

**Y Pwyllgor Iechyd a Gofal Cymdeithasol**

**Y Bil Trawsblannu Dynol (Cymru)**

**Ymatebion i'r Ymgynghoriad  
Ionawr 2013**

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**Health and Social Care Committee**

**Human Transplantation (Wales) Bill**

**Consultation Responses  
January 2013**

**Y Bil Trawsblannu Dynol  
(Cymru)**

**Human Transplantation (Wales)  
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**Consultation Responses**

\* Ar gael yn y Gymraeg/Available in Welsh

**Ymatebion gan sefydliadau/Responses from Organisations**

HT(Org)1	Mainc Esgobion yr Eglwys yng Nghymru	Bench of Bishops of the Church in Wales
HT(Org)2	Ffederasiwn Cenedlaethol yr Arennau	The National Kidney Federation
HT(Org)3	Esgobion Catholig yng Nghymru	Catholic Bishops in Wales
HT(Org)3a	Atodiad	Annexe
HT(Org)4	Comisiwn Moeseg Rhoddwyr Organau y DU	UK Donor Ethics Commission
HT(Org)5	Gwaed a Thrawsblaniadau'r GIG	NHS Blood and Transplant
HT(Org)6	Cymdeithas y Cleifion	Patient Concern
HT(Org)7	Cymdeithas Trawsblaniadau Prydain	British Transplantation Society
HT(Org)8	Cyngor Biofoeseg Nuffield	Nuffield Council on Bioethics
HT(Org)9	Cyngor Cynrychioli Iddewon De Cymru	South Wales Jewish Representative Council
HT(Org)10	Athro Ceri Phillips, Prifysgol Abertawe	Professor Ceri Phillips, Swansea University
HT(Org)11	Cymdeithas Cleifion Arennau Cymru	Welsh Kidney Patients Association
HT(Org)12	Pwyllgor Rhoi Organau Bwrdd Iechyd Prifysgol Caerdydd a'r Fro	Cardiff and Vale University Health Board Organ Donation Committee
HT(Org)13	Yr Ymddiriedolaeth Ffibrosis Systig	Cystic Fibrosis Trust

HT(Org)14	Arweinydd Clinigol Rhoi, Organnau Bwrdd Iechyd Cwm Taf	Clinical Lead Organ Donation, Cwm Taf Health Board
HT(Org)14a	Tystiolaeth atodol	Supplementary evidence
HT(Org)15	Coleg Brenhinol y Nyrsus	Royal College of Nursing
HT(Org)16	Sense a Deafblind Cymru	Sense and Deafblind Cymru
HT(Org)17	Cymdeithas Meddygaeth Liniarol Prydain Fawr ac Iwerddon	Association for Palliative Medicine of Great Britain and Ireland
HT(Org)18	Cymdeithas Feddygol Prydain	British Medical Association
HT(Org) 18a	Atodiad	Annexe
HT(Org) 19	Y Gymrodoriaeth Feddygol Gristnogol	Christian Medical Fellowship
HT(Org)19a	Atodiad	Annexe
HT(Org)20	Y Gymdeithas er Gwarchod Plant heb eu Geni	Society for the Protection of Unborn Children
HT(Org) 20a	Atodiad	Annexe
HT(Org)21	Sefydliad Prydeinig y Galon	British Heart Foundation
HT(Org)22	Coleg Brenhinol yr Ymarferwyr Cyffredinol	Royal College of General Practitioners
HT(Org)23	Christian Action Research and Education	Christian Action Research and Education
HT(Org)24	Y Gymdeithas Feddygol Gatholig	Catholic Medical Association
HT(Org)25	Sefydliad Aren Cymru	Kidney Wales Foundation
HT(Org)25a	Tystiolaeth atodol	Supplementary evidence
HT(Org)25b	Tystiolaeth atodol	Supplementary evidence
HT(Org)26	Bwrdd Iechyd Prifysgol, Abertawe Bro Morgannwg	Abertawe Bro Morgannwg, University Health Board
HT(Org)27	Yr Awdurdod Meinweoedd Dynol	Human Tissue Authority
HT(Org)28	Yr Athro Saunders	Professor Saunders
HT(Org)29	Cymdeithas Grefyddol y Cyfeillion Cyfarfod Crynwyr Aberystwyth	Aberystwyth Quaker Meeting Religious Society of Friends
HT(Org)30	Anscombe Bioethics Centre	Anscombe Bioethics Centre
HT(Org)30a	Atodiad	Annexe
HT(Org)31	Y Sefydliad Cyfreit heg Islamaidd	Institute of Islamic Jurisprudence
HT(Org)32	Y Gymdeithas Feddygol Islamaidd	Islamic Medical Association

### HUMAN TRANSPLANT (WALES) BILL

Like our Roman Catholic counterparts, we, as Bishops of the Church in Wales, would like to bring the following points to your attention regarding this Bill.

1. We strongly support organ transplantations. We see such gifts to others as the greatest gifts that can be given to other human beings. The Church in Wales was consulted and involved in producing the NHS Blood and Transplant leaflets encouraging organ donation from a Christian perspective. We therefore support the Heart to Heart campaign to encourage people to sign the donors' register.
2. However, a gift by definition is a voluntary donation by one person to another - and therein lies the difficulty we have with this Bill. Deemed or presumed consent is neither a gift nor a consensual act. It assumes that if you have not opted out of organ donation, your organs can be used after death. We cannot see how a failure to opt out can be interpreted to mean consent to the transplantation of organs. It turns the definition of donation on its head.
3. Such a Bill as this changes the relationship between individuals and the State, between doctors and their patients and raises a question about individual human rights.
4. The Welsh **Government believes that by allowing "someone in a qualifying relationship to the deceased immediately before death to provide information that would lead a reasonable person to conclude that the deceased would not have consented" is allowing** relatives a say and is a soft out option. That is at variance with its previous statements

regarding a soft out option where relatives could veto transplantation where someone had not opted out. This could potentially lead to very difficult encounters between relatives and medical staff.

5. During the consultation period, most of the reactions received were negative in character which the Government has decided to ignore, attributing it to an orchestrated campaign. In 2008, a UK Task Force as well as the **Assembly's Health Committee rejected such an approach.** Given the fact that Wales has seen a 49% increase in donation rates since 2008, encouraging people to donate would seem to be a better way forward.
6. It is arguable that countries which have such a scheme as is proposed (e.g. Spain) have seen an increase in donors only when transplantation services have been vastly improved.
7. We would be pleased to appear before the committee to present our views on this matter during the scrutiny stage of the legislation.

**The Most Rev'd Dr Barry Morgan**

Archbishop of Wales

On behalf of the Bench of Bishops of the Church in Wales

Dear sirs

Please find pasted below the NKF's Policy covering this matter :-

## **Passed by the NKF September 1999 (amended 2008)**

### **ORGAN DONOR SYSTEMS**

#### **The gift of life**

The National Kidney Federation supports the concept of altruism in organ donation whereby organs for transplantation are a gift by the deceased donor.

The system supported by the NKF (which currently does not operate in the UK) is known as 'opting-out', or presumed consent, whereby a person is assumed to consent to donation unless they register their choice not to donate. Such choice would be maintained on a Register. The Federation actively campaigns for this change to the "opt out" system.

Donation from someone who consented to donation whilst alive no longer requires the approval of the next of kin, although in practice this is sought.

In the meantime the Federation continues to encourage those who wish to donate organs after their death, to ensure that their name is on the NHS Organ Donor Register.

Organ Donation is overseen by the "Human Tissue Authority" and operated by UKTransplant.

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#### **Note(s)**

The system, which currently operates in the UK, is known as 'opting-in'; the making of a conscious choice by an individual to donate to save life or improve the quality of life of others, by taking steps individually to place their name on the central register of organ donors.

The alternative to the UK system and supported by the NKF is 'Opting out' and is the system described above. Many European countries operate such a system and whilst the evidence of its effectiveness is unclear, it should at least ensure that relatives know that their loved one had not specifically elected not to donate.

A survey of Federation members in November 1994 showed a majority in favour of an 'opting-in' system of organ donation; however, recognising that there was an increasing shortage of organs for transplantation in the UK, the National Kidney Federation carried out a further survey via its Kidney Life Magazine in summer 1999 which showed a significant majority favouring the opt out system. The Federation

then voted at its September 1999 Council meeting to support an 'Opting-out' system in the UK, providing that all necessary safeguards for the donor and donor relatives remained in place. The decision was made soon after the BMA announced that it had decided to support an 'opting-out' system.

The publication (and full acceptance by Government) of the 2008 Organ Donation Task Force report, promises important changes to the Transplantation infrastructure within the NHS so that Transplantation becomes the usual – not the unusual. It is thought that these changes when fully implemented will increase the number of transplantation operations by 50% over a five year period commencing in 2008. In the NKF's view the number of operations then being performed will rise to 75% of the known need.

The Federation will encourage members of the public who wish to donate organs after their death to join the NHS Organ Donor Register, whichever system is in place.

### About The NKF

The National Kidney Federation is unique because, although there are a large number of kidney charities, the NKF is the national kidney charity actually run by Kidney Patients for Kidney Patients – it covers the whole of the UK.

Most Renal units have a **Kidney patient Association (KPA)** specifically attached to that unit, however, in 1978 these independent charities realised that they needed a national organisation to fight their cause as renal provision was in dire difficulties, overstretched, and under resourced. If ever there was a case of post code provision, renal disease was it! Currently there are 69 KPAs and they come together as the controlling Council of the National Kidney Federation, the KPAs are both the ears and the eyes of the NKF and its controlling force. Patients are the Officers of the NKF, the Executive Committee of the NKF and the workforce of the NKF. Apart from six members of staff, all other personnel are either Kidney patients or carers of Kidney patients.

Unlike other kidney charities, the NKF has only two roles campaigning for improvements to renal provision and treatment, and national patient support services.

### **Campaigning**

The NKF lobbied for, and got, an **All Party Parliamentary Kidney Group** of 174 MPs and Lords established in Parliament and they feed that group on a day to day basis with the information needed to keep renal disease in front of the nose of Government.

They maintain a continuous dialogue with Ministers and the Department of Health. They attend all of the main Political Party Conferences, and they joined with others under the BMA umbrella to be founder members of the **Transplant Partnership**.

When the Government announced that 34,000 renal patients were too small a group to warrant a **National Service Framework** the NKF took action. They formed with others a new charity **The Kidney Alliance**, and then worked with other members of it to create a Dialysis version of a National Service Framework (NSF) of their own. Then, they launched this document within the House of Commons in front of the very Ministers who had rejected the idea of an NSF. The Government took only 4 weeks from that day, to reverse their decision and announce a Renal NSF of their own. Quite a victory for any group, let alone a group of very ill patients! Part 1 of the Renal NSF was published by the Department of Health on 14 January 2004 ([click here](#) for more information) with part 2 following in February 2005. The NKF provided considerable support and input to the Department of health during the preparation of these two vital documents.

## Patient Support Services

The National Kidney Federation provides and maintains a **website** which has rapidly become the hub of the renal community. This website [www.kidney.org.uk](http://www.kidney.org.uk) is vast, being larger than 5,000 pages and viewed by more than 200,000 patients, carers, renal professionals, doctors and nurses worldwide every year. The site is even more incredible when it is realised that like the NKF itself, the website was built by kidney patients. If the subject is renal, the answer is on this fantastic website. Above all the website has brought patients real information about their condition, and it has put patients in touch with each other. It has given kidney consultants, doctors and nurses a chance to talk with each other, and with patients, about issues and concerns that before the website they may have been completely unaware of.

For those that do not have access to computers, the NKF runs a low call cost **National Kidney Patients HELPLINE** (0845) 601 02 09 which takes about 200 calls a week from patients, carers and healthcare professionals, and the NKF distributes its own magazine *Kidney Life* completely free of charge four times a year to more than 19,000 renal patients.

Because the Medical Information on the NKF website is so comprehensive, the Federation decided that the website would become the basis of all future **Kidney Disease leaflets**. Within two years of that decision the NKF became the largest provider of renal leaflets in the UK. Whether you are an individual facing a Kidney Biopsy and just want one leaflet, or a Renal Unit requiring three thousand leaflets on Anaemia, the solution is simple. You ring the Helpline and say what you need, then the information is downloaded into a set format, printed out, and put in the post that very same day. Thousands of different leaflets are possible, from travel insurance and holidays, to dialysis, transplantation and living donors.

Sadly problems continue for many renal patients and frequently the Helpline finds it necessary to refer the matter to its own **Advocacy Officer team**, who then brings into play their experience of the issues, the problems and the frustrations of current provision. Many patients and carers have been helped by the National Advocacy Officer and many KPAs have taken up a local fight with his assistance. The Advocacy Officer also represents the NKF at many management and Commissioning meetings.



Once a year the NKF holds its own **National Conference** to which more than 400 renal patients attend over a three day period. This is a very special occasion and one that takes much organisation. However, it is very successful and it provides a platform for the NKF to listen to patients, and for patients to tell the NKF where the shortcomings are in renal provision. Frequently, Government ministers and healthcare professionals are on hand to hear for themselves the issues, but above all it is an opportunity for a thorough exchange of views.

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Health and Social Care Committee  
 Human Transplantation (Wales) Bill  
 HT(Org)3 - Catholic Bishops in Wales

December 2012

Dear Ms Butler

### Human Transplant (Wales) Bill

When the above Bill comes before the Welsh Assembly for debate, we, the Catholic Bishops in Wales, ask you to consider the following points:

We support the profound generosity which lies at the heart of human organ donation.

The positive ethos of organ donation as a free gift, however, will be endangered by an ill judged if well intentioned proposal to move from voluntary donation to presumed consent.

'Presumed consent' is not consent. If organs are taken without the prior, free and express consent of the deceased, or even against the express wishes of relatives, then it becomes organ transplantation but has ceased to be organ *donation*. The Bill stipulates that the law will "deem" that someone has consented, but if the only evidence of consent is an absence of objection, then this "deeming" is a legal fiction. It is not real consent.

Human rights such as personal autonomy and the relationship between the state and the citizen are compromised by this proposal.

Respect for the human body after death is also compromised.

The right to privacy and respect for personal beliefs and religion are disregarded.

The Bill gives no right for a next of kin to object. It would be inhumane to procure organs in cases where this is opposed or has given rise to strong aversion, or acute distress, or is done without prior knowledge of such removal, and particularly as there is no positive evidence that the person even wished to donate.

The Government seems to have ignored evidence and representation which disagrees with its proposal. The evidence does not show that this legislation is necessary and it carries with it a real danger to the trust between doctors, patients and relatives.

We thank you for considering these concerns and for further information we attach a copy of the Joint Response to the White Paper of the Roman Catholic Church in Wales, The Church in Wales and the Wales Orthodox Mission.

Yours sincerely,

*+George Stack*

The Most Revd George Stack  
 Archbishop of Cardiff

*+Peter M Brignall*

The Rt Revd Peter Brignall  
 Bishop of Wrexham

*+Tom M Burns*

The Rt Revd Tom Burns  
 Bishop of Menevia

**Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper**

**A joint response on behalf of The Roman Catholic Church in Wales, The Church in Wales, and the Wales Orthodox Mission**

**Summary**

1. *This response primarily addresses the proposals in the White Paper at the level of principle. It is based on the conviction that organ donation is a profoundly Christian positive act. Our main concern is that the positive ethos of donation as a free gift is being endangered by an ill-judged if well-intentioned proposal to move from voluntary donation to presumed consent. However, if organs may be taken without consent, this is no longer "donation". This is not just a health matter but concerns serious human rights issues such as personal autonomy, as well as questions about the relationship of the state and the citizen. At the same time the belief that presumed consent would itself increase the number of organs available for transplantation is not supported by the available evidence, as is shown below (paragraphs 16 – 25).*

*Organ transplantation enjoys a high level of public support but it also involves the sensitive issue of respect for the human body after death, people's human right to privacy and respect for personal beliefs and religion. These are areas that need to be negotiated with care and, as far as possible, by consensus legislation. We therefore urge the Welsh Government to revisit the process and establish a cross party committee that could consider all the evidence submitted to the previous enquiries of the last three years: the Organ Donation Task Force, the Welsh Assembly Committee, the U.K. Parliament's Welsh Affairs Committee and also the substantial research conducted by the Universities of Ulster and Johns Hopkins.*

**Response**

2. The Welsh Government has invited responses to the White Paper both "*on particular aspects of the policy proposals*" and "*on the proposals more generally*".<sup>1</sup> This response will primarily address the proposals at the more general level, for it is important to resolve questions of principle before considering how to implement proposals in practice.

**The value of organ donation**

3. The basis of this response is a shared conviction that organ donation is essentially a profoundly Christian act that is positive both in its consequences for the recipient and as an expression of human solidarity across society. Nothing in this submission should be interpreted as a rejection of the practice of donation of organs after death where this is done with due sensitivity to medical, cultural and ethical considerations. On the contrary, the concerns that are raised here are precisely that ill-judged proposals might endanger the ethos of donation.

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<sup>1</sup> Welsh Government Consultation Document *Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper* Number: WG13956, p. 18.

4. Taking their starting point from Christ who healed the sick and who gave Himself for the good of others, Christians have welcomed the benefits that have come through organ transplantation. From the very first there have been strong authoritative voices that would encourage donation.<sup>2</sup> There is, of course, diversity between and within Christian communities as there is diversity in wider society. There are differences of education, of personal and family experience, and different levels of trust in the establishment. There are also differences of view both about the practice of transplantation and about whether, and if so, how the law should change. This submission therefore cannot and does not presume to represent the views of every member of our respective communities. Nevertheless, precisely for this reason, the submission strongly urges that the law ***should not presume that individuals or their families would consent to donate their organs***. While there is some evidence of a greater level of donation among Christians,<sup>3</sup> and this is an activity that all Churches have encouraged,<sup>4</sup> it cannot be presumed that all Christians have decided to donate their organs, and still less can this be presumed for the population as a whole.
5. This joint submission also expresses the concern that any change in the law should protect marginalised communities and individuals, especially those who are socially excluded or who have difficulty in making their views heard. As Christians we are particularly aware of the way that minorities, including religious minorities, can be endangered by the majority, as for example when the majority does not adequately respect the need for consent from someone who is a member of a minority community.

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<sup>2</sup> For example, in 1956 when solid organ transplantation had yet to become common practice, Pope Pius XII argued that that would not be “a violation of the reverence due to the dead”. Rather, organ donation from the dead was justified because of “the merciful charity shown to some suffering brothers and sisters” (Allocution to Eye Specialists 14 May 1956).

<sup>3</sup> Researchers have shown a statistically significant correlation between Catholicism and rate of donation (Parliamentary Office of Science and Technology “Organ Transplants” *Postnote* October 2004 Number 231, page 2, quoting Gimbel et al. 2003. *Progress in Transplantation* 13:15-23). <http://www.parliament.uk/documents/post/postpn231.pdf>, To date researchers have not investigated the relation between rate of donation and Christianity for other Churches, but there is no reason to think it any less.

<sup>4</sup> Pope John Paul II said that, “We should rejoice that medicine, in its service of life, has found in organ transplantation a new way of serving humanity”. Hence the Catechism of the Catholic Church states that “Organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity.” For further references see UK Transplant leaflet of Christianity and organ donation [http://www.uktransplant.org.uk/ukt/how\\_to\\_become\\_a\\_donor/religious\\_perspectives/leaflets/christianity\\_and\\_organ\\_donation.jsp](http://www.uktransplant.org.uk/ukt/how_to_become_a_donor/religious_perspectives/leaflets/christianity_and_organ_donation.jsp)

## The necessity of consent

6. Pastors, theologians and Church leaders agree that offering organs for donation can be a significant act of charity, and a reflection of God's freely-given love and care for us, including the gift of life. A few examples should suffice:
7. "Above all, this form of treatment is inseparable from a *human act of donation*. In effect, transplantation presupposes a prior, explicit, free and conscious decision on the part of the donor or of someone who legitimately represents the donor, generally the closest relatives. It is a decision to offer, without reward, a part of one's own body for the health and well-being of another person. In this sense, the medical action of transplantation makes possible the donor's act of self-giving, that sincere gift of self which expresses our constitutive calling to love and communion."<sup>5</sup>
8. "Christian faith is a positive motivation for organ donation and a powerful incentive for many people to donate."<sup>6</sup> Organ donation is "an expression of the faith-based virtue of helping others; you might call it the 'generous gift' approach ... agreeing yourself to donating your own organs is easily understood as one person's generosity towards others."<sup>7</sup>
9. From the point of view of Orthodox Christian ethics, organ or tissue donation can be understood as a generous and virtuous act. Organ transplantation "makes it possible to give effective aid to many patients who were earlier doomed to death or severe disability... The transplantation of organs from a living donor can be based only on the voluntary self-sacrifice for the sake of another's life. In this case, the consent to explantation becomes a manifestation of love and compassion". The same principle applies to posthumous donation. "The posthumous giving of organs and tissues can be a manifestation of love spreading also to the other side of death."<sup>8</sup>

## What is wrong with "presuming consent"?

10. The fundamental Christian objection to presumed consent is that this contradicts the rationale and ethos of donation. "Presumed consent" is not consent. Silence is not consent. If organs are taken for transplantation without consent there is no giving, there is only taking.

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<sup>5</sup> John Paul II *Address to 18th International Congress of the Transplantation Society* (29 August 2000).

<sup>6</sup> Church of England Mission and Public Affairs Division: Response to the House of Lords EU Social Policy and Consumer Affairs sub-committee call for evidence (Inquiry into the EU Commission's Communication on organ donation and transplantation: policy actions at EU level), October 2007, paragraph 2.

<sup>7</sup> John Davies, Bishop of Swansea and Brecon

<sup>8</sup> Russian Orthodox Church's document *The Basis of the Social Concept*, XII.7 Problems of Bioethics.

11. It is sometimes said that Christianity has no official position on "opt-in" or "opt-out" systems of organ retrieval.<sup>9</sup> However it is difficult to reconcile "opt-out" systems with the clear Christian commitment to voluntary donation. If the organs are taken without the prior consent of the deceased, or permission of a relative or friend speaking on behalf of the deceased, then the deceased is no longer a *donor* and taking the organs is no longer an act of *donation*. It is taking without asking. From a Christian perspective this fails to respect the enduring human meaning of the body. Instead of transplantation being an act of donation, an expression of solidarity between people, it becomes merely the medical use of a body.
12. Pope John Paul II clearly stated that without consent "organ transplantation and the grafting of tissue would no longer correspond to an act of donation but would amount to the dispossession or plundering of a body."<sup>10</sup> This understanding is also expressed in the Catechism of the Catholic Church which lays down that organ donation "is not morally acceptable if the donor or his proxy has not given *explicit consent*."<sup>11</sup>
13. From an Orthodox perspective, "donation... cannot be considered a duty. Therefore, the voluntary consent of a donor in his lifetime is the condition on which explantation can be legitimate and ethically acceptable".<sup>12</sup> Hence "the so-called presumptive consent of a potential donor to the removal of his organs and tissues, sealed in the legislation of some countries, is considered by the Church to be an inadmissible violation of human freedom".<sup>13</sup>
14. Within the context of the present debate, the Archbishop of Wales has given voice to this same shared Christian understanding of organ donation. "There is another theological argument. Organ donation surely ought to be a matter of gift. If one takes organs without consent, on the assumption that by not opting out, a person is tacitly assenting, then that is no longer a free gift to others. An organ donation ought to be precisely that, a gift, an act of love and generosity. Giving organs is the most generous act of self-giving imaginable but it has to be a choice that is freely embraced, not something that the State assumes. Put more crudely, it turns volunteers into conscripts. Presumed consent is not really consent at all, merely the assumption that there are no objections."<sup>14</sup>
15. The Christian tradition supports the idea that the state may require us to do (or refrain from doing) certain things with regard to our bodies, for our own good or that of others (for example, safety legislation; the smoking ban, even potentially applied to private cars where

<sup>9</sup> Edwards, S. *Discussion document Introduction of an opt out (presumed consent) system in the context of Organ Transplantation* Welsh Assembly Government, 2008, Handout, <http://wales.gov.uk/topics/health/publications/health/guidance/discussion/?lang=en>

<sup>10</sup> John Paul II *Address to The Society for Organ Sharing* (20 June 1991).

