserlen ystadegau swyddogol iechyd ataf.

Rwyf yn croesawu sylwadau'r Pwyllgor Iechyd a Gofal Cymdeithasol ynghylch pa mor aml y mae'r ystadegau swyddogol ar gael, a pha mor hygyrch ydynt. Byddaf yn rhoi sylw i'r sylwadau hyn wrth i mi ystyried ymatebion yr ymgynghoriad yn gyfan gwbl.

Yn y ddogfen ymgynghori, fe welwch mai'r cynnig o dan sylw yw rhyddhau mwy o amser ystadegwyr Llywodraeth Cymru i sicrhau bod y gwaith o ddadansoddi ac adrodd ar ymchwil yn ôl pwnc yn cael sylw mwy ystyriol a holistig. Fodd bynnag, er na fydd y datganiadau ar ystadegau swyddogol yn cael eu cyhoeddi mor aml, rydym yn ceisio gwneud hyn mewn modd sy'n sicrhau bod yr wybodaeth reoli yn parhau i fod ar gael i'r cyhoedd o leiaf mor aml ag yn y gorffennol.

Mantais arall y cynnig hwn yw'r potensial i sicrhau bod gwybodaeth reoli yn cyrraedd y cyhoedd cyn gynted ag sy'n bosibl gan sicrhau bod y ddadl gyhoeddus yn defnyddio gwybodaeth o'r dystiolaeth fwyaf addas a chyfoes. O ganlyniad i hyn, yn achos gwybodaeth am adrannau Damweiniau ac Achosion Brys, bydd yr wybodaeth ar gael 10-15 diwrnod ynghynt ac er nad yw'r broses sicrhau ansawdd mor fanwl â'r un ar gyfer yr Ystadegau Gwladol credwn ei bod o ansawdd sy'n ddigon da i'w chyhoeddi.

Mae croeso ichi gyflwyno unrhyw sylwadau manwl pellach i'r ymgynghoriad - byddem yn ddiolchgar amdanynt. Hefyd, rydym yn croesawu sylwadau ac adborth gan bobl sy'n defnyddio ein hystadegau ar unrhyw adeg. Am hynny, ni ddylech ystyried mai yn ystod yr ymgynghoriad hwn yn unig y dylid eu hanfon.

Yn gywir

Glyn Jones

Prif Ystadegydd Dros Dro



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Eitem 10b

Lesley Griffiths AC / AM
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref SF/LG/3553/12

Dr Mark Drakeford AM
Chair, Health and Social Care Committee

Mark.Drakeford@wales.gov.uk

16 January 2013

Dear Mark,

At the Health and Social Care Committee on 5 December I agreed to provide Members with information on the following:

- capital project slippages,
- a breakdown by Health Board of how the additional £82m for the NHS will be allocated,
- how the Welsh Government will be feeding into the review of the balance of competences between the UK and the EU and;
- the provision of mental health services for staff working in the armed forces and emergency services

I have also received your letter of 7 January in which you request additional information on the provision of neuroscience services in Wales and the Welsh Government's review of capital expenditure and will respond in due course.

1. I agreed to share with the Committee a list of capital programmes where there has been project slippage. These projects are attached as an **annex** to this letter.

2. I have distributed the additional £82 million on a non-recurrent basis to Health Boards in line with the assessed level of risk as follows:

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1NA

Wedi'i argraffu ar bapur wedi'i ailgylchu (100%)

English Enquiry Line 0845 010 3300
Llinell Ymholiadau Cymraeg 0845 010 4400
Correspondence: lesley.Griffiths@wales.gsi.gov.uk
Printed on 100% recycled paper

	Proposed Allocation
	£m
Abertawe Bro Morgannwg	10
Aneurin Bevan	10
Betsi Cadwaladr	15
Cardiff and Vale	25
Cwm Taf	10
Hywel Dda	8
Powys	4
Public Health Wales NHS Trust	0
Velindre NHS Trust	0
Welsh Ambulance Service NHS Trust	0
Total	82

3. I also agreed to provide further information on the balance of competences between the UK and the EU. The Welsh Government is responding on the basis of the scope of different EU competences in Wales and so individual Ministers are, and will be, reviewing those policy areas. In my own case, we have initially offered to assist the UK Government in engaging with Welsh stakeholders in feeding in their own comments. I am currently looking across my portfolio to assess whether there are points I would wish to raise at this stage.

4. Serving armed forces personnel are the responsibility of the Ministry of Defence and only transfer to the NHS on discharge. As far as veterans are concerned, our All-Wales Health and Wellbeing Service grew out of a successful Ministry of Defence and Welsh Government funded pilot service which ran between 2008 and 2010 in Cardiff and Vale NHS Trust area. This was the subject of a full evaluation and its success has led us to fully fund the service to operate across Wales. Part of our agreement to fund the service, includes the need to provide regular progress reports and we are also considering what further evaluation is needed. Together for Mental Health contains a range of veteran specific commitments and our multiagency National Partnership Board, which oversees implementation of the strategy, will keep these under periodic review.