<sup>11</sup> *Catechism of the Catholic Church*, 2296, emphasis added.

<sup>12</sup> Russian Orthodox Church's document *The Basis of the Social Concept*, XII.7.

<sup>13</sup> *Ibid.*

<sup>14</sup> <http://www.churchinwales.org.uk/structure/bishops/sermons/b43.php>

children are present; illegal drugs; in extreme cases, taking children into state care if parents are unable or unwilling to act in their best interests, or if they refuse essential medical treatment). Some Christians also argue that the state should be able to use organs from dead bodies without our explicit voluntary consent. However, those who argue in this way must acknowledge that taking organs without consent is not "donation". The call to use organs without consent is no more or less than a call to abandon donation as the basis for organ transplantation.

### Would presumed consent increase rates of transplantation?

16. It should not be taken for granted that changing the law to a system of opt-out / presumed consent would necessarily increase the availability of organs for transplantation. While some studies have shown a higher level of transplantation on average in countries with presumed consent laws,<sup>15</sup> it is very difficult to show that this is due to such laws or that a change in the law in itself would necessarily have a positive effect.
17. Changing to a system of presumed consent was rejected by the House of Commons in 2004. The Department of Health, having reviewed the evidence from different countries, stated that "it considers changing legislation to be a high-risk strategy. Without clear public support, presumed consent may be counterproductive, leading to reduced donation rates."<sup>16</sup>
18. In 2008 the Organ Donation Taskforce was asked to consider the case for a change in the law to presumed consent. They commissioned research from the University of York which concluded that "The evidence identified and appraised is not robust enough to provide clear guidance for policy".<sup>17</sup> After the comprehensive review (still perhaps the best to date) the Report concluded that it was "not confident that the introduction of opt-out legislation would increase organ donor numbers, and there is evidence that donor numbers may go down."<sup>18</sup>
19. The country with the highest rate of organ donation is Spain, which has a law which allows organs to be taken with presumed consent. However, when Dr Rafael Matesanz, President of the Spanish National Transplant Organisation, gave evidence to the Organ Donation Taskforce, he was explicit: presumed consent was not the reason for the success of the Spanish system. He reiterated this at a briefing on presumed consent reported in the *British*

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<sup>15</sup> E.g. A. Abadie and S. Gay, "The Impact of presumed consent legislation on cadaveric organ donation: a cross-country study," *J. Health Econ* 25 (2006): 599-620 who suggested that presumed consent countries have roughly 25-30% higher donation rates than informed consent countries.

<sup>16</sup> Parliamentary Office of Science and Technology, p. 3.

<sup>17</sup> Organ Donation Taskforce (2008) *The potential impact of an opt out system for organ donation in the UK: A report from the Organ Donation Taskforce*, Department of Health, London, paragraph 11.2, [http://www.ics.ac.uk/the\\_potential\\_impact\\_of\\_an\\_opt\\_out\\_system\\_to\\_organ\\_donation\\_in\\_the\\_uk](http://www.ics.ac.uk/the_potential_impact_of_an_opt_out_system_to_organ_donation_in_the_uk)

<sup>18</sup> Organ Donation Taskforce 11.5.

*Medical Journal*.<sup>19</sup> When asked if a presumed consent law was the reason for the success of the Spanish system, he said:

"Is it because of the law? Not likely. We have always had the same law. The families are always approached. They always have the last decision, and there are great variations from region to region."<sup>20</sup>

20. In the light of this evidence it should not be surprising that the cross party committee of the Welsh Assembly which considered presumed consent in 2008 came to a similar conclusion. The majority of the Health, Wellbeing and Local Government Committee judged that "organ donation rates can be improved significantly without introducing presumed consent. More than that, we feel there is a danger that moves to legislate in Wales ahead of the rest of the UK could be a distraction from more productive improvements and could alienate public support for organ donation if not handled properly."<sup>21</sup>
21. The two most recent studies to look at presumed consent are from the University of Ulster and the Johns Hopkins University School of Medicine. In October 2011, a team from the University of Ulster compared donation rates for England, Wales, Scotland and Northern Ireland over two decades and also compared these rates with those of other European countries. They concluded that "Further exploration of underlying regional differences and temporal variations in organ donation, as well as organisational issues, practices and attitudes that may affect organ donation, needs to be undertaken before considering legislation to admit presumed consent."<sup>22</sup>
22. The key paragraph from the Ulster study reviews the evidence from different countries. It is worth quoting in full:

"Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population (Scandiarttransplant personal communication, 2011), was comparable with that of Germany (14.5 deceased donor per million population) and Denmark (14.0 deceased donors per million population); both of which require informed consent. The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009. The nation with the highest donor rate (34.4 deceased donors per million population in 2009), is Spain, which operates a 'soft' form of presumed consent where next of kin can object to organ donation. Yet, the impact of the

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<sup>19</sup> *British Medical Journal* 2008; 337: a1614.

<sup>20</sup> Organ Donation Taskforce 11.3. The fact that in practice Spanish physicians do not take organs without permission has led some studies to characterise Spain as having "presumed consent" legislation with "informed consent" as actual practice, see Parliamentary Office of Science and Technology, p. 2 quoting Council of Europe; National Transplant Organisation.

<sup>21</sup> National Assembly for Wales, Health, Well-being and Local Government Committee, *Committee Inquiry into Presumed Consent for Organ Donation* (July 2008), p. 32, 10.3. <http://www.assemblywales.org/cr-ld7192-e.pdf>

<sup>22</sup> McGlade D, Rae G, McClenahan C, et al. "Regional and temporal variations in organ donation across the UK (secondary analyses of databases)" *BMJ Open* (2011). doi:10.1136/bmjopen-2011-000055, p. 6



legislation has been questioned and the high rate of donor activity attributed to the 'Spanish Model' that demands an integrated approach with dedicated transplant coordinators, mainly intensive care physicians, involved in procurement. This highly coordinated network and the respect for autonomy given to the individual and their relatives is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years."<sup>23</sup>

23. In November 2011 John Hopkin's University published the results of in-depth interviews with transplant experts in 13 European nations with presumed consent legislation. They found that, despite the laws, the process of organ donation in those countries did not differ dramatically from the process in countries, such as the United States, that require explicit consent. "Opt-out is not the magic bullet; it will not be the magic answer we have been looking for," said Dorry L. Segev, an associate professor of surgery at the Johns Hopkins University School of Medicine and leader of the study published online in the journal *Transplantation*. Implementing presumed consent legislation, Segev argued, would take a huge amount of time and energy with minimal payoff. Many countries with presumed consent have much lower rates of organ donation than the United States, he noted.

"With opt-out the perception becomes, We will take your organs unless you take the time to fill out a form. That's a dangerous perception to have. We only want to use donated organs from people who intended to donate."<sup>24</sup>

24. It is notable that the latest figures for 2010-2011 show that Wales has already achieved a significant increase in its rate of donation. At 27.7 deceased donors per million<sup>25</sup> this is now higher than the United States and is among the highest in Europe. There is every reason to think that further increases can be made through building on this success in public education, communication with relatives and more effective systems of transplant coordination. This real improvement has occurred without changing the law on consent. With high levels of public support, and recent initiatives giving significant improvements in rates of donation, this is no time to abandon the principle of voluntary donation.
25. Some people clearly believe that changing the law from opt-in to opt-out would itself improve the rate of transplantation, and this has been the basis of a very effective media campaign by some groups. However, this belief is simply not justified by the available evidence. It is a myth.

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<sup>23</sup> Ibid, p. 6.

<sup>24</sup> John Hopkins Medicine, News Release 11/29/2011  
[http://www.hopkinsmedicine.org/news/media/releases/presumed\\_consent\\_not\\_answer\\_to\\_solving\\_organ\\_s\\_hortage\\_in\\_us\\_researchers\\_say](http://www.hopkinsmedicine.org/news/media/releases/presumed_consent_not_answer_to_solving_organ_s_hortage_in_us_researchers_say) citing Brian J Boyarsky, Erin C Hall, Neha A Deshpande, R Lorie Ros, Robert A Montgomery, Donald M Steinwachs, Dorry L Segev "Potential Limitations of Presumed Consent Legislation" *Transplantation* 09/2011; DOI: 10.1097/TP.0b013e31823173e0.

<sup>25</sup> UK Transplant Organ Donation Activity 2011  
[http://www.uktransplant.org.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/organ\\_donation\\_activity.pdf](http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/organ_donation_activity.pdf)

## Can we reasonably presume that people have consented?

26. It is frequently stated that "90 per cent of people in the UK say they support organ donation, but to date only 30 per cent have joined the NHS Organ Donor Register",<sup>26</sup> in which case it might seem reasonable to presume that people would consent, if people are given ample opportunity to "opt out". However, this 90% figure is from a survey by UK Transplant in 2003 which asked if people were "in favour of organ donation in principle"<sup>27</sup>. It was not a survey of how many people themselves wished to donate their organs. A more recent survey for Yougov in 2007 found that 62% of people were willing to donate.<sup>28</sup> This is a more realistic figure. There is evidence that people in Wales are more willing to donate,<sup>29</sup> but research carried out by the University of Swansea in 2008<sup>30</sup> found that, if an opt out system were established in Wales only 60% would "definitely not opt out" with a further 16% saying they would be unlikely to opt out. This leaves 24% who would opt out, might opt out, or who did not know. Interestingly, in the same poll, 24% of people said they strongly disagreed with presumed consent and a further 15% said they tended to disagree with presumed consent.<sup>31</sup>
27. These figures show that a significant percentage of people in Wales (between 24% and 39%) disagree with presumed consent and would not be willing for their organs to be taken without their prior consent or permission from those closest to them. As not everyone will get around to making their wishes known, it cannot reasonably be "presumed" that people have not made their wishes clear would have wanted their organs to be used for transplantation. There is a fair chance (perhaps one in four) that they would not have wanted this.

### Improving refusal rates

28. In current practice (both in Wales and in most other countries), whether or not a person has signed the Organ Donation Register (or equivalent), specialist nurses and consultants also

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<sup>26</sup> For example, National Assembly for Wales Research Service *Organ and Tissue Donation* Paper number: 11/068, p. 3 <http://assemblywales.org/11-068.pdf> quoting NHS Blood and Transplant, Organ Donation online.

<sup>27</sup> UK Transplant Bulletin Issue 47 Summer 2003, p. 11  
[http://www.uktransplant.org.uk/ukt/newsroom/bulletin/archive\\_bulletins/bulletin47\\_summer2003/bulletin47.pdf](http://www.uktransplant.org.uk/ukt/newsroom/bulletin/archive_bulletins/bulletin47_summer2003/bulletin47.pdf)

<sup>28</sup> UK Transplant "Support grows for presumed consent" News release 19 October 2007 citing YouGov survey for BMA [http://www.uktransplant.org.uk/ukt/newsroom/news\\_releases/article.jsp?releaseId=190](http://www.uktransplant.org.uk/ukt/newsroom/news_releases/article.jsp?releaseId=190)

<sup>29</sup> McGlade et al. "Regional and temporal variations in organ donation", p. 1.

<sup>30</sup> Opinion Research Service, from Swansea University conducted a telephone survey using structured questions to a representative sample of the Welsh population between 14th November and 8th December 2008.

<sup>31</sup> Welsh Assembly Government *Consultation Paper on Options for Changes to the Organ Donation System in Wales* (May 2009), p. 27.  
<http://www.wales.nhs.uk/sites3/Documents/773/Organ%20Donation%20consultation%201doc%20-%20English.pdf>

ask the relatives whether they would permit organs to be taken. In the United Kingdom around 43% of families refuse permission. This is far higher than in other countries, such as Spain, where the refusal rate is around 9%.<sup>32</sup> How can this issue be addressed?

29. The Organ Donation Task Force found that, whereas the overall family refusal rate is around 40%, if the person is on the Organ Donation Register then the refusal rate drops to 10%.<sup>33</sup> This shows that families are generally supportive of the removal of the organs *when they know that this is what the person wanted*. The most effective way to increase rates of family permission for donation is therefore to encourage people to sign the Organ Donation Register and to encourage people to talk about the issue with relatives and those close to them. Any move that weakens the Organ Donation Register and leaves relatives unsure of what the deceased would have wanted is likely to increase refusal rates among relatives.
30. It should also be noticed that refusal rates in the United Kingdom are significantly higher now than they were in the 1990s. It is likely that there are many causes for this increase, including the Alder Hey scandal in 1999 where organs were kept without consent.<sup>34</sup> A number of reports have emphasised the importance of maintaining public trust in the system and the importance of the principle of consent in maintaining this trust.<sup>35</sup>

#### Consultation with relatives

31. The proposals in the White Paper call for a "soft opt-out" system in which the relatives will always be consulted. It is clearly important for the relatives and those close to the deceased to be consulted. However, the idea of "consultation" or of being "involved in the process" is ambiguous. The law needs to state unambiguously whether, in the absence of an explicit statement of the wishes of the deceased, the relatives will be able to refuse permission for the removal of organs.
32. A duty to consult, as currently proposed in the White Paper, is much weaker than a right to refuse permission. However, if relatives have no right to refuse permission in law, this represents a move of power away from the relatives of the deceased and towards the state.

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<sup>32</sup> Organ Donation Taskforce, 11.3.

<sup>33</sup> Organ Donation Taskforce, 1.15.

<sup>34</sup> According to the Parliamentary Office of Science and Technology (p. 3), in the 1990s the family refusal rate was 30% whereas by 2004 it had reached 42%.

<sup>35</sup> "Trust, however, is key to the success of the organ donation system in the UK. If public trust is shaken, organ donor numbers are likely to fall rapidly and could take many years to recover", Organ Donation Task Force 4.6; "Comments provided highlighted concern that an opt-out system had the potential to damage the relationship of trust between clinicians caring for people at the end of their life." Welsh Assembly Government Consultation Paper, p. 10; "...and others believe due to the general public's mistrust for the Government they will resist this type of system being imposed on them." National Assembly for Wales Research Service, 4.1; "Without clear public support, presumed consent may be counterproductive, leading to reduced donation rates." Parliamentary Office of Science and Technology, p. 3 emphasis added.

This is not just a matter of health but is about the right of the state to dispose of a body in a certain way even in the face of objections from closest relatives.

33. In practice it seems doubtful that specialist nurses in organ donation in Wales would want the power to overrule relatives so that organs were taken from those who had not given consent in the face of opposition from those who were closest to them. However, if this would not happen in practice, why does the Welsh Government need to create a power that would not be used? *This power seems unnecessary while at the same time it threatens to undermine the very concept of free donation on which organ transplantation has hitherto relied.*

#### The process of public consultation

34. In addition to grave concerns about the central proposal in the White Paper, there are also problems with the way in which this proposal has been brought forward.
35. Organ transplantation enjoys a high level of public support but it also involves the sensitive issue of respect for the human body after death. It involves people's human right to privacy and respect for personal beliefs and religion.<sup>36</sup> This is an area that needs to be pursued with care and, as far as possible, by consensus legislation.
36. It is of extreme concern that while responses are being invited on the proposals in the White Paper, the central proposal, which is the shift from donation to presumed consent, is presented as a *fait accompli*. This approach threatens to polarise debate and to alienate those who have reasonable concerns about this proposal. Whatever the exact shape and scope of the eventual law, this is not the way to secure a broad consensus.
37. We therefore urge the Welsh Government to revisit not only the proposals but also the process. This issue is one that should be resolved as far as possible through open dialogue and consensus building and by a process that can secure the widest possible support. It should not be a party political issue. What is needed to rescue this process is for some independent, academic, or cross-party body to conduct a genuinely open consultation which would consider a range of possibilities without prior commitments to a particular legislative proposal. They might reasonably look at systems that include aspects of opt-in, opt-out and mandated choice. It would also helpfully consider the evidence submitted to the previous enquiries of the last three years: to the Organ Donation Task Force,<sup>37</sup> to the Welsh Assembly Committee<sup>38</sup> and to the U.K. Parliament's Welsh Affairs Committee<sup>39</sup> and to consider the

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<sup>36</sup> Some of these issues were raised in evidence submitted to the Welsh Affairs Committee when it considered Legislative Competence Consent for Organ Transplantation from a deceased adult. However, as the LCO was withdrawn, that Committee was not able to weigh this evidence or explore these human rights issues.

<sup>37</sup> Organ Donation TaskForce.

<sup>38</sup> National Assembly for Wales (July 2008).

<sup>39</sup> Welsh Affairs Committee Sixth Special Report into Proposed Legislative Competence Orders relating to Organ Donation and Cycle Paths (HC 896) <http://www.parliament.uk/business/committees/committees-a-z/commons-select/welsh-affairs-committee/inquiries/parliament-2010/organ-donation-lco/>, see in particular

research conducted by the Universities of Ulster<sup>40</sup> and John Hopkins<sup>41</sup>. For it is not at all clear that the present proposals have benefitted as much as they might from the evidence available.

38. If the proposals in the White Paper are not subject to independent scrutiny then there is a real danger that a change in the law would alienate a significant proportion of the public and undermine the positive image of organ donation and the reputation of Wales. For while a high rate of voluntary donation speaks of a culture of generosity, a system of presumed consent would "turn donation into action by default".<sup>42</sup>

The Most Rev George Stack, Archbishop of Cardiff (Roman Catholic)

The Most Revd Dr Barry Morgan, Bishop of Llandaff, Archbishop of Wales (Church in Wales)

The Very Revd Archimandrite Father Deiniol, Administrator, Wales Orthodox Mission (Eastern Orthodox)

The Rt Rev Thomas Burns, Bishop of Menevia (Roman Catholic)

The Rt Revd Gregory Cameron, Bishop of St Asaph (Church in Wales)

The Rt Revd John Davies, Bishop of Swansea and Brecon (Church in Wales)

The Rt Revd Wyn Evans, Bishop of St David's (Church in Wales)

The Rt Revd Andrew John, Bishop of Bangor (Church in Wales)

The Rt Rev Edwin Regan, Bishop of Wrexham (Roman Catholic)

The Rt Revd Dominic Walker, Bishop of Monmouth (Church in Wales)

The Rt Revd David Wilbourne, Assistant Bishop of Llandaff (Church in Wales)

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Written evidence submitted by the Anscombe Bioethics Centre (which presents a Roman Catholic view) and written evidence submitted by The Wales Orthodox Mission.

<sup>40</sup> McGlade et al. "Regional and temporal variations in organ donation"

<sup>41</sup> Boyarsky et al. "Potential Limitations of Presumed Consent Legislation"

<sup>42</sup> As argued by UK Transplant: National Assembly for Wales, Health, Well-being and Local Government Committee, Committee Inquiry into Presumed Consent for Organ Donation - Evidence from UK Transplant.

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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](http://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.

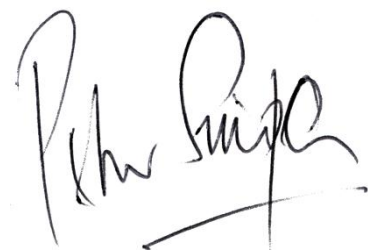
As I mentioned earlier, decisions about DCD donations need to be made whilst the potential donor is still alive. These decisions can be ethically challenging, since there are a range of interventions that might be carried out on a dying patient that will optimise the condition of organs, but have no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

## **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 6<sup>th</sup> 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 ‘decease’ 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
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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"/>

Annexe

## 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, 4<sup>th</sup> Floor, Cathays Park Cardiff, CF10 3NQ or email to [organdonation@wales.gsi.gov.uk](mailto: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](http://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

## Annexe

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

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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.

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**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 18<sup>th</sup> 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.

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**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.

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### 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 18<sup>th</sup> 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?

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### 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.

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## **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:

## **HUMAN TRANSPLANTATION (WALES) BILL**

**From Joyce Robins, Co-director Patient Concern**

### **Introduction**

Patient Concern is an independent voluntary organisation set up 13 years ago with the aim of promoting choice and empowering patients. Our core principle has always been active informed consent applicable in any medical context. Joyce Robins was one of the founders and has been Co-Director from the beginning.

### **Consultation Response**

The main change to be brought about by the planned Bill is the concept of ‘deemed’ consent. Deemed is a somewhat archaic word normally meaning ‘consider’ or ‘regard as’ and is absent from common vocabulary. It has presumably been chosen to avoid the term ‘presumed’, which has attracted much criticism. However it still means ‘pretend’ consent i.e. it is pretending that a patient has agreed to donation when they have done no such thing. In no other walk of life is the absence of refusal regarded as consent.

We consider the principles underlying this Bill to be unethical and unacceptable.

All the major studies of the organ donation system, including the Welsh Assembly’s own health committee (at which Patient Concern gave oral evidence), once they had considered all the evidence in depth concluded that the opt out system was the wrong way to go. They found no causal link between a change in the law and rising donation rates and decided that there were far more effective ways of increasing the donation rate. In fact, they considered that changing the law would only distract from the measures that need to be taken to improve the infrastructure so that real change is possible. The measures suggested by the ODTF are now on line to deliver a 50% increase by early this year, increasing to 60% by 1216-17, without spending millions on changing the law.

Opting out is a fundamental departure from the UK norm and our work with patients shows that, as a concept, it is poorly understood. The idea that any amount of publicity will ensure that everyone fully understands their options and the need to exercise them is fanciful. The experience of uploading summary care records under an opt-out system illustrates this point. When Patient Concern opposed this system we were assured that the blitz of information would be such that everyone would know and understand the changes. Later reports showed that in spite of all the publicity (including a letter to every household) most people had no idea that it had happened. The result is that millions of records have been uploaded without patients’ knowledge or consent.

This belief in a ‘silver bullet’ approach to solving the organ donor shortage has the potential for a number of unintended and unwelcome results. It is no longer honest to

talk about 'donation' in the context of this Bill. A donation is a gift, willingly given, and that cannot be assumed under these proposals. If families feel that they have no real say in what is happening to the body of a loved one, even though that person has not made a conscious choice, lasting damage could be done to the whole aura of the transplant programme.

It is important to remember UK history, which has involved major scandals involving organ removal without permission. This brought into being the Human Tissue Act 2004; its whole purpose being to ensure that consent is a positive action. Its Code of Practice spells this out. Presumably the Code will now be rewritten to take this right away from Welsh people. We consider this a backward step.

Memories may have dimmed but it would only take a couple of errors, where it could be shown that organs had been taken against the wishes of the deceased, to reawaken them and cause a media firestorm which could damage the whole transplantation process. Alder Hey set back organ donation in the UK by ten years and is one of the reasons that our transplant rate is so poor. We should remember that 2010 mistakes on the organ donor register, ignoring exclusions made by some donors, achieved global publicity. More publicity of this type could cause a serious backlash.

One of the fundamental beliefs behind the legislation is that this step will ensure that people talk more about the subject within their families and make their wishes known. We would suggest that this is a pious hope, unlikely to be realised. The death taboo is still strong – it is a subject that many people cannot and will not consider. Almost everyone cares what happens to their property in the future, yet only 30% of us make a will. This is a parallel with the proportion of apparently willing people who sign the donor register.

There can be no 'full involvement' of families once the right of refusal is taken from them. Refusal at the bedside among ethnic minorities is currently 75%. There is a real danger that an element of coercion is being introduced if they are then forced to justify their belief that this is not what their loved one wanted while someone – there is no explanation of who is to judge – 'assesses' the evidence. The system where a trained counsellor can take time to help the family reach the decision that is right for them is a distinctly preferable scenario to introducing legal obligation.

There may be many reasons for the disparity between the numbers of those who profess willingness to donate in a poll and those who sign the register – one being whether a 'yes' vote in the street reflects reasoned judgment taken after consideration. We note that mandated choice (far more likely to be informed choice) was the favoured route chosen by Welsh people in the early consultation but this was hastily abandoned as being too difficult. The simple solution of giving every patient an opportunity of opting in or out any time they access any form of health care – just as routinely as we record our next of kin seems a simple and obvious solution.

The implication that only a change in the law would suffice is simply spurious and smacks of political opportunism.

14 January 2013

**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.



## Nuffield Council on Bioethics

16 January 2013

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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](http://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](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-](http://www.nuffieldbioethics.org/sites/default/files/files/Welsh_opt-out_consultation_Jan_2012.pdf)

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Katharine Wright

[out\\_consultation\\_Sept\\_2012%281%29.pdf](#)

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 underline.

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*<sup>1</sup>, 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.<sup>2</sup> More information about the inquiry, method of working and resulting report can be found at: [www.nuffieldbioethics.org/donation](http://www.nuffieldbioethics.org/donation)

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

<sup>2</sup> 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/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).<sup>3</sup>

- 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.<sup>4</sup> 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.<sup>5</sup> 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

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<sup>3</sup> 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.

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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.

## Nuffield Council on Bioethics

16 January 2013

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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](http://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](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-out\\_consultation\\_Jan\\_2012.pdf](http://www.nuffieldbioethics.org/sites/default/files/files/Welsh_opt-out_consultation_Jan_2012.pdf)

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**Director**  
Hugh Whittall

**Assistant Directors**  
Dr Peter Mills  
Katharine Wright

[out\\_consultation\\_Sept\\_2012%281%29.pdf](#)

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*<sup>1</sup>, 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.<sup>2</sup> More information about the inquiry, method of working and resulting report can be found at: [www.nuffieldbioethics.org/donation](http://www.nuffieldbioethics.org/donation)

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

<sup>2</sup> 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/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).<sup>3</sup>

- 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.<sup>4</sup> 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.<sup>5</sup> 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

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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.
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### **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.

My name is Stanley Soffa. I am chairman of the South Wales Jewish Representative Council and in submitting this document I am not expressly putting forward the opinion of the Jewish Community in South Wales because organs are donated by individuals and not by organisations, whether or not they are Jewish, but I hope that my comments will be of assistance.

Since the summer of 2012 I have been involved in making submissions on behalf of the Jewish Communities of South Wales and with Rabbi Rose of Cardiff United Synagogue attended a consultation event on the 6<sup>th</sup> August following which we were invited to a meeting with members of the Medical Directorate in October 2012. Later that month Lisa Gerson of Cardiff United Synagogue and I attended a meeting of the Welsh Assembly's Faith Communities Forum chaired by the First Minister where I put forward the Jewish perspective and in November we, together with Rabbi Rose, had a meeting with Cognition.

I do not intend repeating what was said on these occasions but lest it be thought that there has been a change in our approach I would specifically refer to two documents provided to the Medical Directorate, one from the Chief Rabbi and the other from the Board of Deputies. Both pre-date the publication of the Bill but the former shows the approach of those members of the Orthodox community for whom Lord Sacks is currently the Chief Rabbi whilst the latter tries to represent all strands of Judaism in the United Kingdom.

Judaism has always accepted and put great emphasis on our duty to save the life of another and this was reiterated in a statement issued by the current Chief Rabbi in January 2011 when he said

*“A living person may donate an organ to save someone else’s life. This is not only permitted but also actively encouraged, provided that in doing so the donor is not putting his own life at significant risk.*

*With regard to donation after death, in principle Halacha (Jewish Law) permits such donation provided that the organ is required for an immediate transplant and not for research”.*

We are therefore encouraging members of the Jewish community to discuss their wishes regarding organ donation and endorse paragraph 43 of the Explanatory Memorandum of 3 December 2012 when it states that “telling close family about wishes relating to organ donation will be one of the key messages of the education campaign which will accompany the new legislation, since uncertainty about what their relative would have wanted is what prevents many families engaging with the organ donation process. This then results in healthy organs being lost to a potential recipient”.

However, where organ donation after death is made in conformity with Jewish practice, the obligation (“*mitzvah*”) to perform an act of “*pikuach nefesh*” (saving a life) rests with the family of the dead person and so a Jewish perspective is that presumed consent diminishes the altruistic gift essence of organ donation and is

perceived to diminish the status and respect with which the body / body parts are held after death.

The definition of “death” has been raised in each of the meetings I have attended and is of importance to many members of the Jewish faith for in the Chief Rabbi’s statement is the following

*“In our discussion with medical professionals involved in the field it has become clear that organs are taken from people after death in two different scenarios. Either they are taken after irreversible damage to the brain stem, or after failure of the circulatory system (in common parlance described as “when the heart beat has stopped”). Both of these scenarios lead to respiratory failure (“when breathing has stopped”), and respiratory failure is an important factor in the definition of death in Halacha. There is a view that brain stem death is an acceptable Halachic criterion in the determination of death. This is the view of some Poskim (Halachicdecisors). However it is the considered opinion of the London Beth Din in line with most Poskim worldwide, that in Halacha cardio respiratory death is definitive.*

*Hence, in view of this, and of the significant Halachic issues relating to the procedure of the donation process itself, we believe that it is imperative that a competent Halachic authority should be consulted by families who find themselves involved in such discussions”.*

Consequently, the preferred organ donation system is that families, including Jewish ones, should be able to consider and reflect, consult religious authorities if they so wish, and if they feel appropriate, give consent.

There is no definition of “death” in either the Bill or the Explanatory Memorandum of 3 December 2012 and this raises concerns. There is assistance regarding the role of the next of kin and careful consideration has been given to the wording of both documents to try and ascertain whether the concerns expressed in the meetings have been resolved.

Two paragraphs appear relevant. At paragraph 42 of the Memorandum it is stated that “under the new arrangements, very little will change in practice because the next of kin will still be asked to confirm details about the deceased’s health and lifestyle which might not be contained in their medical records and which could affect their suitability as a donor.” This clearly relates to suitability. It then refers to the separate issue of “consent” by confirming that “it is for the deceased to decide whether to opt in, opt out or have their consent deemed. The wishes of the deceased, whether it be through deemed or express consent should be made known to the family by NHS staff as part of the discussions. The legislation provides families with the right to provide information about whether the deceased would not have consented to their consent being deemed. Families will also continue to have an involvement in the process at a practical level”.

Paragraph 42 has to be read in conjunction with paragraph 44. This is intended to assist in understanding the role of the next of kin. Various scenarios are set out, the first of which relates to deemed or presumed consent and again confirms

that “the deceased’s consent to donation will be deemed because they had the opportunity to express a wish not to be a donor (opt out) but did not do” and continues “However, the next of kin will be able to say whether they have any information that would lead a reasonable person to conclude that the deceased person would not have consented. This could include, for example, where the deceased had ever discussed the matter with them and expressed a view to the effect that they did not want to be an organ donor. Section 4(4) of the Bill provides that any person in a qualifying relationship, as set out at section 17(2) will be able to provide this information. It is not the intention to prescribe the type and quality of information which will fulfill this requirement, since this will be a matter of judgment in each individual case. However, examples of evidence could include details of conversations with the deceased which a person could reasonably believe took place; conversations which can be verified by another person; or other information which could be accepted as reasonable” but stresses that “in the context of providing this information, it is, as a matter of law, the wishes of the deceased which are relevant”. This is repeated by stating that “Where relations do not produce any information about the wishes of the deceased, then they will be in the position of knowing the deceased had not opted out, and had made no further wishes known. In these cases, the default position is that the deceased was in favour of donation and, as a matter of law, the deceased’s consent is deemed.”

It may be that our concerns are satisfied because paragraph 44 does contain this proviso “However this does not mean organ donation will automatically proceed as there will then be a discussion with the family about the donation process, including the medical history of the deceased. Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families by insisting on donation. It is important to be clear, however, that families do not have a legal veto because the law will recognise the deemed consent of the deceased as having precedence”.

It is further noted that in a “frequently asked question” section on the Welsh Assembly website the following paragraph is included under the heading “will there be a role for the family of the deceased in deemed consent cases?”

“Those close to the deceased therefore do not have a legal right to overrule the decision of the deceased to have their consent deemed. Clinical teams will nevertheless have a duty of care towards the family members and if there are very strong objections or distress then organ donation will not go ahead”.

This wording is different to that in the December 2012 Explanatory Memorandum as it refers to the clinical team having a “duty of care towards the family members’ and “if there are strong objections or distress, then organ donation will not go ahead” and it would be helpful to everyone if the wording in all published documents was identical but in a press release when laying the Bill before the Assembly the Health Minister, Leslie Griffiths, said, *“the role of the family is critical in informing the final decision on what happens to their relative’s organs. The wishes of the deceased are paramount and the vast majority of the people of*

*Wales do expect their wishes to be what really counts. For that reason, as is the case now, the family has no legal right to veto, but in practice a clinician would never add to their distress by insisting on donation".* So according to the Health Minister whilst the Bill does not legally allow the family to have a legal veto the clinical team will, in practice, not insist on removal and, if she is correct, it seems that this will apply in situations where a deceased has decided to opt in.

It is therefore possible that our concerns whilst not overcome by the wording of the Bill might be covered by the extracts from the Explanatory Memorandum and Questions and Answers BUT the position of the Jewish Community is that stated in the Board of Deputies submission namely submission "organs are donated by individual Jews not by Jewish organisations" and perhaps I will change this to read "in Wales organs are donated by individual Welshmen and Welsh women and not by the Welsh Government".

11 January 2012



## **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**

Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)11 – Welsh Kidney Patients Association



# Welsh Kidney Patients Association

## *Cymdeithas Cleifion Arennau Cymru*

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Vice President Dr. Andrew Williams M.D., F.R.C.P.  
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Registered Charity No. 1050907

Website: [www.wkpa.org.uk](http://www.wkpa.org.uk)

### **Health and Social Care Committee Inquiry: Human Transplantation (Wales) Bill**

#### **Introduction**

The WKPA which is run entirely by unpaid volunteer patients and carers, is the only independent renal charity covering the whole of Wales. The Association aims to work on behalf and to the benefit of its membership of over 2,500 renal patients, including pre-dialysis, dialysis and transplant patients (and carers), throughout Wales. The WKPA magazine '*Kidney Matters Wales*' is currently sent to 1,350 individual patients and to every dialysis unit in Wales.

Our Association provides a means of liaison and consultation with the various organisations with responsibility for providing renal services across Wales. At every opportunity, we provide input from the patients' perspective and aim to highlight and raise awareness of their needs. The WKPA undertakes regular surveys and questionnaires to ascertain the views of its members on all aspects of their renal care enabling us to represent our members in the most effective manner and campaign for improvement. During 2007 and 2009, we conducted surveys of our members with regard to the introduction of the soft opt out system in Wales. In both these surveys approximately 80% of our membership voted in favour of introducing the 'soft opt out law' in Wales. The WKPA's response to the Inquiry into Presumed Consent on Organ Donation, held by the Assembly in 2008, supported the introduction of the soft opt out law. In addition the WKPA submitted responses in favour of the soft opt out law to the Welsh Government White Paper (Proposals for legislation on organ and tissue donation) in January 2012 and to the Draft Human Transplantation (Wales) Bill in September 2012.

The letter of acknowledgement (Oct 8<sup>th</sup> 2012) for the latter response states:

*“We are very grateful for all the point you raised. In particular, your comments about the role of the family and questions on residency issues are very helpful and will be given careful consideration as we move forward.”*

As an Association we are pleased to have received specific feedback clearly indicating that our comments highlighting concerns on the issues quoted above have been duly noted for future reference.

On behalf of WKPA members we hereby submit the following response to the Health and Social Care Committee’s Inquiry/ Consultation into the above Bill.

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## **1. The Individual provisions set out in the Bill.**

*Section 2: relating to the promotion of transplantation.*

The WKPA supports that it must be the duty of Welsh Ministers to:-

- a) promote transplantation in the UK and is pleased that it is recognised by the WG that transplantation is a means to improving the health of people in Wales. In addition, because any organs that become available for transplantation in Wales will be allocated by NHSBT on a UK wide basis, this will include improving the health of people in the UK as a whole.
- b) It is essential that Welsh people are aware of transplantation and the related issues involved in organ donation and thereby able to make informed judgements and decisions.
- c) The public must be made aware of the changes that the Human Transplantation (Wales) Bill will make to the organ donation system in Wales. Equally there is a need to provide clarification that specific aspects of the manner in which transplantation proceeds will remain unchanged in accordance with the Human Tissue Act of 2004 (eg. consultation with and regard for families’ wishes). Particular care must be taken to ensure that everyone in Wales who may “qualify” as “potential donor” is aware of the need to “opt out” of the system should they so wish. The meaning and difference of “deemed consent” and “express consent” should be explained in simple language so that there is no confusion in people’s understanding of the law. Additionally, the relevance of the expression ‘soft’ opt out must be emphasised.

*Section 3: relating to lawful transplantation activities.*

Transplantation in Wales has been lawfully carried out to date under the Human Tissue Act (2004) the WKPA supports the authorisation of all lawful transplantation activities as described in this section of the Bill.

*Sections 4-8: relating to consent.*

In its response to the Draft Human Transplantation (Wales) Bill in September 2012, the WKPA stressed the need for the Welsh Government to explain in language that can be easily understood all the issues relating to consent, both deemed or expressed. In addition, there must be clarity on issues concerning the consent of children and those lacking capacity. Legislation requires that terminology used be such that makes the law infallible. The WKPA trusts that all the necessary safeguards have been included to prevent any organ or tissue being removed from a body without the consent of the deceased or the next of kin.

*Sections 9-11: relating to offences.*

Again, transplantation has been a legal activity in Wales to date under the Human Tissue Act (2004) and as such, the WKPA supports the Human Transplantation (Wales) Bill's commitment to ensure that there will continue to be no offences committed regarding the illegal use of organs or tissues in Wales.

*Sections 12-20: which makes general provision.*

The WKPA has no comment to make on the above sections except to state that it realises the need to amend and/or incorporate parts of the Human Tissue Act 2004.

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

The WKPA can see no potential barriers to the implementations of these provisions. Opt out systems are operating successfully in other countries. Studies have shown that, where there is an opt out system on organ donation, organ donation rates are higher. It has been stated that these higher rates are not solely due to an opt out system and that the necessary infrastructure plays a part in these higher donation rates. However, in Wales both through establishment of Health Board Organ Donation Groups to implement and introduce the recommendations of the ODTF, and the excellent facilities available at the new transplant unit at UHW, more transplant operations are currently being performed than was envisaged. In addition, the allocation of organs will still be made under the guidance of NHSBT, any increase in numbers of organs becoming available following the introduction of the Bill will be used throughout the UK.

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

The WKPA does not envisage any unintended consequences arising from the Bill.

In its response to the White paper on the proposals for legislation on organ and tissue donation submitted in January 2012, the WKPA states the following:-

*"The WKPA supports the new soft opt law safe in the knowledge that there will be ample opportunity for people to opt out and loved ones will continue to be consulted about donation. Over the years our members have trusted NHS staff to advise and oversee their treatment and to act ethically and within the guidelines for organ donation. There is no reason to believe they will not continue to act responsibly and sensible in implementing this change in procedure here 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)**

Paragraph 93 of the Explanatory Memorandum states:

*“This Regulatory Impact Assessment appraises the impact of the WG’s draft Human Transplantation (Wales) Bill. It is found that the benefits associated with an increase of one donor per year more than offset costs incurred”*

The RIA also states:

*“the cost of a kidney transplant is £50,000 at 2011/12 prices, and there is a follow-up cost each subsequent year of £8,000. Each year there is a saving in kidney dialysis avoided of £28,000.”*

A kidney transplant has an average life span of approximately 11 years, thus making a saving of £308,000 per patient. The Assessment continues to make assessment on the cost benefits of other major transplant operations e.g. liver, heart.

However to any transplant recipient, the benefits of a successful transplant are immeasurable and cannot be quantified in terms of value. In addition, following transplantation, sick people are able to return to work and contribute to society in normal ways, e.g. paying taxes.

4

**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).**

The WKPA has no comment to make regarding the powers in the Bill for Welsh Ministers to make subordinate legislation other than to trust that the legal aspects of the Welsh Government to pass such a law has been thoroughly researched and that the WG has the capacity and power to do so.

**Concluding Statement**

The WKPA has supported the initiative to introduce a soft opt out law on organ and tissue donation in Wales since 2007. The Association has had representation on the Welsh Government’s Voluntary Stakeholder’s Group meetings, and is represented on the communications sub group of the All Wales Donation and Transplantation Advisory Group. We will campaign for the introduction of the ‘soft opt out law’ with the conviction that it will benefit the people of the UK as a whole.

John Reeve

Chair

17<sup>th</sup>, January 2013

10 January 2013

**Response to the Consultation Paper on the Human Transplantation (Wales) Bill**  
**December 2012**

The observations of the Cardiff and Vale University Health Board Organ Donation Committee are as follows

**1) Re: Title of Bill**

The title of the Bill 'Human Transplantation (Wales) Bill, doesn't mention 'donation'. Will the public, if asked, be able to relate the 'opting out' legislation as mentioned in the media, to the 'Transplantation Bill' as there is no mention of donation in the title?

We accept that the ultimate aim is for transplantation to occur, but for the public it should be donation that is emphasised as it is the assent/consent for donation on the public's part that makes transplantation possible.

**2) Re: QALY**

Our understanding is that when NICE assesses cost-effectiveness per QALY for drugs, £30 000 is used as the cut-off point, above which the drug is not deemed to be cost-effective. We note the figure quoted here is £60 000. Could we have some clarification please?

**3) Re point 134 of Human Transplantation (Wales) Bill, Explanatory memorandum:**

As identified on previous occasions the increase in donor numbers estimated at 15 per year will have an impact on resources, especially in critical care. The conversion rate of DCD donors is about 22% therefore for 1 donor who goes on to donate organs we have 3 potential donors where consent is gained but who don't die in the required timeframe. The workload on the critical care departments can't be calculated by looking at donors alone ie. 15, but is more likely to be about 4 times that ie. 60 patients per year. This will have a significant impact on critical care provision as bed numbers per population in Wales is relatively low when compared to other developed countries.

**4) Re: Reasons given by relatives for refusal of consent for organ donation**

At present we monitor all potential organ donors and we review the data with the SNODS at the Organ Donation Committee meetings. We also document the reasons for relative refusal however this is only done when a SNOD is involved in the request for donation. We suggest that to assist in determining the effect of the Bill it may be useful do collect this data routinely in all of Wales, as this may identify areas where work is needed to increase donation going forward.

5) **Re: Practical issues raised at the stakeholder and public consultation meetings which we would like to highlight.**

a) **Re:ODR**

In our view it is imperative that there is only one UK wide register for the public to express their wishes regarding donation, whether they wish to opt in or out, to ensure that opposing views are not logged on different registers.

b) **Re: Establishing residency**

There are concerns as to how the SNODS would be able to accurately identify residency of the potential donor, especially of hours, without speaking to the relatives. One of the benefits of the Bill is seen to be that the introduction to the conversation with the relatives would include the fact that the potential donor hadn't opted out, but this would not apply to those not resident in Wales and therefore it won't be possible to start the conversation with the fact that they hadn't opted out prior to establishing residency.

NB this may have considerable implications for litigation.

c) **Query re: Consent forms**

Would the Bill require a change in the current consent forms and would there be different forms required for those who are resident in Wales and those who are not?

d) **Organ Donation Taskforce Recommendations and NICE guidelines**

The Bill will not be a substitute for the Organ Donation Taskforce Recommendations made in 2008. For the Bill to be successful it is essential to adhere to the Taskforce Recommendations and the guidelines developed by NICE, in particular those in relation to referral of all potential donors and collaborative requesting.

6) **Re: Ease of opting-out**

In order to provide a balanced option the system of opting out must be clear and as easily accessible as the one for opting in.

7) It remains a concern that individuals may opt out due to the 'presumed 'nature of the Bill.



## **Cystic Fibrosis Trust Response to Welsh Government Proposals for Human Transplantation Bill Scrutiny**

### **What is Cystic Fibrosis?**

Cystic Fibrosis is one of the UK's most common, life-threatening inherited diseases, affecting over 9,000 people in the UK. The faulty gene causes CF is carried by 1 in 25 people, and 1 in every 2500 babies in the UK is born with Cystic Fibrosis. It is a life-long illness, affecting a person from birth to death.

While new treatments and better management of care are helping people with Cystic Fibrosis live longer, many will reach a point at which receiving a transplant, be it lung, heart-lung or liver, is their only option to prolong life significantly. Despite this, nearly half of all people with CF on the transplant waiting list will die before they receive a transplant.

### **About the Cystic Fibrosis Trust**

The Cystic Fibrosis Trust was founded in 1964 and is the UK's only national charity working to fund research into a cure and effective treatments for Cystic Fibrosis and to ensure appropriate clinical care and support for people with Cystic Fibrosis. It aims to ensure that people with CF receive the best possible care and support in all aspects of their lives, and provides information, advice and support to anyone affected by Cystic Fibrosis.

While new treatments and better management of care are helping people with Cystic Fibrosis live longer, many will reach a point at which receiving a lung transplant is their only option to prolong life significantly. The Cystic Fibrosis Trust supports efforts to ensure that all those with CF who are assessed as suitable for a lung transplant receive one.

The Cystic Fibrosis Trust are in the process of developing a dedicated programme of work with NHS Blood & Transplant, and other organisations, to develop a national standard for transplant services.

In addition, the Cystic Fibrosis Trust will continue to fund research into ensuring more organs are available for transplant, such as the 'reconditioning' lungs programme.

### **Our view**

Following a consultation with the CF Community including those with CF, their parents and carers and physicians from the CF and transplant field the CF Trust feel able to welcome the Welsh Government proposals to change organ donation legislation. We support a change in the system of how we donate organs, in the hope of increasing the number of transplants that are undertaken.

**see off cf**

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Patron: HRH Princess Alexandra, the Hon. Lady Ogilvy, KG, GCVO President: Duncan Bluck CBE

Cystic Fibrosis Trust registered as a charity in England and Wales (1079049) and in Scotland (SC40196)

A company limited by guarantee registered in England and Wales number 3880213

Registered office: 11 London Road, Bromley, Kent BR1 1BY

Although we hope that the introduction of the soft opt out would have a significant positive effect on transplant rates, we know that more needs to continue to be done, as indicated by the Organ Donor Taskforce's 14 recommendations. As people with cystic fibrosis predominantly require lung transplants and donated lungs are especially vulnerable to being damaged prior to transplant, we are supportive of the change of approach to focus on utilising existing donors, not simply recruiting more.

Whilst the emphasis to date has been on getting people to sign the national organ donation register, it is absolutely clear that unless other fundamental problems are also addressed, this will be of modest benefit.

Below are aspects of the bill that need to be considered:

### **Section 2, relating to the promotion of transplantation**

A national debate needs to take place on organ donation and transplantation so that the profile of the issue is increased, and the general public has a better understanding of the realities of transplantation. Many people currently sign up to the Organ Donor Register, but do not discuss it with their family which leaves the family a painful decision at the hardest possible moment. It is only when donating your organs after death becomes usual, not unusual, that we will be on the road to giving people on the waiting list real hope. The CF Trust agree that we need to change culture of organ donation so relatives know patients wishes, and we agree that the 'Have a Heart to Heart' programme is a positive move forward which we support.

We would also support Health Ministers being an advocate of organ donation.

### **Sections 4-8, relating to consent**

To ensure individuals receiving a transplant are able to make informed choices they must be given sufficient information and suitable guidance. A patient needs to be informed of organ donor health before being transplanted to allow make the consent truly informed, and allow them to weigh up the potential risks and consequences following transplantation.