Regarding mental health services for emergency services staff, access to services is through mainstream mental health provision. I would expect all services provided to this group, as with other groups and individuals, to be based on clinical need. Employers need to recognise the impact of mental illness, not only on individuals, but also on the public services they provide and their responsibility as employers to ensure the emotional, as well as physical safety of their employees. For instance, fire-fighters are at increased risk of developing mental health problems due to the nature of their work. Arranging for access to mental health specialists can often take time to arrange, leading to the individual remaining disabled and off work. To address this, the NHS and South Wales Fire and Rescue Service have formed a partnership around the local NHS Traumatic Stress Service. This enables fire-fighters to receive early psychological assessment and treatment from a nurse therapist trained in cognitive behaviour therapy or referral to a consultant liaison psychiatrist.

The National Partnership Board will ensure services for all are prioritised according to clinical need and mental health services are in place to cater for the general populations' needs as and when they arise, irrespective of their employment status. This is something I expect the Board to emphasise as part of the implementation of the Mental Health Strategy.

Regards
Lesley

Lesley Griffiths AC/AM

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Annex 2

Name of LHB/Trust and scheme	Available for Transfer	Status and projected end date
	£m	
Aneurin Bevan Local Health Board		
Strategic Critical Care Centre (SCCC)	1.157	Revised Outline Business Case to be submitted in Dec-12. The projected completion date remains unchanged as mid-2017
Royal Gwent Hospital General Infrastructure	1.748	Business case currently under scrutiny. Projected completion date Jul-2013
Sub Total AB	2.905	
Abertawe Bro Morgannwg University Health Board		
HealthVison Swansea Phase 1b Reprovision of Stores	0.500	Business case currently under scrutiny. Projected completion by Mar-2014
Reshaping Mental Health Services in Swansea Phase 8 Low Secure	3.340	Business case currently under scrutiny. Projected completion date is mid-2014
Sub Total ABM	3.840	
Betsi Cadwaladr University Health Board		
Development of Bryn y Neuadd	0.235	Business case is expected to be submitted in Mar-2013
Ysbyty Gwynedd Accident & Emergency dept	1.250	Business case currently under scrutiny. Projected completion date is Nov-2014
Renal Alltwen	1.150	Business case is expected to be submitted in Jan/Feb-2013
Llandudno Minor Injuries Unit	0.740	Business case under scrutiny. Projected completion is Nov-2013
Llandudno Women's and Rheumatology	0.100	Business case not yet submitted.
Sub Total BCU	3.475	
Cardiff & Vale University Health Board		
Llandough Elderly Mentally Infirm	0.800	On site with estimated completion date of Oct-2015
Neurosciences	0.250	On site with estimated completion date of Mar-2013
University Hospital of Wales remodel Emergency Care	0.550	Estimated start date of Feb-2013
Sub Total C&V	1.600	
Cwm Taf Local Health Board		
Ysbyty Cwm Cynon, Prince Charles Hospital upgrades and Merthyr Health Park	1.271	Schemes completing and accounts finalising showing a net underspend
Prince Charles Hospital Renal Dialysis	1.707	Scheme now being taken forwarded via alternative funding route
Merthyr Health Park Medical Education	0.584	The Business Justification Case is under scrutiny. Projected completion of Sep-2013
Sub Total CT	3.562	

Name of LHB/Trust and scheme	Available for Transfer	Status and projected end date
Hywel Dda Local Health Board		
Prince Phillip Hospital Elective Short Stay	0.837	Business case not submitted due to awaiting outcome of consultation
Aberaeron Community Services	0.150	Business case not submitted due to awaiting outcome of consultation
Cardigan Community Services	1.684	Business case not submitted due to awaiting outcome of consultation
Angiography/ pacing	0.500	Business case not submitted due to awaiting outcome of consultation
Neonatal level 2 and complex obstetrics	1.500	Business case not submitted due to awaiting outcome of consultation
Information Management & Technology Infrastructure	1.000	Business case not submitted due to awaiting outcome of consultation
Bronglais Front of House	1.069	On site with estimated completion date of Dec-2015
Withybush Renal Dialysis Unit	2.769	On site with estimated completion date of 25 Oct 2013
Energy Project	6.922	Programme will be implemented over multiple phases. First business cases expected to be submitted in Feb-2013. Estimated completion of programme is Dec-2013
Sub Total HD	16.431	
Powys teaching Health Board		
Llandrindod Wells	0.270	Strategic Outline Case under scrutiny. Programme will be implemented over multiple phases. Programme expected to be completed by Mar-2015
Newtown & Welshpool Theatres	0.090	Business case not yet submitted. No estimated completion date at present.
Sub Total Powys	0.360	
NHS Wales Informatics Service		
Intelligent Integrated Audit Provision	0.750	Project not being taken forward.
Sub Total NWIS	0.750	
Velindre NHS Trust		
Velindre Redevelopment SOC	0.200	Business case not yet developed. No estimated completion date at present.
MRI Scanner Replacement	1.400	Business case not yet submitted. Projected completion is Sep-2013
Sub Total Velindre	1.600	
Welsh Ambulance Services Trust		
North East Wales Ambulance Resource Centre Works	0.350	Business case not approved but completion date is projected for Aug-2014
Sub Total WAST	0.350	
Sub Total	34.873	