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

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

**see off cf**

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Due to the multi organ complications of cystic fibrosis, and the impact of transplant medication on the body, Individuals with cystic fibrosis sometimes need liver and/or lung transplants at different stages of their lives. Individuals requiring a liver transplant will often have transplant care based in Birmingham and lung transplants in hospitals in London or Newcastle. There is a significant geographical distance between Wales and each these hospitals but needs and requirements for patients in Wales should be met optimally, regardless of their location. We want to ensure that individuals are gaining a good standard of care from specialist teams pre and post transplant over the whole of the UK.

It is essential that should Wales increase the rate of donation through these changes in legislation, donor organs are best utilised by being best matched to maximise long term outcomes. It is essential progress is measured in this area, through a national system of monitoring outcomes to ensure each patient attains the best outcome from their transplant and that transplant centres across the country support each other to achieve this.

We would want to ensure that individuals requiring a transplant are receiving adequate psychological support throughout the whole transplant process. This includes pre transplant, waiting for transplant and post transplant. We believe that this will help post transplant health status as individuals can be supported effectively and are able to explore issues surrounding transplant as well as end of life issues if the transplant does not come in time. This psychological support may be extended to family and friends, who often become carers of those requiring a transplant.

Whilst formulating our response to this consultation, the Cystic Fibrosis Trust has consulted with the CF community, including people with Cystic Fibrosis, families of people with CF and physicians within the CF and transplant fields. This response reflects their views and concerns regarding the proposed changes in the organ donation system.

### **Conclusion**

The Cystic Fibrosis Trust supports the Welsh government proposals to legislate for an opt out organ donation register in Wales, but we are aware that legislation alone will not be enough to significantly improve transplantation rates.

We hope that such a change in legislation will lead to a UK wide re-appraisal of the current situation, and a much needed discussion of organ transplantation, ultimately leading to increased donation rates across the UK.



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**Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)14 – Clinical Lead Organ Donation, Cwm Taf Health Board**

Dariusz Tetla  
Clinical Lead Organ Donation  
Cwm Taf LHB  
[Dariusz.tetla@nhs.wales.uk](mailto: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

**Evidence to Health and Social Care Committee**

**Human Transplantation (Wales) Bill**

**Further suggestions from Professor Vivienne Harpwood**

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

*Deemed or presumed?*

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

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

In my view there is a strong case for grasping the opportunity that we have now in Wales to produce clear legislation which can readily be understood by the majority of the population. We have tabula rasa in this respect, and clarity is particularly important in legislation that directly affects such a deeply personal and sensitive matter as consent in medicine.

Since the use of the word *deemed* in connection with what is generally understood as *presumed* consent, could be seen as a deliberate attempt to obfuscate one of the main objectives of the Bill, why not be honest with the people of Wales? This is a Bill aimed at winning hearts and minds, accompanied by a publicity campaign entitled “Heart to Heart”, encouraging families and friends to express make their wishes about organ donation known to those close to them. This reinforces the argument in favour of clarity. The position is that *consent may be presumed in the absence of compelling evidence to the contrary*, and everyone affected by the legislation needs to know that.

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

#### *Clumsy use of language in parts*

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

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

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

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

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

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

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

#### *Conjunction with the Mental Capacity Act 2005*

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

*An additional chart would add clarity*

Why not add a chart to cover all categories of patients?

*Proposed duty on Welsh Ministers to promote organ donation.*

At present, donors are being lost because there are insufficient numbers of critical care beds. Will the new duty on Ministers result in an increase in the number of critical care beds as part of the restructuring of healthcare services in Wales? Have the financial implications of this been taken into account?



Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)15 - Royal College of Nursing

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17 January 2013

Mark Drakeford AM  
Chair of the Health and Social Care Committee  
National Assembly for Wales  
Cardiff Bay  
Cardiff  
CF99 1NA

Dear Mr Drakeford AM,

Thank you very much for your letter of the 6<sup>th</sup> December 2012 inviting the response of the Royal College of Nursing (RCN) to your Inquiry into the general principles of the Human Transplantation (Wales) Bill.

On 24th July 2009 the RCN Council was asked to consider our position on organ donation. At this meeting Council agreed to support the retention of the current opt-in system and closely monitor progress against the Organ Donation Taskforce Report recommendations up to 2013. RCN Council would then be asked to consider if there was a need to change the RCN's position in light of the progress against the Organ Donation Taskforce recommendations. **Therefore, the RCN does NOT at present favour a legislative change to an opt-out system for organ or tissue donation.**

The RCN continues to support NHS Blood and Transplant's strategy of 'changing public behaviour with regard to organ donation' and 'maximising conversion of

potential donors into actual donors' by means other than adoption of an opt-out approach to consent. The further views expressed below on the Bill and Draft Explanatory Memorandum should be understood in this context.

Cont.....

17 January 2013

## **Residency**

One of our significant concerns is that the arrangements and tests for establishing residency are clear enough to deal with cross-border challenges. There is not sufficient detail in the Draft Explanatory Memorandum on safeguards that need to be in place to deal with issues arising from diverse cultural models of residency.

For example, given the significance placed in the proposals on residency, the Explanatory Memorandum should acknowledge the importance of, and anticipate strategies for, specific engagement with the gypsy and traveller community.

## **Communication and Education**

We are also concerned about the effectiveness of any public awareness campaign to adequately explain this change in the law. The need for a greater level of public understanding about organ donation is widely acknowledged, and the RCN regards it as essential that relevant education should begin at an early age. It may also be useful to undertake a survey of public knowledge before and after any campaign to evaluate which sections of the population may need further activity and which methods were acceptable and effective. In addition to the Welsh Government's commitment given to specific consultation with BME groups, the Explanatory Memorandum must indicate what strategies will be pursued to ensure optimal public understanding in communities communicating in languages other than Welsh or English. Strategies suggested by the RCN are employing health care professionals, link workers and interpreters/ advocates from minority ethnic groups, checking a patient's understanding of what has been said to them, and ensuring that information has been translated appropriately in a culturally sensitive way, and educating health care professionals on the health beliefs of different cultural communities.

The communication plan will also need to target health professionals to explain the impact on their individual areas of practice. It must also be clear how the new system will impact on students resident in Wales and how this will be communicated to them.

If a new system were to come into operation in Wales, a pressing concern of the Royal College of Nursing would be the need for training and education for nursing

staff. Nurses and health care support workers are the largest staff group in the NHS and the most likely to be in direct daily contact with patients and families. Specific resources must be developed and targeted at this group.

We are also aware that the majority of Local Health Boards are currently operating a suspension of training for nursing staff as a financial savings measure.

Cont.....

17 January 2013

Chief Executives and Nurse Directors must be supported with a specific ministerial authorisation to implement the training and education necessary to implement the significant process of change proposed.

Nurses can be the first clinicians to broach this difficult subject with relatives of potential donors. When patients become critically ill and consideration is being given to whether they will be suitable for organ donation, nurses play a central role in the assessment to establish their suitability, and a key component of the role of the nurse is to endeavour to ensure that end-of-life care conforms to what are known to be, or can be reasonably assumed to be, the expectations of the patient. In our 2009 consultation, some concerns were expressed by our members that public trust in nurses' ability to fulfil this role could be undermined by adoption of an opt-out system of donor registration. The thought was that a perception of a conflict of interests might arise, whereby the nurse's role in caring for the dying patient might be regarded as secondary to the nurse's role in facilitating retrieval of organs for transplantation. To minimise the possibility of such a misconception of the role of the nurse, and to improve public understanding of organ donation, the RCN strongly encourages the Welsh Government to make explicit the principle that organ and tissue donation should be integrated into the culture of best practice in end-of-life care. The RCN believes that this will have a substantially beneficial impact on donation rates.

Nurses have consistently highlighted the benefits of an open and honest process in encouraging donation, as well as increased support for relatives at the end of life. It is understandable that the needs of recipients of organs are usually emphasised in discussion about donation ethics and policy. However, the RCN suggests that it is equally important for willing potential donors that a culture should continue to evolve in which donation is recognised as an important element of person-centred end-of-life care. Effective communication and recording the individual's preferences and wishes enables both the individual and their carers to become empowered. Such a culture would also enable those close to the dying person to understand that their role in facilitating a loved one's donation is not a threat to the interests of the patient, but

rather enables them to ensure that the wishes of the patient are as far as possible realised.

Cont.....

17 January 2013

### **Individual Clinician Concerns**

The RCN 2009 member consultation also revealed that some nurses might have concerns specific to involvement in donation processes in an opt-out system. These concerns were relevant to wider consideration of the possibility of an individual's 'conscientious objection' to participation in organ retrieval and transplantation. Sometimes, individual healthcare professionals perceive the grounds for such an objection to be based on religious or cultural origins. Regardless of an individual's specific reasons for wishing to be excluded from facilitating donation and transplant, it is an important matter of policy that such 'conscientious objections' (whether enduring, modifiable or perceived) should be anticipated, and that adequate guidance for the management of such eventualities should be provided for. It is essential that clinicians' duty of care in such circumstances is clearly defined in such guidance.

For example, in what circumstances and for what reasons can a clinician elect to withdraw from donation and transplant procedures? What processes should be recommended for individuals and clinical services to reflect on and learn from such incidents in order to improve services on subsequent occasions? In particular, what strategies for training and education should be provided for staff to ensure that any personal decision taken to withdraw from donation is as far as possible based on informed choices. We understand that in some cases individuals who have taken a decision to withdraw have been asked to find a replacement member of staff and procedures should be put in place within the organisations involved to prevent such a situation.

As part of their professional registration with the Nursing and Midwifery Council (NMC), all nurses in the UK are personally accountable for their actions and omissions in their practice, and must always be able to justify their decisions. Failure to comply with their code of conduct may bring their fitness to practise into question and endanger their registration. The NMC code sets out clear standards of conduct, performance and ethics for nurses. We would urge the Welsh Government to consult with the NMC on any of the systems and processes that it establishes in the future.

## **Additional Resources**

The RCN acknowledges the detailed discussion in the Draft Explanatory Memorandum of the anticipated resource implications of adopting a 'soft' opt-out system, but wishes to state its concerns about the need to provide adequate resources to implement any strategy to improve rates of donation.

Cont.....

Healthcare professionals and the public need to be assured at all stages that the Welsh Government's encouragement of the population to be more supportive of organ donation and transplant is matched by appropriate financial commitment on the part of government.

To conclude, the RCN wishes to strongly emphasise that introduction of any new system or approach to organ donation requires corresponding investment in public education and expansion of infrastructure. Identifying larger numbers of willing donors is only valuable if the supporting infrastructure is able to cope with the additional workload.

Kind regards

Yours sincerely

**TINA DONNELLY**  
**DIRECTOR, RCN WALES**

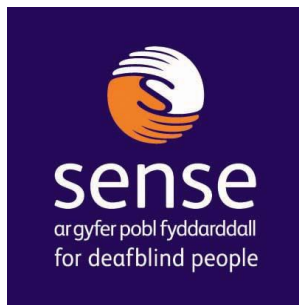
## *ABOUT THE ROYAL COLLEGE OF NURSING (RCN)*

*The RCN is the world's largest professional union of nurses, representing over 400,000 nurses, midwives, health visitors and nursing students, including over 23,000 members in Wales. The majority of RCN members work in the NHS with around a quarter working in the independent sector. The RCN works locally, nationally and internationally to promote standards of care and the interests of patients and nurses, and of nursing as a profession. The RCN is a UK-wide organisation, with its own National Boards for Wales, Scotland and Northern Ireland. The RCN is a major contributor to nursing practice, standards of care, and public policy as it affects health and nursing.*

*The RCN represents nurses and nursing, promotes excellence in practice and shapes health policies.*

**Submission to Health and Social Services Committee from Sense and Deafblind Cymru - Human Transplantation (Wales) Bill and Explanatory Memorandum**

**Organisations responding**



Sense is a national charity that supports and campaigns for children and adults who are deafblind. We provide tailored support, advice and information as well as specialist services to all deafblind people, their families, carers and the professionals who work with them. In addition, we support people who have a single sensory impairment with additional needs.



**DEAFBLIND**  
**·CYMRU·**

Deafblind Cymru's vision is that people who are deafblind or have a combined sight and hearing loss should have equal rights, access and opportunities as all other citizens within society. Deafblind Cymru is an organisation of and for people who are deafblind or have a combined sight and hearing loss. We champion the rights and interests of all people who are deafblind or have a combined sight and hearing loss and deliver quality services to support individuals to have autonomy and control over their lives.

## Comments on the Bill

Sense and Deafblind Cymru's response relates to the Health Committee's invitation for evidence about "Any potential barriers to the implementation of these provisions and whether the Bill takes account of them".

### 1. Communication plan

The current draft of the Equality Impact Assessment highlights different groups that will be targeted in the communication plan, including deaf and hard of hearing people; blind and partially sighted people; and people with learning disabilities.

We welcome the draft Explanatory Memorandum's references to people with single sensory loss. However, we are not reassured that the communication plan has addressed deafblind people and believe it might not have paid due regard to them. Therefore, we would recommend that people with dual sensory loss are treated as a unique group as well as blind and partially sighted people and people who are deaf or hard of hearing.

### 2. Why deafblind should be considered separately

Deafblind people have combined sight and hearing difficulties. A range of congenital or acquired conditions can cause deafblindness. The issues faced by deafblind people are not simply a combination of the separate issues faced by blind and deaf people.

The Welsh Government has issued statutory guidance to local authorities on deafblindness (issued by the then National Assembly for Wales in 2001). The statutory guidance said:

"They are a unique group, who cannot always benefit from mainstream services or services for people who are either blind or deaf (but able to compensate partially for the loss of one sense by using the other)."

The statutory guidance also said:

"It is the way in which one sensory impairment impacts upon or compounds the second impairment which causes the difficulties even if, taken separately, each single sensory impairment appears relatively mild."

Deafblind people are generally more isolated from society because of the difficulties they face with communication, mobility and access to information. They may access media infrequently or not at all and can have small social networks.

The statutory Deafblind Guidance (2001) requires local authorities in Wales to identify and contact deafblind people and maintain a record of them. These local



authority registers can be used as a starting point to find deafblind people and ensure communication to them is in the most accessible form. However, not all registers will be up to date.

Research estimates commissioned by Sense reveal a higher prevalence rate of deafblindness than the rates found by local authorities in Wales (see Robertson J and Emerson E, Estimating the Number of People with Co-Occurring Vision and Hearing Impairments in the UK, 2010). The Welsh Local Government Association said the registers “vastly underestimated” the number of deafblind adults in Wales (WLGA, Sensory loss in the adult population in Wales, May 2012).

Sense Cymru and Deafblind Cymru can use our networks, newsletters etc to help raise awareness of the changes the Bill will enact. However, this does not replace the need for public agencies to be aware of deafblindness, to consult with local authorities to ensure deafblind people are identified and to carry out their responsibilities to give due regard to deafblind people in Wales in the communication plan.

### 3. Accessible ways to register wishes

Deafblind people will need a range of accessible methods to find out about the changes the Bill will introduce and to opt-out or register their wishes. Deafblind people come from a range of backgrounds and have different circumstances. They include people who are hearing and sight impaired from birth or early childhood; those blind from birth or early childhood who subsequently acquire a hearing loss that has a significant functional impact; those who are profoundly deaf from birth or early childhood who subsequently acquire a significant visual loss; and those who acquire a hearing and sight impairment later in life that has a significant functional impact. Some within this group may not even call themselves ‘deafblind’.

Depending on the severity of their dual sensory loss people make use of residual or useful vision or hearing; use tactile means; or alternative formats:

a) Tactile communication, such as Deafblind Manual, block or finger spelling. For the small number of people who communicate solely using these methods the public information would have to be delivered in person.

b) Alternative languages, such as British Sign Language (including adapted methods of signing such as Visual Frame for those who are also partially sighted or hands-on signing for those who are also blind). This would also include videos in BSL that could be featured on the Welsh Government, NHSBT etc websites.

c) Alternative formats, such as large print, braille and audio.

If the current methods of opting into the organ donation system were used for the opt-out system we believe there would be a number of practical issues. For example, the NHS Blood and Transplant Service website lacks a textphone number, which is used by deafblind people who have some useful sight or in conjunction with a braille

reader (and by deaf people). The Text Relay service ([www.textrelay.org](http://www.textrelay.org)) can be used to connect a person using a telephone with a person using a textphone.

There is also an option listed to send a text message at present to join the organ donation register but if text messaging were possible for registering wishes in the new system there would need to be an explanation about what would happen next. That is, whether a text message would be a valid way to register wishes (and how a deafblind person would know their wishes had been registered) or whether it is treated as a request for further information or contact (and whether further contact would use accessible communication).

#### 4. Congenitally deafblind people

The Welsh Government and its agencies may also encounter extra difficulties communicating the changes to congenitally deafblind people, who were deafblind from birth or before they acquired language. This means their formal language may be limited. Some congenitally deafblind people have co-occurring or connected cognitive disabilities but if their sole condition is deafblindness they can usually make decisions about concepts that are familiar to them. However, explaining abstract or novel concepts about mortality, their own organs and the consent system could be very difficult or impossible. People in this situation therefore not have the capacity to make a decision.

We believe the legal framework set out in the Bill will deal with this. However, we recommend that the Welsh Government produces a code of practice to explain these concepts to healthcare professionals. The Welsh Health Minister is currently implementing changes in response to a report, *Accessible Healthcare for People with Sensory Loss in Wales* (2012), which described examples of poor sensory loss awareness among a range of healthcare professionals. Before the Bill's provisions are enacted we would like consent to be explained clearly and concisely to health professionals and any others who will be involved in implementing them. The code of practice for the Mental Capacity Act 2005 provides a good model in this respect. It includes a series of scenarios throughout to explain the Act's provisions in practical terms. A similar document for the Human Transplantation Bill would be valuable and should include scenarios about consent and dual sensory loss.

#### **Contact details**

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**Response to the Welsh Assembly Health & Social Care Committee  
consultation on the draft Human Tissue (Wales) Bill, January 2013**

**From the Association for Palliative Medicine of Great Britain and Ireland**

We support any ethically sound attempt to see an increase in organ donation and transplantation rates in Wales and the UK as a whole. We would like to comment on some of the current consultation questions.

We doubt that “deemed consent” is a form of consent. We think that it is harmful and wrong to use this term for an opt-out system of organ donation.

The family’s role is not clear enough. There are some ambiguities in the account of what influence they have over decisions and whether this role amounts to exercising a veto over retrieval. Resolving these would help to clarify their role. Families’ experience of decisions around the end of life is pivotal in influencing their bereavement reactions and is a significant public health problem as well as one with specific and direct effects on public confidence in organ transplantation.

On capacity, we think that it needs to be made more clear how and when the judgement of capacity should be made within the requirements of the Mental Capacity Act (2005).

Our principal remaining concern is around donation following circulatory death (DCD). Whereas in donation following brainstem death (DBD) all additional interventions are performed after death (defined by brainstem criteria), DCD can entail having additional interventions in the last hours of life purely to facilitate subsequent retrieval and we have concerns about establishing whether these are in the dying person’s best interests.

When a decision on DCD is taken before withdrawal of life sustaining treatment, the person is alive but usually incapacitated. According to the provisions in this Bill, in the case of DCD decisions on transplantation activities and on interventions in support of those activities would not be covered by “deemed consent” because the person is alive at the time, but could not be based on express consent because of incapacity.

It is normally contrary to a person’s best interests to continue non-therapeutic interventions (interventions which do not benefit the patient) if doing so would cause distress. Intervention in support of DCD can be in a person’s best interests on the basis of her express consent because it allows her wishes to be fulfilled. It may be in his/her best interests on the basis of “deemed consent”. There is a risk, although perhaps small, that the donor’s end of life care is harmed by such interventions. We suggest that in the case of DCD care must be taken not to compromise the care of the dying donor for the sake of what amounts to non-consensual retrieval.

Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)19 - Christian Medical Fellowship

Dear Sir/Madam,

Thank you for the opportunity to respond to the consultation on the Human Transplantation (Wales) Bill.

Please find attached our response which is also detailed in full following.

CMF has over 4,000 British doctors and 800 medical students as members. Through the International Christian Medical and Dental Association (ICMDA) we are linked with like-minded colleagues in over 90 other countries. 154 doctor members reside in Wales and there are 63 student members at the two Welsh medical schools.

The Christian Medical Fellowship has on a number of previous occasions expressed concern with the principles underpinning this Bill. We sent in a detailed response to the initial public consultation:

[http://admin.cmf.org.uk/pdf/publicpolicy/Welsh\\_organ\\_donation.pdf](http://admin.cmf.org.uk/pdf/publicpolicy/Welsh_organ_donation.pdf)

and the subsequent draft Bill:

[http://admin.cmf.org.uk/pdf/publicpolicy/Organ\\_donation\\_Bill\\_response\\_0912.pdf](http://admin.cmf.org.uk/pdf/publicpolicy/Organ_donation_Bill_response_0912.pdf). We have expressed significant opposition to both the concept of introducing presumed consent and the wording and operation of the draft Bill itself.

We note that similar concerns have been raised by other religious groups, notably Catholic and Muslim organisations.

### **Can consent truly be 'presumed'?**

Presumed consent in effect equals no consent, unless there is an extensive public information programme, which would need to capture *the entire adult population* including those on the margins of society. Only this would ensure that those who do not opt out of donation have made an explicit choice, rather than doing so by default, by ignorance or by a lack of knowledge or understanding.

It will be almost impossible to guarantee that everyone is informed and understanding of 'deemed consent', knows their options and can easily opt out. Can consent be truly assumed from those who are disorganised, apathetic, disabled, less well educated or informed, isolated, lacking full capacity, of different languages and race, suffering from (temporary) mental illness, dependent, those who have less ready access to information and those who change their minds? As a minimum, the importance of allowing families a veto in such cases is obvious.

This makes the whole concept of 'presumed', or 'deemed', consent ethically problematic as well as complex, and very costly, to administer.

It is not even the most effective way to increase organ donor numbers. Research published in Transplantation has found that donation rates in countries with opt-out laws do **not** differ dramatically from countries requiring explicit (opt-in) consent. Moreover: *'...countries with the highest rates of deceased donation have national and local initiatives, independent of PC, designed to attenuate the organ shortage.'* (See also: Coppen, R., Friele, R., Marquet, R. and Gevers, S. (2005). 'Opting-out systems: no guarantee for higher

donation rates.' Transplant International 18: 1275-1279).

## **The Role of Families**

Although the Welsh government has said all along that it will introduce 'soft' opt-out legislation, allowing the family of the deceased a role in the final decision, **the Bill as it stands does not in fact allow for this**. While provision is made in the draft memorandum (p20), there is no provision in the Bill itself for providing distressed relatives with a right to object to the removal of organs when no consent was given by the deceased.

Some people fear that if they became seriously ill, they would receive less thorough treatment if they were donors than if they were non-donors because doctors want their organs. This fear – which need not be well founded to have an effect – would increase if the family's views were known to be overridden. People look to their families to protect them when they cannot protect themselves.

The Bristol and Alder Hey controversies were fuelled by the perception that families had no real power in decision-making with respect to what happened to their loved one's body parts. They also showed how crucially important the body is to bereaved parents and friends, and illustrated the need to respect the human body, even in death, and not cause unnecessary distress to the mourners who have to live with the memory for the rest of their lives.

## **Conclusion**

CMF is supportive of organ donation in principle. However we do not support presuming consent when it has not been given, nor do we support overriding the family and the important role they should play.

If this Bill becomes law, it is essential that the need to respect the views of the surviving family is within the legislation itself. The National Assembly for Wales should amend the Welsh Government's Bill to make this commitment clear.

Yours faithfully,

Philippa Taylor

**Head of Public Policy**

**Christian Medical Fellowship**

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## **British Medical Association Cymru / Wales**

**January 2013**

### Introduction

BMA Cymru Wales is pleased to provide evidence to Health and Social Care Committees inquiry into the general principles of the Human Transplantation (Wales) Bill.

The British Medical Association represents doctors from all branches of medicine all over the UK. It has a total membership of almost 150,000 including more than 3,000 members overseas and over 19,000 medical student members.

The BMA is the largest voluntary professional association of doctors in the UK, who speak for doctors at home and abroad. It is also an independent trade union. BMA Cymru Wales represents some 7,000 members in Wales from every branch of the medical profession.

### Overview

The BMA is delighted that the Welsh Assembly Government is showing strong leadership on this issue within the UK and is moving ahead with an opt-out system for organ donation in Wales. You may be aware that the BMA has been campaigning for an opt-out system for organ donation for many years. We are delighted that Wales is leading on this important change.

We are very pleased that the default position under the Bill, if people choose not to make their views known, will be to save lives. Over time this will lead to a change in philosophy within society so that donation becomes seen as the usual thing to do. As stated in our response to the consultation on the draft Bill, however, our preferred model is a standard form of soft opt-out as practised in other countries, rather than the combined opt-in/opt-out system proposed in the Bill. We have some concerns that introducing this 'hybrid' system carries some risks, of:

- making the system too complicated leading to confusion or misunderstanding
- making the already complex task of informing the public about the changes even more difficult
- leading to uncertainty among the family about the individual's wishes and
- ultimately, reducing some of the anticipated benefits.

We recognise that this may be an interim measure, in order to address the complications caused by other parts of the UK retaining an opt-in system, with a view to the whole of the UK moving to a full opt-out system in the future. If this is the case, this should be made clear as other parts of the UK will be closely monitoring the success of the Wales system as part of their own policy development.

If the system is adopted, as presently described – in either the short or the long term – it will need to be very carefully monitored. We support the Welsh Government's commitment to undertake research to identify areas that are both successful and also those that are less successful. Despite these concerns, we believe that, with proper and careful implementation, it will be a significant improvement on the current system.

In addition, the BMA:

- believes that opt-out should apply to those over 16 rather than 18
- questions the benefit of allowing people to nominate someone to make decisions after their death under an opt-out system;
- is unclear about the rationale for removing the possibility of consent from someone in a qualifying relationship if a nominated individual is unable to give consent
- believes the Bill should refer to the period during which the individual has had capacity, since the new system was in force, rather than how long they have lacked capacity and
- would wish to see a Regulation making power in the Bill to exclude certain forms of transplantation from the deemed consent provisions – such as face and limb transplants.

## Section 2 – Duty to promote transplantation

The way an opt-out system is implemented is crucial to its ethical acceptability. Key to this is that information about the new system, and how it will affect individuals, must be available to all people who will be affected by it. We are very pleased, therefore to see this duty to inform the public specifically included in the Bill. We also welcome the detailed consideration that has been given to how this will be achieved in practice (as set out in the explanatory memorandum).

## Section 4: Consent: adults

### *Opt-in/opt-out*

The consent model chosen by the Welsh Government differs from the model suggested by the BMA in its evidence to the consultation exercise. The Welsh system gives the individual more options to choose from - opt in, opt out, nominate a spokesperson to make the decision and also the essential change of principle which deems consent in the absence of any recorded decision. The BMA has concerns, however, that this is a complicated model that risks causing confusion for individuals. Conveying the range of options, and the differences between them, will add to the complexity of the message to be conveyed.

### *Nominated individuals*

A standard opt-out system would not include provision for nominated individuals and it is unclear why this has been included. The BMA is also concerned that where an individual has nominated someone to make the decision, and that person cannot be contacted, nobody else can give consent. This is a change from the current situation (under the Human Tissue Act 2004) and the rationale for this change is unclear. The Human Tissue Authority's code of practice says at para 108: '[t]he nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practicable to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship.' Not allowing anyone else to consent, if the nominated individual is unable to do so, increases the chance of organs being lost unnecessarily. For example, if a man nominated his wife to make decisions and both were involved in a road traffic accident such that she was unable to communicate his wish, the organs could not be used; even if other family members knew that he wished to donate, the Bill, as currently drafted, would prevent this from happening. If there is to be a system for nominating individuals to make decisions, the process should mimic that under the Human Tissue Act.

It is also unclear how, in practice, information about the fact that someone has appointed a nominated individual would become known to the treating team. Is there to be provision on the register for this? Or, is the onus on the individual to ensure, during his or her lifetime that this information is known to relevant people (such as the GP or family members) who can then inform the treating team? Given that a failure to recognise that the individual had nominated an individual would result in consent being deemed, it must be clear whose responsibility it is to establish whether someone has nominated an individual to make decisions.

## Section 5: Consent: excepted adults



The Bill includes as 'excepted adults' individuals who have lacked capacity for 'a significant period before dying' the BMA feels that the length of time they have lacked capacity is irrelevant. The relevant issue is whether they have *had* capacity for a reasonable period of time since the new system was implemented and therefore had the opportunity to opt out if they wished to do so. If it would be helpful to quantify this, rather than rely on subjective assessments of a 'reasonable period', it could be set at 6 months, in order to be consistent with the residency requirement and the period given to people approaching their 18<sup>th</sup> birthdays. An individual who dies 10 years after the new system came into force may have lacked capacity for nine years but in the first year, knew about the system and wanted to donate, therefore did not opt out. In our view this should be sufficient for consent to be deemed. Therefore, the definition of excepted adult should refer to the period for which they have had capacity, since the new system came into effect, rather than the period for which they have lacked capacity.

#### Section 6: Consent: children

The BMA believes that the opt-out system should apply at the age of 16, given that this is the age at which young people are legally deemed to be competent to make their own decisions. At 16, there is a presumption that young people can make all kinds of very important and complex decisions regarding their care and treatment including the decision to opt-in to organ donation. The BMA can see no reason for setting a different age for young people to opt-out of organ donation than for other important decisions.

#### Additional comments

##### *Relationship between this Bill and the Human Tissue Act 2004*

It is unclear why some parts of the Human Tissue Act relating to transplantation have been repeated in the Bill and others have not. For example, clause 12 of the Bill repeats the provisions for preservation for transplantation in the 2004 Act but the provisions in the 2004 Act concerning provision for living organ donation are not repeated in the Bill. Thus the consent provision for living donation is included in the Bill but not the safeguard of requiring Human Tissue Authority approval of all cases. The explanatory notes makes clear (at para 8) that this safeguard will still apply (under the 2004 Act) but for the avoidance of doubt, this should be made explicit.

##### *New forms of transplantation*

It is unclear whether the new system would apply to new forms of transplantation such as face or limb transplants. In the BMA's view express consent should continue to be required for such procedures for the foreseeable future, and a Regulation making power should be included in the Bill to exclude such forms of donation. Para 20 of the explanatory memorandum explains that such transplants are currently excluded from the current opt-in arrangements but does not state the situation regarding the Bill. Even if, in practice, new forms of donation would not be subject to deemed consent, there would be benefit in formalising this within the Bill for the avoidance of doubt. It would be unfortunate if, following a news story about face or hand transplants, a number of people opted out of donation erroneously believing their face or limbs could be used on the basis of deemed consent.

##### *Further information on the BMAs position*

Please find enclosed, for your information, a copy of the BMAs response to the Welsh Governments previous consultation which outlines further many of the points above.

## Draft Human Transplantation (Wales) Bill and Explanatory Memorandum:

### Consent to organ and tissue donation in Wales

#### Consultation response form

Name:	BMA Cymru Wales
E-mail:	lmerredy@bma.org.uk
Telephone number:	029 2047 4646
Address:	5 <sup>th</sup> Floor, 2 Caspian Point, Cardiff Bay
Town:	Cardiff
Postcode:	CF10 4 DQ
Organisation (if applicable):	BMA Cymru Wales

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, 4<sup>th</sup> Floor, Cathays Park Cardiff, CF10 3NQ or email to [organdonation@wales.gsi.gov.uk](mailto: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](http://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

### *Comments-*

The scenarios in the explanatory memorandum are helpful in this regard and we are glad that this section covers individuals who lack capacity and children and young people (paragraph 33 – 38). However more detail is needed about the role of clinicians in determining consent and talking to relatives.

It is particularly important to make clear that, in relation to the deceased wishes; any deemed consent will have legal precedence. Although this is covered in the explanatory memorandum the consultation document is not adequately clear with regards to the fact that families do not have a legal veto over the donation itself. But also that as currently stands, donation will not go ahead in the absence of member(s) of the deceased family - or a person in one of the relationships listed in the Bill - because they are needed to provide details about the deceased residency and lifestyle.

We believe the Bill also needs to be clear on the process that will be followed in a situation when the deceased family provide information about the deceased wishes which is considered to be unreliable / does not meet the criteria of being the 'sort of information any reasonable person could agree with'. There also needs to be supporting guidance for individuals involved in this process.

The role of the UK ODR and how it will work once the Wales register comes into existence needs further detail. This is especially the case for individuals from Wales who die outside of Wales, or individuals who are not from Wales but die in Wales.

There is some confusion regarding the situation of adults who lack capacity which needs to be clarified. There are two issues here. First, in paragraph 25 - it is suggested that adults who lack capacity can register a decision to be a donor or not to be a donor. If they lack capacity to make the decision, they cannot make the decision and consent will be needed from a qualifying relative after death. The situation is a bit clearer in paragraph 29, although it still refers to people who lack capacity registering views. This might be intended to refer to someone who lacks capacity but expressed a wish to donate, or not to donate, before capacity was lost but again care is needed with the wording to ensure that this is clearly explained.

Many patients lose capacity shortly before death - for example following a road traffic accident. These people, who previously had capacity, should not be treated as lacking capacity for the sake of this legislation. The relevant factor, in determining whether 'deemed consent' would apply should be whether the individual has had capacity at any time since the new legislation was introduced. If they had capacity and chose not to opt-out, they should be deemed to have consented and this should apply even where capacity has subsequently been lost. Where an individual has never had capacity, or lost capacity before the change in the law, they should not be deemed to have consented and it should be for the family or a nominated person to consent, or not.

The BMA believes that the opt-out system should apply at the age of 16, given that this is the age at which young people are legally deemed to be competent to make their own decisions. At 16, there is a presumption that young people can make all kinds of very important and complex decisions regarding their care and treatment including the decision to opt-in to organ donation. The BMA can see no reason for setting a different age for young people to opt-out of organ donation than for other important decisions.

## Question 2

Is the role of the family clear?

Yes  No

### Comments-

Despite paragraph 27 being clear that families do not have a legal veto, there is some wider ambiguity within the documentation about the role of the family. In paragraph 23 of the consultation document, it says the family 'will be able to provide information about [the individual's] wishes'. This implies that there would be no presumption in favour of donation. This section should also detail what kind of information would be acceptable.

In an opt-out system, the family should be asked if they were aware of any unregistered objection but would not be expected to try to guess what the individual would have wanted (because under an opt-out system, if individuals had not opted out, the presumption would be that they wished to donate). This may simply be a matter of loose wording but it is important to be absolutely clear on these points so as not to cause confusion.

The role of the family and the importance of talking to relatives and those close to you about donation should be a central message in the publicity surrounding the implementation and ongoing operation of this policy.

We believe that there should be further consideration here about the role of the clinician in talking to families and in determining consent.

On page 11-12 of the draft explanatory memorandum it says:

“Where relations do not produce any information about the wishes of the deceased, then they will be sensitively encouraged to proceed with organ donation. It is the case that those close to the deceased do not have the legal right to veto or overrule the decision of the deceased to have their consent deemed. Clinical teams will nevertheless, have a duty of care towards the surviving relatives and if there are very strong objections or distress, then organ donation is unlikely to go ahead.”

The use of the term ‘Duty of Care’ in this context, without definition or reference, causes us some concern. This phrase has adopted a very specific meaning in medicine and is strongly associated with the existence of legal obligations; and therefore may be subject to misinterpretation.

While the BMA takes a pragmatic approach to this – i.e we have previously said that insisting on donation in the face of the family’s strong and sustained opposition is likely to add to their distress as well as, potentially, generate public hostility towards organ donation - we are concerned as to what, in legal terms, this ‘duty of care’ would mean for the healthcare team.

To be clear, BMA Cymru Wales believes that clinicians must be sensitive to the views and beliefs of the family, but that this needs to be expressed appropriately and clearly in the legislation.

We therefore would recommend, unless there are overwhelming reasons to continue with the phrase ‘duty of care’ to replace it with reference to paragraph 29 of the General Medical Councils Good Medical Practice:

29. ‘You must be considerate to relatives, carers, partners and others close to the patient, and be sensitive and responsive in providing information and support, including after a patient has died. In doing this you must follow the guidance in Confidentiality.’

### Question 3

Are the arrangements for the registration of wishes clear    Yes     No

#### *Comments-*

It is important that both the Wales register and the UK Organ Donor Register map across each other effectively. The precise mechanism to ensure this takes place is unclear. It is also not totally clear as to whether a person can be on both the ODR and the Welsh register.

It is disappointing that despite option C (a register containing only opt-out information) being 'by far the most popular option' (page 21 of the explanatory memorandum) this is not what is being proposed. By giving people the option to both opt-in or opt-out using the register in Wales, there is a real risk that families who realise their relatives have not opted-in, when given the opportunity, will assume they did not want to donate and therefore object to donation. In reality many of these people will have wanted to donate and believed (entirely reasonably) that their decision not to opt-out was sufficient to ensure this wish would be acted upon. This introduces confusion and potentially undermines the system.

We can understand why it is desirable to give people in Wales the option to opt-in, in case they die outside Wales (before the rest of the UK has caught up and introduced an opt-out system) but we do not believe that the option chosen is the best way to achieve this. It would, in our view, have been better to keep the Wales register as just opt-out and allow people to sign up to the UK-wide ODR if they want to donate in the event of their death occurring outside Wales. This might lead to a few people being on both registers. In order to reduce the risk of this happening, when people sign up to the opt-out register they could be reminded that if they have already signed up to the ODR they should ask for their name to be removed. Duplication need not be problematic in practical terms. If someone has signed up to the opt-out register in Wales, and dies in Wales, their refusal will be binding and so the fact that they have also, at some stage in their life, given consent for donation is irrelevant. If they are on both registers and die elsewhere in the UK the fact they have opted out in Wales should be discussed with the family. Unless the family has specific information about the individual's intentions, it is likely that the most recent decision would be taken to represent the individual's wishes.

In the Equality Impact Assessment (paragraph 163) it is mentioned that the legislation allows people with strong religious beliefs to opt in to donation, 'thus preserving the concept that organ donation is a gift on an individual level'. This may have been an additional factor in the decision to allow people to actively opt-in using the Welsh register. The BMA believes that organ donation is always an individual gift and should be perceived and presented as such - a decision not to opt out is as much a gift as taking steps to opt in. Making this statement undermines this notion and, as explained above, allowing people to opt-in as well as opt-out using the Welsh register risks undermining the new opt out system.

The BMA strongly believes that:

- o the register in Wales should only record those who wish to opt-out of donation
- o individuals who live in Wales should be able to continue to sign up to the UK-wide ODR in case they die outside Wales

o when people opt-out in Wales they should be reminded that if they have previously signed up to the ODR they should now ask for their name to be removed in order to avoid confusion.

#### Question 4

Are the arrangements for establishing residency clear? Yes  No

#### *Comments-*

The three stage residency test, of which all criterion must be met, appears to be satisfactory although we are not best placed to answer this question.

Detail is needed as to whom will be participating in discussions with the next of kin, how they will be supported and the process to follow when uncertainty arises. There also appears to be a number of phrases in this section which require further legal definition such as 'ordinarily resident'.

We do not have any ethical objection for the appropriate use of medical records to assist in determining points two and three of the residency criteria.

We do not know enough about the local 'gazetteer' system for determining an individual's residency to be able to comment fully.



### 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

#### *Comments-*

We fully support the content of the EIA, we are especially pleased to see sections on disability, race and religion have been duly considered and feature prominently in the analysis. We have specifically raised the under-representation of the BME communities on the ODR as a concern and are pleased that it is recognised with specific action proposed to ensure that all communities are included in dedicated communication strategies.

### 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

#### *Comments-*

We fully support the need for a comprehensive communications campaign and for a reasonable period of time between the Bill receiving Royal Assent and coming into force – the two years lead in time does seem appropriate. It is essential for the success of this policy that the setting up of the register and informing people in all sections of society of the change, is undertaken openly, publically and seamlessly.

As we stated in previous consultation responses the BMA believes that publicity, dialogue and full public awareness are the biggest factors in the successful move to a system of soft opt-out. We are supportive of the proposed duties placed on the Welsh Ministers in relation to this.

The success of publicity around organ donation since the publication of the first ODTF report – for example the Tell a Loved One campaign - can be seen from the fact that, according to figures from NHS Blood and Transplant there has been a 49% increase in deceased organ donors in Welsh hospitals between 2007/08.

However, there still does need to be 100% public awareness of the change from opt-in to opt-out. This requires the use of every possible resource and communication tool and in multiple languages (including brail and sign) in order to reach all corners of Wales and all sections of society.

The publicity, information and dialogue behind this change needs to be fully and appropriately resourced, there is no doubt this will require dedicated investment.

It is vital that this publicity starts at school to get the issue of donation into the public consciousness and to ensure people – especially young people - know that they have a choice to make; this will also encourage dialogue with parents and families at home.

It is also important that high level publicity across the whole of Wales continues after implementation, to encourage continuing awareness of what will be a permanent system for Wales.

It will need renewed ideas on how to ensure that donation, and the choice individuals have to register their objection, becomes an embedded part of the Welsh identity and part of what it means to live in Wales. The Welsh Government will need to work closely with third sector groups – particularly those working with people new to Wales.

We are pleased that the Welsh Government has adopted the BMAs suggestion of safeguarding the rights of those who lack mental capacity by making every effort to help those lacking capacity to understand the change in law and make a decision along with support and involvement of a nominated or responsible adult.

All publicity requires imagination and new and different ways of communicating – including alongside the traditional mechanisms using concerts, sporting and cultural events, popular culture, social media, industry, agriculture, membership and professional organisations etc.

By no means will this be a small endeavour, and the importance of a sound communications strategy should not be underestimated if the scheme is to succeed and gain the confidence of the public and the professionals.

## 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:

### Specific Comments

Page 8, paragraph 30: it is not clear why, if a nominated person is unable to give consent, donation could not proceed with the consent of a qualifying relative. There could be a situation for example, where an individual nominated a partner to make the decision but both were involved in an accident and unable to communicate. In such circumstances, the individual's family may be willing to give consent but, based on the information here, would be unable to do so. It is not clear why that is the case and we would welcome clarity over the legal issues surrounding this.

Under the Human Tissue Act, if the nominated individual is unable to give consent, the nomination is disregarded and the family can give consent. (The HTA's code of practice says: 108. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practicable to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraphs 109–114). ) It is unclear why this is being changed.

Page 9, paragraph 31: people actually have four options because they could also nominate someone to make the decision for them, as explained in paragraph 29.

Page 10, paragraph 38: as mentioned in the general comments, it is essential that the legislation is clear that when talking about patients who lack capacity (for whom consent is not to be deemed), it is referring to patients who have not had capacity since the legislation came into force. If not, it could be taken to refer to all patients who lack capacity in the period leading up to their death and, as mentioned previously, most patients, who are being considered for donation, will lack capacity at that time.

### Regulatory Impact Assessment

Paragraph 102: the statement about Spain is misleading. Although the law is based on opt-out, in practice consent of the family is always sought and so it operates more in line with an opt-in system than an opt-out one.

Paragraph 153: we are unsure of the meaning of the following statement: "It must be emphasised again that if there is evidence available of the wishes of the deceased, those wishes should be respected with *no judgement regarding mental capacity*". It is stated earlier that when an individual signs up to the ODR there is no check on capacity. This is appropriate and in line with the law under which adults are assumed to have capacity unless there is reason to believe the contrary. This sentence appears to go further, however, and say that capacity is irrelevant, but in some circumstances it may be appropriate to consider capacity. If doubts are raised about the individual's capacity at the time the decision was made, for example, it would be appropriate to make further enquiries before relying on the decision, although the onus will be on those who argue there was a

lack of capacity to provide evidence to support their case.

### **In the draft Bill**

s15(4)(a) we assume this should be 2013 and not 2004?

### **General**

We would welcome more detail on the role of clinicians / the impact the changes may have on healthcare professionals. This would be especially useful, for example, in relation to talking to relatives, and in determining mental capacity as specified in this consultation document.

Detail is needed on the publication of accompanying guidance.

Consideration should also be given to what will happen as new forms of donation are found – such as face or limb donation. For example should an opt-in system continue to operate for these new forms of donation? This is an important consideration in any move to opt-out, especially as complicating the policy may encourage more people to opt-out of donation entirely. We have previously argued that face donation (or other new types of donation) should continue to be based on an opt-in system with consent required from the donor while alive or the family after death. Welsh Government legislation may therefore need to contain provision, such as a Regulation making power, in order to exclude certain organs from the opt-out system.

Importantly - and fundamental to the operation of an opt-out system - the issue of capacity in NHS Wales also needs to be considered. There are a number of questions which need answering in relation to this – can NHS Wales cope with an increased number of donors? Do we have the network, infrastructure and number of healthcare professionals in place to support this policy? Are there enough ITU beds? Are tissue retrieval teams located in the best possible sites to enable access to all hospitals in Wales within one hour? And will performance / success be monitored - and if so, how?

## **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:

Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)19 – Christian Medical Fellowship

Dear Sir/Madam,

Thank you for the opportunity to respond to the consultation on the Human Transplantation (Wales) Bill.

Please find attached our response which is also detailed in full following.

CMF has over 4,000 British doctors and 800 medical students as members. Through the International Christian Medical and Dental Association (ICMDA) we are linked with like-minded colleagues in over 90 other countries. 154 doctor members reside in Wales and there are 63 student members at the two Welsh medical schools.

The Christian Medical Fellowship has on a number of previous occasions expressed concern with the principles underpinning this Bill. We sent in a detailed response to the initial public consultation:

[http://admin.cmf.org.uk/pdf/publicpolicy/Welsh\\_organ\\_donation.pdf](http://admin.cmf.org.uk/pdf/publicpolicy/Welsh_organ_donation.pdf)

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We note that similar concerns have been raised by other religious groups, notably Catholic and Muslim organisations.

### **Can consent truly be ‘presumed’?**

Presumed consent in effect equals no consent, unless there is an extensive public information programme, which would need to capture *the entire adult population* including those on the margins of society. Only this would ensure that those who do not opt out of donation have made an explicit choice, rather than doing so by default, by ignorance or by a lack of knowledge or understanding.

It will be almost impossible to guarantee that everyone is informed and understanding of ‘deemed consent’, knows their options and can easily opt out. Can consent be truly assumed from those who are disorganised, apathetic, disabled, less well educated or informed, isolated, lacking full capacity, of different languages and race, suffering from (temporary) mental illness, dependent, those who have less ready access to information and those who change their minds? As a minimum, the importance of allowing families a veto in such cases is obvious.

This makes the whole concept of ‘presumed’, or ‘deemed’, consent ethically problematic as well as complex, and very costly, to administer.

It is not even the most effective way to increase organ donor numbers. Research published in Transplantation has found that donation rates in countries with opt-out laws do **not** differ dramatically from countries requiring explicit (opt-in) consent. Moreover: ‘...countries with the highest rates of deceased donation have national and local initiatives, independent of PC, designed to attenuate the organ shortage.’ (See also: Coppen, R., Friele, R., Marquet, R. and Gevers, S. (2005). ‘Opting-out systems: no guarantee for higher

donation rates.' Transplant International 18: 1275-1279).

## **The Role of Families**

Although the Welsh government has said all along that it will introduce 'soft' opt-out legislation, allowing the family of the deceased a role in the final decision, **the Bill as it stands does not in fact allow for this**. While provision is made in the draft memorandum (p20), there is no provision in the Bill itself for providing distressed relatives with a right to object to the removal of organs when no consent was given by the deceased.

Some people fear that if they became seriously ill, they would receive less thorough treatment if they were donors than if they were non-donors because doctors want their organs. This fear – which need not be well founded to have an effect – would increase if the family's views were known to be overridden. People look to their families to protect them when they cannot protect themselves.

The Bristol and Alder Hey controversies were fuelled by the perception that families had no real power in decision-making with respect to what happened to their loved one's body parts. They also showed how crucially important the body is to bereaved parents and friends, and illustrated the need to respect the human body, even in death, and not cause unnecessary distress to the mourners who have to live with the memory for the rest of their lives.

## **Conclusion**

CMF is supportive of organ donation in principle. However we do not support presuming consent when it has not been given, nor do we support overriding the family and the important role they should play.

If this Bill becomes law, it is essential that the need to respect the views of the surviving family is within the legislation itself. The National Assembly for Wales should amend the Welsh Government's Bill to make this commitment clear.

Yours faithfully,

Philippa Taylor

**Head of Public Policy**

**Christian Medical Fellowship**

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**The National Assembly for Wales Health and Social Care Committee**

**Consultation on the Human Transplantation (Wales) Bill**

**January 2013**

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It will be almost impossible to guarantee that everyone is informed and understanding of 'deemed consent', knows their options and can easily opt out. Can consent be truly assumed from those who are disorganised, apathetic, disabled, less well educated or informed, isolated, lacking full capacity, of different languages and race, suffering from (temporary) mental illness, dependent, those who have less ready access to information and those who change their minds? As a minimum, the importance of allowing families a veto in such cases is obvious.

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## Submission by the Society for the Protection of Unborn Children (SPUC) to the Health and Social Care Committee of the National Assembly of Wales regarding the *Human Transplantation (Wales) Bill*

The intent of this Bill to increase organ donation rates is laudable, and this is demonstrated in Wales which has amongst the highest organ donation rates in Europe.<sup>1</sup> Organ donation is generally viewed in a positive light in the community and its representation as a ‘gift of life’, when carried out in an ethically sound manner, is well established. This perspective is particularly the case for the major faiths, and the Catholic Church for example has described organ donation as contributing to an “authentic culture of life”.<sup>2</sup>

There are two key principles that underlie an ethically sound approach to organ donation. The first is that a donation is a gift that should be voluntary and free from any coercion. The second is that the human dignity of both donor and recipient must be paramount. Both donor and recipient should be provided with the best medical care available prior to and during transplantation, and where death occurs, the deceased must be treated with dignity. Does this Bill uphold these principles, and what other issues does it raise?

### *Consent*

Informed consent is now firmly established as one of the key principles that underlies modern medical practice. Informed consent ensures that individuals have sovereignty over their body and are able to have a say in how they are to be treated. This extends beyond death inasmuch as respect for the deceased person also means respect for their wishes about how their body is to be treated after death.

This Bill treats the notion of consent in an incongruous way to the extent that what is commonly understood by consent is at risk of being corrupted.

An opt out system is often referred to as a presumed consent system, the idea being that where someone’s wishes are not known we might presume upon some grounds what they might actually have wanted. The Bill goes one step further by using the phrase ‘deemed consent’. The meaning conveyed by this terminology is that the State is simply able to call lack of consent, consent. That is to say, it renders the notion of true consent meaningless by confounding it with its opposite.

*The idea that the absence of an objection represents informed consent is plainly nonsense and consent that is not informed is valueless.*<sup>3</sup>

On several occasions the Bill’s Explanatory Memorandum perpetuates the incongruity.

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<sup>1</sup> <http://www.bbc.co.uk/news/uk-wales-politics-16797510> and <http://www.walesonline.co.uk/news/wales-news/2012/08/23/organ-transplants-in-wales-increase-18-as-uk-donations-hit-record-highs-91466-31684837/#.UPcQd8JBYyN.email>

<sup>2</sup> Address by Pope John Paul II to the 18<sup>th</sup> International Congress of the Transplantation Society 2000. See [http://www.vatican.va/holy\\_father/john\\_paul\\_ii/speeches/2000/jul-sep/documents/hf\\_jp-ii\\_spe\\_20000829\\_transplants\\_en.html](http://www.vatican.va/holy_father/john_paul_ii/speeches/2000/jul-sep/documents/hf_jp-ii_spe_20000829_transplants_en.html)

<sup>3</sup> Rafael Matesanz & John W Fabre, Too many presumptions: Advocates of a presumed consent system of organ donation are ignoring the weakness of the evidence. *The Guardian* 17 November 2008. See <http://www.guardian.co.uk/commentisfree/2008/nov/17/organ-donation-health/print>

*When it comes to giving consent to organ donation, it is for the deceased to decide whether to opt in, opt out or have their consent deemed.*<sup>4</sup>

But how can the deceased be said to have decided whether to have their consent deemed when the driver behind deemed consent does not know what the deceased would have wanted?

Furthermore, by setting into law an incongruity, this Bill risks corrupting the notion of informed consent so that its operation in other contexts might also become confounded. For example, might the concept of deemed consent be applied to organs and tissues for research or commercial purposes in the future? What about Involuntary euthanasia as practised in Holland and Belgium, where the patient is unable to resist, the doctor or nurse may feel 'empowered' to administer a fatal dose on the grounds that the patient can be presumed to have given consent because she did not leave a living will to forbid it.<sup>5</sup>

Moreover, the principle of free and informed consent is the cornerstone of opposition to the commercialization of organ 'donation', and more particularly the deplorable business of trafficking in human organs. Erosion of this principle in one context such as promoted by this Bill, will lead to its erosion in these other contexts where exploitation occurs, making them more difficult to control.

Implementation of an opt out system is based upon the hope that the donation rate will increase. Whether it will is addressed below, but despite the Explanatory Memorandum attempting to suggest that deemed consent is a choice someone makes, in reality it is more than likely that some who do not wish to become organ donors will end up having their organs removed. At the very least, deemed consent means we simply do not know, but given the fact that a significant number in the community do not want to donate their organs, any increase in donation rate will likely come from these people. Evidence from previous consultations show that voluntary organ donors often strongly resent their donation being taken for granted and turned into a compulsory 'donation'.<sup>6</sup>

Wellesley describes it as follows:

*Despite only 29% of the population being on the NHS organ donor register, when families are asked if they will offer their deceased relative's organs for donation, 59% agree. This figure is remarkably similar to the 62% of adults who say they would be happy to donate their organs. There doesn't appear to be a significant gap between the proportion of people who actually donate and those who say they are willing to do so.*

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<sup>4</sup> Welsh Government, *Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes*, 3 Dec 2012, p18 at 42.

<sup>5</sup> Stateline Centraal Bureau voor de Statistiek, Deaths by Medical end-of-life decision; age, cause of death. Updated on 11 July 2012.

<http://statline.cbs.nl/StatWeb/publication/?VW=T&DM=SLen&PA=81655ENG&LA=en>;

Bregje D Onwuteaka-Philipsen et al, Trends in end-of-life practices before and after the enactment of the euthanasia law in the Netherlands from 1990 to 2010: a repeated cross-sectional survey, *The Lancet*, July 2012; [http://press.thelancet.com/netherlands\\_euthanasia.pdf](http://press.thelancet.com/netherlands_euthanasia.pdf); Els Inghelbrecht et al, The role of nurses in physician-assisted deaths in Belgium, *Canadian Medical Association Journal*, 6/15/10 vol. 182 no. 9 <http://www.cmaj.ca/content/182/9/905.full.pdf+html>

<sup>6</sup> <http://wales.gov.uk/consultations/healthsocialcare/organ/?lang=en&status=closed> See responses 41, 54, 88, 91, 116 & 32 others in White Paper Consultation Nov. '11 -Jan.'12

*If an opt out system is able to achieve donation rates higher than 62% then it must be taking organs from unwilling donors.<sup>7</sup>*

He goes on to say:

*Given that consent rates are already 59%, we do not need a radical overhaul of the system; we need ways of encouraging people to want to donate.<sup>8</sup>*

One of the problems with the current system is that there remains uncertainty about consent to organ donation. That is, some who may be candidates for organ donation have not joined the organ donor register, and next of kin end up deciding on their behalf, or if there are no surrogate decision makers, the uncertainty means donation does not proceed. However, an opt out system does nothing for uncertainty and in fact there is the potential for it to be exacerbated if poor communication means people remain unclear about how the system works, or if there is a backlash through loss of trust in the authorities.

Deemed consent also corrupts the notion of donation itself. When someone gives freely of something so precious that allows another to live, it involves a certain respect for persons to honour that free choice. Just as commercialization of organ 'donation' would diminish human dignity by placing a monetary value upon body parts, that is, effectively objectification, deeming consent diminishes human dignity by taking body parts from someone without knowing anything about their deeply held core beliefs relating to treatment of their body after death. For some religious groups this is particularly pertinent.

Considerable effort has gone into establishing the conceptual and cultural framework surrounding organ donation as a free gift. Implementing an opt out system risks gradually undermining that effort. While this does not *appear* to have happened in countries like Spain, its highly coordinated transplant system is almost certainly responsible for the high rates, and the opt out aspect of the system may be doing nothing directly or may hinder even better rates. Matesanz describes the presumed consent law as irrelevant to their high donation rate.<sup>9</sup>

Organ donation as a freely given gift is also important for recipients. Might they not want to be assured that the organ they have received was genuinely *donated* by someone? Concern about how organs are obtained is likely to be an important question of conscience for recipients and potential recipients alike.

### *State Overreach and Trust*

The question of trust or maintaining good faith regarding organ donation relates to both the health professions and to the State.

Trust has already been damaged by the Alder Hey scandals about tissue and organ retention without consent, and while it is not known to what extent these practices may have influenced organ donation rates, there is at least reason to suspect they might have done so. The Human Tissue Act 2004 was enacted to restore trust by embedding the concept of informed consent. There have been two periods when there was a significant drop in the donation rate: when Panorama identified a significant chance of organ

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<sup>7</sup> Hugo Wellesley, A nudge in the right direction for organ donation – but is it enough? *British Medical Journal* 343:778-9, 15 Oct 2011.

<sup>8</sup> *Ibid.*

<sup>9</sup> Matesanz & Fabre, *Op. Cit.*, 2008

donors being left untreated in A&E<sup>10</sup> and the Alder Hey scandal.<sup>11</sup> Currently, those who don't wish to become donors cite reasons related to trust.

... concern about “the level of respect given to a deceased person’s body” and “whether doctors make every possible effort to help patients identified as potential donors” are two of the most commonly cited reasons for not wanting to register as a donor.<sup>12</sup>

With an opt out system, the State, through the health system and professions, might be seen as ‘taking’ organs without explicit consent. Some will view this as State overreach, and there is then a risk that this could exacerbate the somewhat damaged trust that already exists in this sensitive area about the use of organs and tissues at the time of death.

Some might argue that since the next of kin and other surrogates can decide on behalf of a person why shouldn't the State be permitted to do likewise? But the State is not in the type of relationship to the individual to be able to consent on his or her behalf. It does not have the personal knowledge or interest necessary to act in that role. As such, an opt out system represents an unacceptable level of interference by an impersonal State in personal life.

An opt out system therefore has the potential to further alienate those who already mistrust the authorities. A perusal of feedback from the public about opt out plans reveals significant numbers of people who currently are registered to donate, but who would deliberately opt out in protest about state interference if a presumed consent system were introduced.<sup>13</sup>

Additionally, there are other concerns about practices within organ transplantation that are controversial and have the potential to lead to mistrust. These primarily surround determination of death criteria.<sup>14</sup> As David W Evans MD, FRCP has noted:

“the basis upon which a mortally sick patient is declared “deceased” – for the purpose of

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<sup>10</sup>[http://journals.lww.com/transplantjournal/Citation/1996/12150/The\\_Panorama\\_Effect\\_on\\_Altruistic\\_Organ\\_Donation.37.aspx](http://journals.lww.com/transplantjournal/Citation/1996/12150/The_Panorama_Effect_on_Altruistic_Organ_Donation.37.aspx)

<sup>11</sup> <http://news.bbc.co.uk/1/hi/health/1475676.stm> Eye transplants hit by Alder Hey

<sup>12</sup> Hugo Wellesley, A nudge in the right direction for organ donation – but is it enough? *British Medical Journal* 343:778-9, 15 Oct 2011.

<sup>13</sup> This issue has been raised by others [for example, Simon Bramhall, Presumed consent for organ donation: a case against. *Ann R Coll Surg Engl* 93(4):270-272, May 2011]. See also public forums, for example: <http://www.guardian.co.uk/society/2012/jul/27/nhs-organ-donor-optout-transplants#start-of-comments>

<sup>14</sup> In a recent paper in the *New England Journal of Medicine*, [Boucek MM *et al.*, Pediatric Heart Transplantation after Declaration of Cardiocirculatory Death. *NEJM* 359:709-714, 2008] heart transplant surgeons described how they modified the definition of death for three brain-damaged infants whose hearts were removed for transplantation into three other infants with severe heart problems. The controversy surrounds the likelihood that the children were not in fact dead. The journal invited two bioethicists, Robert Truog and Franklin Miller, to write a commentary [The Dead Donor Rule and Organ Transplantation. RD Truog & FG. Miller, *NEJM* 359:674-675, 2008], which is when the controversy really began to deepen. The essential line taken by Truog and Miller is that it really doesn't matter whether the patient is dead or not. Instead what really counts is whether informed consent has been given. In their assertion that it is “perfectly ethical” to remove organs from patients who are *not really* or *convincingly* dead, they give voice to the utilitarian ethic, which is that the outcome – organs that save people's lives - is really so good that traditionally unethical means can be justified.

acquiring his or her organs for transplantation without legal difficulties – is very different from the basis upon which death is ordinarily diagnosed and certified and that highly relevant fact is not fully and generally understood.”

The proposals ignore the facts concerning this area of scientific dispute, yet this is a question with enormous ethical implications. Most organ donors are unaware that their hearts may be beating when their organs are taken, and that they may be pink, warm, able to heal wounds, fight infections, respond to stimuli, etc. They are also unaware of common practices of paralyzing and (sometimes) anaesthetizing supposedly brain dead donors before their organs are taken. Simply signing a donor card does not in any way indicate that the prospective consenting donor understands what will be involved, and those who are merely ‘presumed to consent’ are likely to know even less.

It is extraordinary that the issue of determination of death, which must govern consideration of so many other issues in organ donation, is so often ignored, in spite of the US President’s Council findings (see appendix) and the growing scholarly literature on the question. That the public are not made aware of the controversy, even in a consultation on organ donation, is deeply regrettable. Notions of informed consent, let alone presumed consent, are meaningless unless the facts of the matter are openly discussed and considered.

As the public detects the erosion of important values in the quest for more organs they will begin to wonder whether too much has been traded. There is already enough risk of generating mistrust from these controversial practices without introducing more. The question of whether so-called ‘brain-death’ or ‘brain stem death’ is actual death.

### *Justice*

There is another reason, based upon justice and equity, why an opt out system is likely to be problematic. Those who are marginalized, poor, disabled, or disenfranchised for whatever reason, and without families or other advocates to stand up for them, are likely to be the ones who either never hear about how the scheme works or suffer some dysfunction such that they never get to the point of making a decision or acting upon it.

It is these vulnerable groups who should be the very ones the State is supposed to care for and whose rights it should defend. An opt out system, by unintentionally disproportionately targeting such individuals for deemed consent, represents an abrogation of the State’s role to impartially protect all members of the community.

*Inevitably, the socially disadvantaged and poorly literate will be less aware of their rights, less likely to care about them in advance and less likely to have confident advocates in the face of medical authority at the time of their deaths.*<sup>15</sup>

### *Will it Work?*

Whether opt out systems *per se* increase organ donation rates remains controversial, and more research is needed to ascertain any potential effect one way or the other.

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<sup>15</sup> Matesanz & Fabre, *Op. Cit.*, 2008

To the readers of this submission the following conclusion from the UK's Organ Donation Taskforce in 2008 will probably be familiar:

*"...after examining the evidence, the Taskforce reached a clear consensus in recommending that an opt out system should not be introduced in the UK at the present time. The Taskforce concluded that such a system has the potential to undermine the concept of donation as a gift, to erode trust in NHS professionals and the Government, and negatively impact on organ donation numbers. It would distract attention away from essential improvements to systems and infrastructure and from the urgent need to improve public awareness and understanding of organ donation. Furthermore, it would be challenging and costly to implement successfully. Most compelling of all, we found no convincing evidence that it would deliver significant increases in the number of donated organs."*<sup>16</sup>

Spain is often cited as an example of the success brought about by opt out systems. However, notably Spain changed its legislation to an opt out system 10 years prior to any change in the donation rate. What made the difference was a highly coordinated transplant system with a focus on intensivists in all major hospitals. According to the Clinical Director of the *Organizacion Nacioanl de Trasplantes* in Madrid, Rafael Matesanz, the evidence for a positive impact of presumed consent is very thin.

*... it [an opt out system] contributes little or nothing to the improvement of organ donation rates and, on the debit side, diverts precious resources to imaginary rather than effective solutions.*<sup>17</sup>

A systematic review of the impact of presumed consent on organ donation rates concluded that an opt out system alone could not account for increased donation rates and whilst there was an association between presumed consent and increased rates, no evidence for causality exists.<sup>18</sup>

A more recent review of kidney donation rates similarly found that countries with presumed consent had higher rates of deceased donation, but notably, kidney donations from live donors were lower.<sup>19</sup> Again, no causal relationship between presumed consent and increased donation rates could be shown.

What then are those things which are likely to make the most difference?

They include factors that influence the numbers of potential donors, such as motor and other accident rates, population age distribution, and the way that death is determined. Also critical are how coordinated the transplant system is, community wealth and investment in health care, and most importantly, the attitudes of the public to organ donation and their level of awareness. And central to public attitude is trust, which will be affected by the degree of ethical probity.

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<sup>16</sup> The potential impact of an opt out system for organ donation in the UK. An independent report from the *Organ Donation Taskforce*. Nov 2008, p 23.

[http://www.dh.gov.uk/prod\\_consum\\_dh/groups/dh\\_digitalassets/@dh/@en/documents/digitalasset/dh\\_090303.pdf](http://www.dh.gov.uk/prod_consum_dh/groups/dh_digitalassets/@dh/@en/documents/digitalasset/dh_090303.pdf)

<sup>17</sup> Matesanz & Fabre, *Op. Cit.*, 2008

<sup>18</sup> Rithalia A, McDaid C, Suekarran S, Myers L & Sowden A, Impact of presumed consent for organ donation on donation rates: a systematic review. *British Medical Journal* 338, a3162, 2009

<sup>19</sup> Horvat LD, Cuerden MS, Kim J, Korval JJ, Young A & Gard Amit X, Informing the Debate: Rates of Kidney Transplantation in Nations with Presumed Consent. *Annals of Internal Medicine* 153:641, 2010

## *Impact on Next of Kin*

An important element of this particular opt out approach is that it is described as ‘soft’, meaning that the next of kin have a say in what is to happen. The explanatory memorandum makes it clear that this soft approach will not lead to exclusion of families at a time of significant distress. However, the Explanatory Memorandum also perpetuates the myth that deemed consent means honouring the wishes of the deceased, and this is what really counts, not what relatives might want.

*... it is, as a matter of law, the wishes of the deceased which are relevant.<sup>20</sup>*

And,

*Where relations do not produce any information about the wishes of the deceased, then they will be in a position of knowing the deceased had not opted out, and had made no further wishes known. In these cases, the default position is that the deceased was in favour of donation and, as a matter of law, the deceased’s consent is deemed.<sup>21</sup>*

In the end, the Bill makes it clear that the next of kin have no power of veto. Even so, the Memorandum states that clinical teams will not “add to the distress of families by insisting on donation”. Which means that, despite the lack of power of veto, effectively families have the final say if they wish, just as they currently do.

What then will this Bill have really changed?

Perhaps in reality what will have changed is that there may now develop a degree of coercive influence over families to agree to donation even though they may be distressed by doing so. Some may comply because the “information” they are able to provide is not, in the eyes of clinical authority, strong enough. To them however, there may be real reasons which are difficult to articulate, especially given the intensity of grieving at such a time.

Dealing with relatives about organ donation at the time of the death of a loved one is hard enough and the approach has always been one of gently encouraging donation.

This Bill risks shifting practice towards more persuasion and perhaps even coercion.

The Bill should be consistent with the expressed concern for the welfare of the next of kin and permit them to have power of veto. Questions can be raised about whether such safeguards for the family will be implemented and respected, and for how long.

## *Other Issues*

### CONSCIENTIOUS OBJECTION

The Bill makes no provision for conscientious objection. This is an important oversight given that considerable objections have been expressed on moral grounds to presumed consent systems. Health professionals ought to be assured by specific reference in this Bill to their right to conscientiously object to practices they may wish to absent themselves from with an adequate explanation on moral, cultural or religious grounds.

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<sup>20</sup> Welsh Government, *Explanatory Memorandum Incorporating the Regulatory Impact Assessment and Explanatory Notes*, 3 Dec 2012, p19 at 44

<sup>21</sup> *Ibid.*

#### WHAT TISSUE, WHAT ORGAN, WHAT PURPOSE?

The Bill permits at 3(2)(b) “removing from the body of a deceased person, for use for that purpose, any relevant material of which the body consists or which it contains.” Relevant material includes anything which “consists of or includes human cells” but excludes embryos, gametes, hair and nails.

Little attention has been given to the different significance of organs and other body parts that can or may be transplanted in the near future. A presumed consent system that effectively transfers ownership of the body to the State could mean that *any* organ or tissue can be used for transplant. There are some important nuances here that relate to identifiability of the deceased as well as to reproductive continuity. In recent surgical operations, faces and whole limbs have been transplanted. Other transplant techniques may permit gonadal tissue to be transplanted, leading to the potential for children to be born whose biological parents are deceased. The purpose for which transplants could be used may also raise ethical questions. For example, genitalia from deceased people may be able to be transplanted in sex change operations, or tissues may be used for cosmetic surgery. While a discussion about the ethics of these matters should take place sooner rather than later, as far as the issue of consent is concerned, ethically more contentious transplantation would become more rather than less problematic under a presumed consent system.

Furthermore, greater interest in foetal tissues for transplant, coupled with no right of veto for next of kin under this Bill, could risk significant distress for women at a very traumatic time. The point is, an opt out system represents a shift away from the rights of the deceased, and also from the rights of the next of kin. If a culture develops within the health system that ‘presumes consent’, there is a real risk of a corrosive effect upon people’s ability to have a genuine say in the face of medical authority.

#### EFFECTIVENESS OF A COMMUNICATIONS STRATEGY

Whenever opt out systems are promoted, advocates always emphasise how effective communication will be to ensure that everyone has clearly had the opportunity to decide to opt out. This is naïve. Besides the fact that the interest in doing so is a recognition that to deny someone that opportunity is a denial of a basic right, in reality communication is never that good and as stated before, the disadvantaged are by far less likely to hear or effectively process such a message. For example, it will be very challenging to ensure effective information for non-English or non-Welsh speaking visitors, people who do not have access to the internet, people who have audio or visual impairments.

If this Bill does pass, what is the likelihood of communications strategies effectively addressing key aspects of organ donation including detail about determination of death and that there remain significant unresolved ethical issues and strong differences of opinion about the process and also about what is being proposed by some in the field? It is also important that people are aware of what can and will be transplanted. If *informed* consent is really the gold standard, then the Government must treat it as such.

There can also be genuine concern that because the Welsh Government appears committed to a presumed consent system, the communications strategy will reflect that position and communicate any putative benefit at the expense of the risks, both ethical and practical.



**Submission by the Society for the Protection of Unborn Children (SPUC)  
to the Health and Social Care Committee of the National Assembly of  
Wales regarding the *Human Transplantation (Wales) Bill***

**APPENDIX: Brain Death Controversies**

The US President's Council on Bioethics in December 2008 was highly critical of current UK practice of seeking to identify 'brain-stem death' as a sufficient basis for the diagnosis and certification of death for transplant purposes. (President's Council on Bioethics, *Controversies in the Determination of Death* (Washington, D.C.: President's Council on Bioethics, 2008)). An influential recent paper on the subject by D. Alan Shewmon ("Brain Death: Can it be Resuscitated" *Hastings Centre Report* 39.2 (2009): 18-24) critically assesses the Council's work and makes a strong case against current UK practice in relation to 'brain stem death', as well as US practice in relation to 'whole brain death'. As Shewmon notes in the paper:

"Just as cigarette ads are required to contain a footnote warning of health risks, ads promoting organ donation should contain a footnote along these lines: "Warning: It remains controversial whether you will actually be dead at the time of the removal of your organs. This depends on the conceptual validity of 'position two' in the analysis of the determination of death conducted by the President's Council of Bioethics. You should study it carefully and decide for yourself before signing an organ donor card." Similarly in conversations with families of patients in total brain failure, representatives of organ procurement organisations should frankly disclose the existence of ongoing controversies over whether their loved one is dead or in a deep, irreversible coma. Of course such information is never given, neither to the public nor to individuals, because it would likely decrease the number of donated organs."

There have been documented cases of 'brain dead' patients maintaining bodily functions for months or even years; for example, growing up and passing through puberty in the case of a child, or sustaining a pregnancy and giving birth to a baby in the case of a pregnant woman. See D. Alan Shewmon, "The Brain and Somatic Integration: Insights Into the Standard Biological Rationale for Equating 'Brain Death' With Death", *Journal of Medicine and Philosophy* 26.5 (2001): 457-478. Moreover, it is well-known to transplant teams that heartbeating donors move when organs are taken, unless they are paralysed by drugs, and that their blood pressure goes up when the incision is made. It is worth noting that some anaesthetists recommend that the supposed 'cadaver' be anaesthetised when his/her organs are retrieved.

Given that the Government is committed to the expense of a programme of public education, would it not make more sense, especially given the poor likelihood of success of an opt out system, to implement an education programme directed at enhancing people's free choices to participate in organ donation. The approximately 40% of the population not prepared to donate represents fertile ground for changing people's minds.

### *Conclusion*

The context in which organ donation occurs is clearly an ethically sensitive one for a range of reasons. The living grieve the loss of a loved one in very unique and personal ways, and while some find some comfort in knowing the death contributed to good for others, some also struggle with uncertainty about whether they made the right decision and honoured the deceased wishes or not. The whole business rests on a fine balance of trust, sensitivity, respect, transparency and genuine care.

It is too great a risk to implement a system which will damage these goods, and an opt out system is such a system.

Other nations have had significant success without presumed consent, and some with it have lower rates than Wales<sup>22</sup>. It is no panacea, and what will be lost in the longer term is not worth any potential short term gain.

Wales should look to the US and Spain's systems of coordination to enhance its donation rates, and set aside deemed consent thereby ensuring it preserves carefully considered and long standing ethical norms.

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<sup>22</sup> For example, Sweden and Israel.



## **Health and Social Care Committee inquiry on the Human Transplantation (Wales) Bill**

Response from BHF Cymru  
January 2012

British Heart Foundation (BHF) Cymru is the nation's leading heart charity. We are working to achieve our mission of a world in which no-one dies prematurely of heart disease. Heart and circulatory disease is Wales' biggest killer claiming over 9,000 lives each year, nearly a third of all deaths. We fund ground breaking medical research, provide support and care to people living with heart disease and advocate for change. We rely on donations from the public to fund our life saving work.

BHF Cymru warmly welcomes this consultation on the Human Transplantation (Wales) Bill. We strongly support the Welsh Government's introduction of a soft opt-out organ donation system and highlighted this in our response to last year's White Paper consultation. BHF Cymru would welcome the opportunity to provide oral evidence alongside this submission.

Currently, heart transplants offer the best chance of long term survival for those patients with severe heart failure. Although the British Heart Foundation's work includes research into regenerative medicine, success of which would render the need for transplants obsolete, for now a heart transplant remains the only hope for survival for patients with severe heart failure.

Unfortunately the current organ donation system does not provide enough organs. Statistics show a continued disparity between levels of support and donation with research showing 65% of the population support organ donation, yet only 25% are signed up to the organ donation register.<sup>1</sup> Until this disparity is resolved, 3 people a month continue to die in Wales whilst waiting for a transplant. Similarly, a number of patients will also deteriorate beyond the point of donation whilst waiting for an organ. Real figures of those in need of transplant are likely to be higher, given that some patients are not placed on the register as their chances of receiving a transplant in time, under the current system, are slim.<sup>2</sup> In the UK in 2011/2, 508 patients died while on the active waiting list for their transplant and a further 819 were removed from the transplant list.<sup>3</sup>

BHF Cymru recognise that soft opt-out legislation in itself is not a 'magic bullet' but rather a key facilitator which must be introduced alongside an organised infrastructure and increased public awareness for a soft opt-out system to succeed.

### **Cost effective**

BHF Cymru agrees with the Explanatory Memorandum that organ donation is a cost effective measure. Even with a small increase in donors the cost of implementing a soft opt-out system will be balanced by the savings made by reducing medical management of

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<sup>1</sup>Organ Donation Task Force. (2008) *The potential impact of an opt-out system for organ donation in the UK*. Department of Health website: pg. 8

[[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_090312](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312)]

<sup>2</sup>Ibid, pg. 6

[[http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH\\_090312](http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_090312)]

<sup>3</sup>NHS Blood and Transplant. (2012) *Organ Donation and Transplantation Activity Report 2011/12*. Pg. 2.

[[http://www.organdonation.nhs.uk/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/activity\\_report\\_2011\\_12.pdf](http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2011_12.pdf)]

conditions, as more donors become available. It is estimated that over a ten year period there would be a net benefit of £2.4million per transplant.<sup>4</sup>

Additional to financial benefits, those who receive donor hearts can see their life expectancy increase from only 1.5 years on medical management, to 18 years.<sup>5</sup> No other form of medical intervention can provide this result. Alongside these financial benefits, there will also be significant psychological gains for patients that no longer have to receive on-going medical management and have the peace of mind of longer term survival.

## International Comparisons

In the UK, Wales has the highest organ donation rate with 28 per million population (pmp).<sup>6</sup> However, compared internationally this figure is low and heart failure patients are still dying unnecessarily. International data shows that an opt-out system is associated with higher donation rates and several studies suggest that it would increase the numbers of organs available for transplantation by up to 30% in the UK.<sup>7</sup> This means that Wales could possibly project an increase of between 14 and 54 donors over a 3-5 year period after the introduction of opt out legislation. Spain, who adopted a soft opt-out system in 1979 now has the highest rate of donation in Europe at 35.3%.

Although caution should always be exercised when comparing health services internationally due to the range of influencing factors including social norms, there nevertheless remain some factors that we can draw comparisons with in Wales such as the importance of infrastructure and public awareness, both of which are highlighted below.

## Promotion

BHF Cymru expressly supports the Welsh Government's inclusion of a sustained, wide reaching public awareness campaign. We also back the Welsh Government's aim to engage all cultural groups within Wales, especially within the Black and Minority Ethnic (BME) community which has significantly low levels of donation, representing just 4% of the organ donation register and a high refusal rate of deceased families with 75% BME families likely to refuse donation.<sup>8</sup> A number of reasons are responsible for this, including religious beliefs, a reluctance to discuss with family and lack of information about donation. The Welsh Government must work hard to ensure they reach out to this community.

BHF Cymru believes that the public awareness campaign also needs to address the issue of family refusal. The main reason for this refusal is that the family did not know the wishes of their deceased. NHS Blood and Transplant (NHSBT) cite that 45% of family refusal is due to families not discussing their wishes.<sup>9</sup> Therefore an important part of the awareness campaign should be encouraging families to make their wishes known before they die.

Additionally, part of the Post Implementation Review, as outlined in the Explanatory Memorandum, must ensure that the necessary steps and infrastructure are in place so that

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<sup>4</sup> Welsh Government (2012) Human Transplantation (Wales) Bill Regulatory Impact Assessment

<sup>5</sup> Department of Health figures included in Explanatory Memorandum. Pg. 48.

<sup>6</sup> NHS Blood and Transplant. (2012) *Organ Donation and Transplantation Activity Report 2011/12*. Pg.10.

[[http://www.organdonation.nhs.uk/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/activity\\_report\\_2011\\_12.pdf](http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/ukt/activity_report_2011_12.pdf)]

<sup>7</sup> Abadie A and Gay S. (2006). 'The Impact of Presumed Consent on Cadaveric Organ Donation: A Cross Journal Study.' *Journal of Health Economics*; 25. Pp. 599-620.

<sup>8</sup> Sims, J et al. (2012). 'Overcoming barriers to registering as an organ donor among minority ethnic groups.' *Race Equality Foundation*. Pg.3. [<http://www.better-health.org.uk/briefings/overcoming-barriers-registering-organ-donor-among-minority-ethnic-groups>]

<sup>9</sup> NHS Blood and Transplant. (9/07/12). Press Release: *Family support for organ donation doubles when wishes are known- Pass it On*. [<http://www.nhsbt.nhs.uk/news/2012/newsrelease090712.html>]

the continuing transient population of Wales, including students and new residents are aware that an opt-out system is in place once the public awareness campaign has stopped.

## **Consent**

BHF Cymru agrees with the definition of ‘deemed’ and ‘express’ consent put forward within the Bill. We feel that the exceptions are clearly worded and agree with a soft opt-out system that, where known, prioritises the wishes of the deceased. We also believe there is appropriate involvement of the family, or next of kin, where the deceased wishes are not known.

## **Infrastructure and training**

BHF Cymru believes that the Welsh Government should provide further detail on the infrastructure in place to ensure a successful transition to the opt-out system. This should include investment in on-going training in implementing and operating in a soft opt-out system for health care professionals particularly for transplant co-ordinators and staff working in intensive care and emergency departments. There needs to be an effective management pathway for donors – donor identification and organ retrieval must become a routine part of hospital practice.<sup>10</sup> The Welsh Government should also ensure that the right financial incentives are in place for a successful move to opt-out. Increasing intensive care beds should be a priority of the Welsh Government before this legislation is implemented.

## **Organ Donation Register and relationship with NHS Blood and Transplant**

BHF Cymru believes it is not yet clear how the Welsh Government will work in practice alongside NHSBT to ensure a smooth transition between the current organ donor register to a new Wales only register.

An opt-out system should be seen by both the Welsh Government and NHSBT as complementary to reaching their united goal of increased occurrence of transplantation. Internationally there is evidence to suggest that the existence of a core central agency overseeing organ donation in opt-out systems is key to its success.

## **Conclusion**

To conclude, BHF Cymru supports the Welsh Government’s introduction of a soft opt-out system through this Bill and agrees with the key definitions proposed. Research shows the benefits of quality of life improvements and reduction in cost of medical management highlights that opt-out is a long term cost effective option.

BHF Cymru is pleased to see plans for a public awareness campaign included within the proposals, particularly the emphasis on engaging hard-to-reach communities. Moreover, we feel that appropriate evaluation needs to be included in this plan to ensure high levels of understanding and on-going training before the Welsh Government ends the campaign.

Similarly, BHF Cymru calls upon the Welsh Government to ensure the appropriate training for hospital staff and donor co-coordinators, in addition to investment in infrastructure such as critical care beds, is made to ensure the success of the system to become an everyday part of hospital life.

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<sup>10</sup> Gelder F, Roey, J et al. (2008). ‘What Is the Limiting Factor for Organ Procurement in Belgium.’ *Acta chir belg.* 108. Pg. 27-30.

Leading on from this, the correct infrastructure and funding needs to be in place to ensure that the formulation of a new register within NHSBT is efficient and robust, so that the public trust in its accuracy. BHF Cymru would like to see greater clarity on the relationship between the Welsh Government and NHSBT to ensure there is no needless confusion surrounding the establishment of a Welsh register and a simultaneous UK wide register. It is crucial that the Welsh Government and NHSBT work together on this introduction.

The UK active transplant waiting list for hearts increased 23.7% in the last year.<sup>11</sup> Alongside this an aging population, and increasing rates of chronic conditions are further exacerbating the shortage of organs. The Welsh Government needs to introduce this legislation quickly and efficiently by 2015.

As the only hope for those with chronic heart disease the Welsh Government are leading the way on organ donation, we hope as an example to the other Governments of the UK.

For more information related to this response, please contact Delyth Lloyd, Public Affairs and Communications Manager, at [Lloyd@bhf.org.uk](mailto:Lloyd@bhf.org.uk) or on 02920 38 24 06.

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<sup>11</sup> NHS Blood and Transplant. *Weekly Statistic Report*. (11/01/13)  
[[http://www.organdonation.nhs.uk/statistics/downloads/weekly\\_stats.pdf](http://www.organdonation.nhs.uk/statistics/downloads/weekly_stats.pdf)].



18<sup>th</sup> January 2013

**To:** Sarah Sargent, Deputy Clerk, Health and Social Committee, National Assembly for Wales

## **Consultation on the Human Transplantation (Wales) Bill**

The Royal College of General Practitioners is the largest membership organisation in the United Kingdom solely for GPs. It aims to encourage and maintain the highest standards of general medical practice and to act as the 'voice' of GPs on issues concerned with education, training, research, and clinical standards. Founded in 1952, the RCGP has over 46,000 members, 1,862 in Wales, who are committed to improving patient care, developing their own skills and promoting general practice as a discipline.

The Royal College of General Practitioners (Wales) welcomes the opportunity to respond to the consultation letter of 6<sup>th</sup> December 2012.

The Bill, as set out, promotes the ideal of donation. It will potentially increase the number of transplants and improve the care of those requiring transplants.

Although General Practitioners on the whole would be supportive of the improvement in the numbers of donor organs for the benefit of those in need, we do not feel that they can be expected to counsel patients about opting out or in of donations.

The system of opting out of transplant will need to be carefully promoted to the public of Wales as there could be much lack of understanding. Patients whose first language is not English or Welsh will need special consideration as they may not understand the implications and special consideration needs to be given to those whose religious or cultural beliefs prevent removal of tissue and organs after death.

There were suggestions that this process would occur at registration at the GP. However, as we are sure you are aware, the work load of general practice has increased considerably over the past few years and additional work outwith general medical service provision would be difficult to contemplate. There would likely be considerable burdens on ensuring 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 as well as training requirements for practice staff to ensure they were competent to take such consent.

We note that there is nothing in the bill about the fact that patients have to register to opt out of being donors or how they will be enabled to opt out; the opting out process was commented on in our previous consultation response, and the details of implementation are also not included in the Bill.

If you have any queries about this response, please do not hesitate to contact us, by emailing Carl Turner at [cturner@rcgp.org.uk](mailto:cturner@rcgp.org.uk)



## **Health and Social Care Committee Consultation on the Human Transplantation Bill**

### **Response from Christian Action Research and Education**

#### **Introduction**

CARE believes that it is a terrible tragedy that during the year 2011-12 it is reported that some 37 people died while waiting for an organ transplant. We very much affirm the importance of organ donation as a means of addressing this challenge and welcome the work that the Welsh Government has undertaken in response to the Organ Donation Taskforce and note that since responding to its proposals there has been a significant increase in the availability of organs for transplant,<sup>1</sup> albeit one that continues to be outstripped by the need. We believe that it is extremely important that the Welsh Government, the National Assembly for Wales and the people of Wales give very careful consideration to how best to close the remaining gap.

CARE very much welcomes the opportunity to respond to the National Assembly for Wales's Health and Social Care Committee as it commences the important task of Stage 1 scrutiny of the Welsh Government's Bill on behalf of the National Assembly for Wales. We believe that there are some outstanding problems with the Welsh Government's Bill and that the National Assembly for Wales, and its Health and Social Care Committee has a great opportunity and responsibility to address these difficulties.

Further the Committee Chair, Prof Mark Drakeford AM's letter calling for submissions the main focus of our comments will address the way the Bill deals with the family of the deceased. In addition we would like to make three comments about assumptions that underpin the Bill one of which is related to a potential unintended consequence or, at least, not immediately apparent consequence.

#### **1) The Bill's Treatment of the Family of Those Whose Consent is Deemed.**

CARE is very concerned that the Welsh Government has described the Bill as a 'soft opt-out Bill,' suggesting that some of the ethical and other concerns raised about 'presumption' (or deeming) need not apply because, although it obviously will not be possible to consult the deceased, it will be possible to consult their living representatives, their family.

During the first consultation process of this Assembly, October 2011 till January 2012, and the parallel public debate in Wales, serious medical and ethical concerns were raised about the presumption of consent. The point was well made that presumed consent is actually not consent at all. As one person put it, you cannot have presumed consent anymore than you can have a square circle. Perhaps more importantly, though, the point was made that any effective health service depends on trust between doctors on the one hand and patients and their families on the other. If this is placed in jeopardy it can have a hugely damaging impact on the efficacy of any health service as Brazil discovered when it introduced presumed consent legislation in the late nineties, legislation it was forced to reverse very soon afterwards because of its impact on the relationship between doctors, patients and their families.

If you discount postcard campaigns and just count the unique responses to the first consultation, the results were rather worrying for the Welsh Government in that just 17% of unique responses were in favour of presumed consent. Opposition to the proposals hung very much around the

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<sup>1</sup> Donation rates have rocketed by 49% in Wales compared with 34% in England and Wales since 2008.



appropriateness of presuming consent; that is introducing legislation that would allow the Government to treat someone who died without expressly stating whether or not they wanted to donate their organs as if they had donated them.<sup>2</sup> In this context although the Welsh Government decided to proceed with their plans, they placed great emphasis on the fact that they were going to introduce a soft opt-out expression of presumed consent and indeed, to further address concerns about presuming consent, they borrowed the language of 'deeming consent' from some pre-existing secondary legislation dealing with adults lacking mental capacity. The point must be made, however, that the effect of deemed consent is exactly the same as presumed consent.

Such was the importance of the soft opt-out message that the first para of the consultation on the draft Bill stated:

*'1. The Welsh Government is consulting on a draft Bill which will introduce a soft opt-out system for consent to deceased organ and tissue donation in Wales.'*

The common sense implication given by this stress on a soft opt-out Bill was that if surviving families were not happy the Bill would make it plain that organs would not be taken from the deceased if they died without expressly stating whether or not they wished to donate their organs. When one studied the Bill, however, it became apparent that no such undertaking had been given. The only significant way in which families were to be involved was if they could actually demonstrate that the deceased had actually expressed a view about whether or not they wanted to donate their organs before they died. Thus in this regard the Bill did not soften the presumption of consent it only provided a new outlet for express consent. Indeed, if you actually read the explanatory notes, and indeed the full consultation, they own up to this and actually suggest that it would be quite impossible to have any other arrangement without placing presumed consent in jeopardy.

Paragraph 27 states of the explanatory notes to the draft Bill stated, ***"those close to the deceased do not have the legal right to veto or overrule the decision of the deceased to have their consent deemed. .... It is important to be clear, however, that this is not a legal veto because the law will recognise the deemed consent of the deceased as having precedence."*** (Bold added)

Thus in reality the draft Bill did not constitute a soft-opt out Bill. It has actually constituted a hard opt out. If one looks beyond the Bill, however, undertakings have been made that suggest that, despite there being nothing to this effect in the legislation, clinicians will not necessarily take organs in practice if the family is unhappy. This extra-legal assurance has actually gone through a significant change between the explanatory notes accompanying the draft Bill and the final Bill.

Paragraph 27 of the explanatory notes to the draft Bill (see above) stated, *"those close to the deceased do not have the legal right to veto or overrule the decision of the deceased to have their*

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<sup>2</sup> The Welsh Government's summary of responses to their proposals for legislation on organ and tissue donation can be read here:

<http://wales.gov.uk/docs/dhss/consultation/120307organdonationsummaryen.pdf>

Total number of responses received: 1,234

Number expressing a view one way

or the other: 1,124 (91%)

Number supportive of proposals: 642 (52%)

Number opposed to proposals: 482 (39%)

Of the 642 responses supporting the Government's proposals, 520 (81%) were identical responses

Number of supportive responses (642) - Identical responses (520) + 2 (identical responses collated according to their source) = 124. Thus, there were only 716 unique responses. **Of this figure, 67%**

**(482) were opposed to the Government's proposals compared to just 17% (124) in favour.**

*consent deemed. **Having said that, clinical teams will have a duty of care towards the surviving relatives and if there are very strong objections or distress, then organ donation is unlikely to go ahead.** It is important to be clear, however, that this is not a legal veto because the law will recognise the deemed consent of the deceased as having precedence.” (Bold added)*

This undertaking caused not insignificant alarm. First the Welsh Government were suggesting that doctors should wait for ‘very strong objections’ and ‘distress’ and even then there was no undertaking that organs would not be taken. This amounted to encouraging doctors to adopting a very cavalier approach that was not at all respectful of the imperative to have regard for the importance of the relationship between the doctor, on the one hand, and the patient and their family, on the other, being based on consent and trust.

Assessing the consultation responses to the draft Bill must have been a very salutary experience for the Welsh Government. In some ways the fact that over 2000 critical identical submissions were made was used to draw attention away from the most important fact about the submissions; namely that **even if you discount all the identical submissions and only count unique submissions the number of negative answers received were greater than the positive responses in answer to all consultation questions** – a quite extraordinary state of affairs.<sup>3</sup> The Welsh Government then sought to redeem the situation by running a poll in the hope that this might demonstrate that if one does not use a self-selecting group like those who choose to respond to consultations and instead run a poll, it would be possible to demonstrate that people generally are in favour. This was even more worrying although very few people picked up on it. The poll showed that only 49%<sup>4</sup> of people supported presumed consent, a very significant drop from 63% earlier in the year.<sup>5</sup>

Instead of stopping, though, the Government just pressed ahead.

In the same way that there was repositioning when introducing the draft Bill with the heavy emphasis on a soft opt-out, so too with the introduction of the final Bill. Although the substance of the Bill itself has not changed in relation to the role of the family, there has been a change in the way that the Welsh Government has engaged with concerns about the role of the family. In announcing the new Bill the Minister said that if the surviving family objected to the taking of organs then they would not be taken.<sup>6</sup> Gone was any reference to waiting for ‘very strong

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<sup>3</sup> If one sets aside the 2000 or so identical responses and counts the remaining unique responses only, on question 1: ‘Have the concepts of deemed consent and express consent been explained clearly enough?’ 80 answered “yes,” 105 answered “no”. On question 2: ‘Is the role of the family clear?’ 61 answered “yes,” 123 answered “no”. On question 3: ‘Are the arrangements for the registration of wishes clear?’ 63 answered “yes,” 115 answered “no”. On question 4: ‘Are the arrangements for establishing residency clear?’ 73 answered “yes,” 95 answered “no”. On question 5: ‘Does the Equality Impact Assessment (EIA) properly set out how the legislation will affect different sections of society, including children and people who lack capacity?’ 67 answered “yes,” 107 answered “no”. On 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?’ 42 answered “yes,” 131 answered “no”.

<http://wales.gov.uk/docs/dhss/consultation/121019responsesen.pdf>

<sup>4</sup> <http://wales.gov.uk/newsroom/healthandsocialcare/2012/121019od/?lang=en>

<sup>5</sup> <http://www.bbc.co.uk/news/uk-wales-politics-17226610>

<sup>6</sup> Ms Griffiths said: “The role of the family is critical in informing the final decision on what happens to their relative’s organs. The wishes of the deceased are paramount and the vast majority of the people of Wales do expect their wishes to be what really counts. For that reason, as is the case now, the family has no legal right to veto **but, in practice, a clinician would never add to their distress by insisting on donation.**’ **Bold added** Julia McWatt, Health Correspondent, New organ donation campaign launched by Welsh Government <http://www.walesonline.co.uk/news/health-news/2012/12/04/new-organ-donation-campaign-launched-by-welsh-government-91466-32356149/>

objections' or 'distress' or the fact that in such contexts it was only 'unlikely' organs would be taken. Moreover this was reflected in the amended explanatory notes: "Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families by insisting on donation."<sup>7</sup>

This new approach appears to suggest that if families object to the removal of organs from their relative that the donation will not go ahead. This is a much more satisfactory but without reference to this on the face of the Bill, this proposal does not present a credible soft-opt out Bill.

The new explanatory notes still adopt a line that rather suggests it would be completely impossible for the legislation to provide a robust expression of the soft opt-out (namely the assurance that where someone dies without expressly stating whether or not they want their organs donated, the views of the family of the deceased would be respected such that if they objected the organs would not be taken) without this nullifying the presumed/deemed consent project entirely.<sup>8</sup> That this is not the case is eloquently demonstrated by the fact that there are presumed consent countries with soft-opt out laws that do rise very effectively to this challenge. Specifically they make provision for the presumption of consent where someone dies without expressly electing one way or the other whether they wish to donate their organs which **make it very plain that if the relatives of such a family are unhappy the organ will not be taken**. Consider legislation from just two such countries we have identified from our international comparison, Slovenia and Latvia. There are other good examples like Belgium and Finland:

#### *Slovenia*

##### *Art.15*

*"The body parts of a dead person who was a Slovenian citizen, or who had permanent residence in Slovenia, may be removed for transplantation purposes when the dead person did not explicitly give his consent but did not explicitly prohibit it either, unless it proceeds from other circumstances that the person would have opposed the removal. If information on deceased's standpoint concerning donorship is contradictory, the removal shall not be carried out. **Notwithstanding the provision from the preceding §, the removal of body parts shall not be carried out when a person who was close to the deceased opposes it. When such persons are reachable, one of them should be informed of the planned removal and of their right to reject.** A reasonable period of time should be given to such a person to make a decision. The body parts of a dead person who was not a citizen or permanent resident of Slovenia may be removed for transplantation purposes on condition that a person close to the deceased gives explicit consent.*

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<sup>7</sup> Explanatory Memorandum to the Human Transplantation (Wales) Bill 2012 <http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs.htm?act=dis&id=241088&ds=12/2012> p20

<sup>8</sup> 'Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families by insisting on donation. **It is important to be clear, however, that families do not have a legal veto because the law will recognise the deemed consent of the deceased as having precedence.**' Welsh Government Explanatory Memorandum, 3 Dec 2012, p. 20. <http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum>

***Persons close to the dead person shall be: spouse, non-married partner, adult children, parents, brothers, sisters, and persons who were, judging from general circumstances, close to the deceased***".<sup>9</sup> (Bold added)

*Latvia*

#### *Section 11*

*Provisions of transplantation in case of the donor's death*

*"It is possible to remove the deceased's tissues and organs for transplantation in case of a donor's death, if the deceased when alive has not prohibited taking tissues and organs from his body and **unless the next of kin have not prohibited to do so**. It is prohibited to take the deceased child's tissues and organs for transplantation, unless allowed by one of parents or a guardian".*<sup>10</sup> (Bold added)

If the Welsh Government is really serious about introducing a soft opt-out system such that organs will not be taken from those who have died without electing one way or another whether they wish to donate if their surviving families object, then they should have made this provision on the face of the Bill, making it a soft opt-out Bill.

First, without this safeguard in the proposed legislation itself, the legislation does not propose a credible or acceptable soft opt-out Bill.

Second, the fact that the Welsh Government has not considered providing the relevant safeguard in the actual legislation necessary, suggests that they don't really take the need to provide a soft opt-out very seriously. (To the extent that there is an attempt to defend this position it seems to be premised on the fanciful notion that all people who have not expressly elected to donate or not donate have nonetheless deliberately and consciously chosen to donate. This will undoubtedly be true in some instances but we cannot be sure that it would be true in all or even most cases. The only way to be clear that all people have made a decision one way or the other would be to introduce mandated choice. The logical problems with the assertion that under the proposed system all people who have died without expressly electing whether or not their organs should be taken on death should be treated by the law as if they have consciously chosen to donate is picked up in more detail below under point 4)

CARE believes that the people of Wales deserve the level of reassurance provided by credible soft legislation (like Slovenia, Belgium and Latvia) so that trust between doctors, on the one hand, and patients and their families, on the other, can be upheld.

CARE would argue that the Health and Social Care Committee, acting on behalf of the National Assembly for Wales and the people of Wales at Stage 1, has a responsibility to:

- i. Recommend that the National Assembly for Wales should amend the Welsh Government's Bill so that the legislation makes it plain that where someone dies without expressly stating whether or not their organs should be taken that the views of the family should be respected such that if they are not happy the organs will not be taken.
- ii. Highlight the significance of the responses to the Welsh Government's consultation and their poll.

## **2) Assumption: Increased organ availability**

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<sup>9</sup> H. Nys, "Removal of Organs in the EU", *European Ethical-Legal Papers N°4*, Leuven, 2007 p28-31

<sup>10</sup> H. NYS, "Removal of Organs in the EU", *European Ethical-Legal Papers N°4*, Leuven, 2007 p16-18

The Welsh Government said that the Bill will have the effect of increasing the availability of organs in Wales by some 25 to 30%. This assertion was then reasserted widely by the media when presenting the Bill. When one drills down into the actual evidence base, however, one soon discovers that there are many different papers with many different findings and that the one the Welsh Government rests its findings on 'Abadie and Gay' provides a particularly upbeat assessment.<sup>11</sup> We are concerned that the Bill has been sold on the basis of these figures which are just from one academic paper in a sea of many others reaching rather different conclusions. Work done at John Hopkins University by *Brian J. Boyarsky, Erin C. Hall, Neha A. Deshpande, R. Lorie Ros, Robert A. Montgomery, Donald M. Steinwachs, and Dorry L. Segev*, for example 'Potential Limitations of Presumed Consent Legislation,' *Transplantation* 2011, provides one such contrary conclusion. Study leader Dr. Dorry Segev, an associate professor of surgery at the Johns Hopkins University School of Medicine, said, 'With opt-out the perception becomes, we will take your organs unless you take the time to fill out a form. That's a dangerous perception to have. We only want to use donated organs from people who intended to donate.'<sup>12</sup> Even if one looks at studies that are more favourably disposed to presumed consent one sees that many are far more reserved about the scale of improvement projected than the Welsh Government relying as it does on Abadie and Gay. Moreover it is interesting to note that the Welsh Government's own international comparison shows that Wales' current organ donation rate 24.9<sup>13</sup> is better than that of most presumed consent countries (16) and similar to that of two.<sup>14</sup> Moreover, one country that is outperforming Wales does not operate on the basis of presumed consent. This clearly demonstrates that presumed consent legislation is not even a key consideration to increasing organ availability.

### 3) Assumption: Beneficiaries

There is a public assumption that any increase in the numbers of available organs from presumed consent in Wales would go to the people of Wales but our understanding is that any increase in organ availability, courtesy of presumed/deemed consent, would go into a pool that could be used by anyone in England or Wales. Given that there are far more people in England it would seem likely that only a small percentage of extra organs from Wales would benefit the people of Wales. Most would go to England. Given the current pressure on the Welsh NHS, is it right to expend so much money and energy on a project that it is far from clear will help (see above) and, if it does, will disproportionately benefit England entirely at Wales' expense?

### 4) Assumption: People Choosing to have Consent deemed

The Welsh Government uses the rather extraordinary phrase

**It is important to be clear, however, that families do not have a legal veto because the law will recognise the deemed consent of the deceased as having precedence.'** Welsh Government Explanatory Memorandum, 3 Dec 2012, p. 20.

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<sup>11</sup> Abadie, A. and S. Gay (2006). "The impact of presumed consent legislation on cadaveric organ donation: a cross-country study." *Journal of health economics* 25(4): 599-620. [http://www.parliament.wa.gov.au/intranet/libpages.nsf/WebFiles/ITS++donor+article+Abadie+06/\\$FILE/donor+article+abadie.pdf](http://www.parliament.wa.gov.au/intranet/libpages.nsf/WebFiles/ITS++donor+article+Abadie+06/$FILE/donor+article+abadie.pdf).

<sup>12</sup> [http://www.hopkinsmedicine.org/news/media/releases/presumed\\_consent\\_not\\_answer\\_to\\_solving\\_organ\\_shortage\\_in\\_us\\_researchers\\_say](http://www.hopkinsmedicine.org/news/media/releases/presumed_consent_not_answer_to_solving_organ_shortage_in_us_researchers_say)

<sup>13</sup> See page 10

[http://www.organdonation.nhs.uk/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/uk\\_t/activity\\_report\\_2011\\_12.pdf](http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/uk_t/activity_report_2011_12.pdf)

<sup>14</sup> See page 58 <http://wales.gov.uk/docs/caecd/research/121203optoutorgandonationen.pdf>

The inference of this is that everyone who does not either expressly elect to donate their organs after death or expressly elect not to do so, has nonetheless made a very deliberate decision to consent, having their consent deemed. It is undoubtedly true that this would be the case in some instances. People who want to donate could think, 'well I don't need to do anything and it will result in donation, therefore I will do nothing in order to donate.' It is however, a massive assumption to suggest that everyone who does not expressly elect to either donate or not donate nonetheless consciously and deliberately decides that they want to donate, having their consent deemed. One would have to invest a far greater sum on publicity than that proposed to come anywhere close to be able to suggest that everyone who does not expressly elect to donate or not has nonetheless consciously and deliberately chosen to become a donor, and have their consent deemed. Even then one could be by no means sure. (The only way one could be sure that everyone makes a decision would be to introduce mandated choice.) On this point it is worth remembering that the consultation question on the draft Bill that received most negative answers was: Do you feel reassured that the Welsh Government is planning the public information campaign thoroughly?' 42 answered "yes," 131 answered "no".<sup>15</sup>

CARE would be very happy to do anything further that might assist the Committee in its deliberations, including in giving oral or further written evidence.

Dr Dan Boucher,  
CARE Public Policy Team,  
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London SW1P 3RF

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<sup>15</sup> <http://wales.gov.uk/docs/dhss/consultation/121019responsesen.pdf>

Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)24 - Catholic Medical Association

Mark Drakeford  
Chair of Health Committee,

Dear Mr Drakeford

I would be extremely grateful if you are able to accept this late submission. I do apologise that I have missed the dead line but the Draft Bill on Human Transplantation in Wales has only recently come to our notice.

I am writing as the President of the Catholic Medical Association and as it happens we recently discussed amongst ourselves the difficult problem of Brain Stem death and Organ Transplantation and the problem of valid consent. While we are all totally supportive of the value of organ donation, we feel that it is vital that in principle it has to remain as a voluntary gift, adhering to the fundamental meaning of donation, either at the time from a living donor, or in advance and fully documented, with donors who have died.

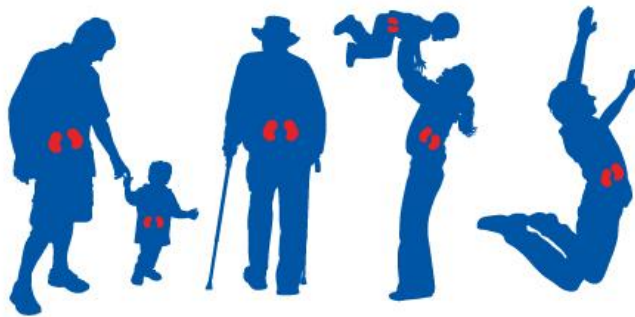
It is well documented how difficult it will be for emergency staff to support relatives if this donating organs had not been in their way of thinking (contrasted to the comfort that good donation can bring families in knowing that the tragic death of their loved one was not utterly in vain, and that some poor suffering soul has benefitted). How can the State really say that it owns the bodies of its citizens? There must be more successful ways of encouraging people to fill in their Donor Cards.

Within the effort to improve donor card uptake, a proper, fair and up to date presentation of Brain Stem Death is urgently needed, as an amount of suspicion surrounds this and is probably preventing some publicly spirited people from signing. Factors such as the recent media coverage of the work of Professor Adrian Owen in Canada who has managed to communicate with "PVS" patients must be alerting the public to the difficulty in assessing the degree of residual brain function in severely brain damaged patients, and instilling some degree of apprehension and uncertainty.

We would be delighted to be of help to you if further facts surrounding this difficult subject from the Catholic Christian perspective are required.

Yours very sincerely

Dr Robert Hardie  
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[robhardie47@gmail.com](mailto:robhardie47@gmail.com)



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.



### **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.

#### REFERENCES

- 1 Michielsen P. Organ shortage-what to do? *Transplant Proc* 1992;24:2391-2
- 2 Alexandre GPJ, Derom F, Godon JP, et al. Etat actuel de la transplantation renale en Belgique. *Acta Chirurg Belg* 1970;69:409-24
- 3 Svendsen E, Hill RB. Autopsy legislation and practice in various countries. *Arch Pathol Lab Med* 1987;111:846-50
- 4 Vanrenterghem Y, Waer M, Roels L, Lerut T, Gruwez J, Vandeputte M, et al. On behalf of the Leuven Collaborative Group for

Transplantation. In: Terasaki P, ed. Clinical Transplants 1988. Los Angeles: UCLA Tissue Typing Laboratory, 1988:91-7

5 Michielsen P. Effect of transplantation laws on organ procurement. In: Touraine JL, et al., eds. Organ Shortage: The solutions. Dordrecht: Kluwer, 1995:33-9

6 Miihlbacher F. Donor recruitment in Austria. In: de Charro FTH, Hessing DJ, Akveld JEM, eds. Systems of Donor Recruitment. Dordrecht: Kluwer, 1992:65-71

7 Gnant MFX, Wamser P, Goetzinger P, Sautner T, Steiniger R, Miihlbacher F. The impact of the presumed consent law and a decentralized organ procurement system on organ donation: Quadruplicating in the number of organ donors. Transplant Proc 1991 ;23:2685-6  
666

## 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.)

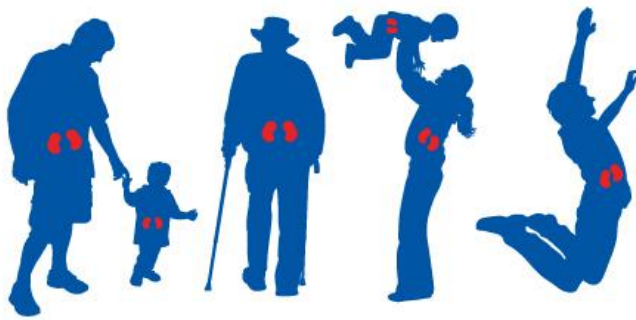
2011: First double leg transplant, by Dr Cavadas and team (Valencia's Hospital La Fe, Spain)

- 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.



Kidney Wales Foundation  
Sefydliad Aren Cymru

Charity Number 700396

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## **The Human Transplantation (Wales) Bill**

### **Evidence to the National Assembly for Wales**

### **Health & Social Care Committee**

#### **Supplementary Evidence by Kidney Wales Foundation**

#### **On European Convention on Human Rights and European Community Law**

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

#### **European Convention on Human Rights**

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

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

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

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

The Report summarised its views in the following way: “*a system that was based on a presumption of consent or authorisation that allowed adequate provisions for a person to opt out would be compatible with the ECHR. Such a system would need to allow a person to indicate their wishes (such as on a register) during their lifetime and also to allow for evidence from family members about the person’s wishes and beliefs after their death. Particular consideration would be needed for some groups of people, in particular children, people who lack the mental capacity to make a decision to opt out and those whose identity was unknown at the time of their death.*”

Annex C to that report contained a careful analysis of the potential Convention issues arising in respect of any opt out system adopted focusing, in particular, on the concept of presumed consent. The analysis was prepared by the Legal Working Group to the Taskforce.

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

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

- (a) Opt out systems operate in a substantial number of European Union and Council of Europe countries and they have never, so far as I am aware, led to any challenge before the European Court of Human Rights<sup>1</sup>;
- (b) The Additional Protocol to the Council of Europe's *European Convention on Human Rights and Biomedicine concerning Transplantation of Organs and Tissues of Human Origin* (ETS No. 186)<sup>2</sup> provides at least some insight into the core standards which the European Court might expect to be respected in this field. It includes the following key provisions, none of which preclude the existence of an opt out system:
  - Signatory States must have a clear legally recognised system specifying the conditions under which removal of organs or tissues is authorised (Article 17);
  - The only absolute bar to organ and tissue removal concerning a deceased person is presented if that person had objected to it (Article 17);
  - The human body must be treated with respect and all reasonable measures must be taken to preserve the appearance of the donor corpse (Article 18);

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

<sup>2</sup> Although the United Kingdom has not signed or ratified this Convention it has been ratified by 12 member States of the Council of Europe. The Convention has only been referred to in the case law of the European Court of Human Rights in an unrelated context (see e.g. *SH & Others v Austria* Application No. 57813/00 1 April 2010 relating to the availability of fertility treatments).

- Signatory States are obliged to take “*all appropriate measures to promote the donation of organs and tissues*” (Article 19);
  - The Convention requires adequate measures for the protection of the confidentiality of any donor (Article 23).
- (c) There is no indication in the approach of the European Commission of the European Community to the issue of transplantation that it considers that such a system would be incompatible with fundamental rights. This is of at least some significance, even having regard to limitations on European Union competence in this area, (see further below).
13. In view of the care of the analysis set out, and to avoid unnecessary repetition, we strongly urge you to bring a copy of the Working Group’s report dated 11 April 2008 and published as Annex C into your evidence.

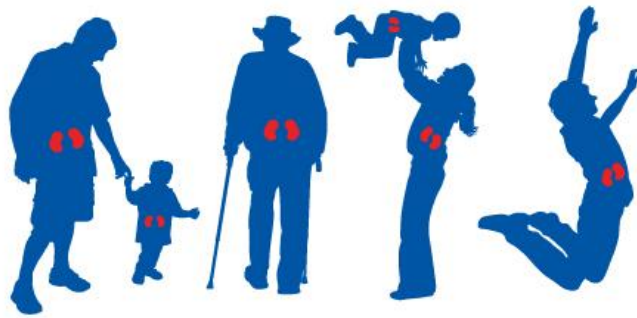
### **European Community Law**

14. A helpful summary of recent developments in European Union governance over organ donation and transplantation, focusing on the Commission’s action plan and the Organs Directive (subsequently Directive 2010/45/EU 7 July 2010) is set out in the article “*Adding Value? EU Governance of Organ Donation and Transplantation*” Ann Maree Farrell, EJHL 17 (2010) 51-79. This article makes the following important points each of which support our views that a **deemed consent system would be compatible with European Community law**:
- (a) The Commission and the Directive allow for flexibility on the part of Member States in relation to the meeting of obligations with respect to e.g. donor consent (see paragraph 4.3 & Directive Article 14);
  - (b) As Farrell explains “*in relation to regulatory requirements covering consent to organ donation, the EU’s competence to act on this issue is circumscribed by Article 168(7) TFEU which states that national provisions regarding the donation or medical use of organs shall not be affected by the adoption of minimum harmonisation measures under Article 168(4)(a) TFEU*” (p. 73);

- (c) The Commission has expressly acknowledged that there is a “*degree of variation as between Member States in relation to the consent regimes that have been adopted in relation to deceased organ donation, reflecting the national specificities of historical, socio cultural protection and political flexibility*” (p. 73 citing Commission Impact Assessment accompanying Communication 30.5.02007 SEC (207) 704 at 24-27).

**Roy J Thomas**

**14 February 2013**



Kidney Wales Foundation  
Sefydliad Aren Cymru

Charity Number 700396

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**The Human Transplantation (Wales) Bill  
Evidence to the National Assembly for Wales  
Health & Social Care Committee  
Supplementary Evidence by Kidney Wales Foundation (2)**

**On lack of donors from Black, Asian and Minority Ethnic backgrounds**

We must draw the Committee's attention to two reports published on 13 of February 2013 by the National Black, Asian and Minority Ethnic Transplant Alliance (NBTA) which show that donors from Black, Asian and Minority Ethnic backgrounds (BAME) must urgently come forward if the prospects for those requiring transplants are to improve.

It is our view given the lack of progress in the UK the only way to do this is by changing the system as proposed by this Bill and ensuring that there are more organs available.

People from a BAME background are three times more likely to need an organ transplant than the rest of the population, but fewer than 2% have recorded their wishes on the NHS Organ Donation Register. Around 90% of white Caucasian patients in need of a bone marrow transplant may find a match, while for BAME individuals the matching rate can be as low as 40%. The best match is likely to come from someone in the same ethnic group as the person needing a transplant, however it is much harder for people from a BAME background because there are fewer people from these groups on the registers. In addition, each different ethnic group is itself diverse, compounding the problem.

For the first time, UK organ and stem cell data on BAME donation has been analysed. The results raise a number of serious concerns about BAME donation that urgently need to be addressed. The findings show:

On organ donation,

- There has been little change in the number of donors after death from BAME background over the last four years. The national figure remains below 50 BAME donors per year.
- There has been an increase in the number of BAME patients awaiting an organ. Around 25% of those on the transplant waiting list are from BAME background.
- While numbers of some ethnicities joining the organ donation register have gone up, there has been no increase in those from a Pakistani, Bangladeshi or African-Caribbean background.

On stem cell donation

- A multi-pronged approach is needed to meet the needs of BAME patients. More BAME donors must be recruited to the registers, more cord blood from BAME mothers should be

collected, and the establishment of registers in countries of origin of BAME people should be supported.

- More must be done to encourage people from BAME background to register as bone marrow donors.

There are supporters of the deemed consent in the Muslim faith. We spend a great deal of time with Muslim families helping them overcome fears of transplantation.

The NBTA reports can be found here [www.nbta-uk.org.uk](http://www.nbta-uk.org.uk)

Every year, 180 people from these ethnic groups die waiting for a transplant because of a chronic shortage of suitable organs.

It is very clear that Faith Groups are in favour of organ donation so why would they not follow other multi faith countries such as Belgium and Singapore in adopting a new progressive approach to organ donation. The new Bill is progressive. Faith Groups have not put up any case to support their claims that the legislation will not work.

The National Kidney Federation note that the findings highlight the fact that a more strategic approach is needed to address the challenges facing patients from BAME background. The responsibility rests with the NHS, NHSBT, hospitals as well as the BAME communities themselves. NBTA has started working with key partners in this area and will closely monitor what happens as the new Organ Transplantation 2020 Strategy is implemented from April 2013 onwards. We believe nothing will be different until there is a fundamental change in the law.

Black and Asian people are dying because there are not enough people from communities coming forward as stem cell or organ donors. This Bill will be the lead Bill for the UK that can change this deplorable situation.

**Roy J Thomas**

**15 February 2013**

**Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)26 – Abertawe Bro Morgannwg University Health Board**

**Members of the Clinical Ethics Committee of ABM University Health Board.**

**In response to the Welsh Government consultation on the draft Human Tissue (Wales) Bill.**

We share the desire to see an increase in organ donation and transplantation rates in Wales and the UK as a whole, applaud the Welsh Government's determination to do so, and support any attempt to do this that is both workable and consistent with wider application of ethical principles. We have engaged with previous Welsh Government consultations in that constructive spirit and we wish respond to the current WHSCC consultation in the same way.

We have specific concerns about some parts of the Bill which risk compromising the goal of increasing donation rates in Wales.

Our most serious concerns are however for the wider implications of the legislative redefinition of consent to include something which is not consent. There is no accepted definition of consent according to which it can be deemed. To redefine it unilaterally risks damaging the proper consideration of consent to treatment in a wide range of settings. We must take both the proper definition of consent, and its application to the proper care of the dying, very seriously.

If the need to redefine consent is driven by a prohibition on non-consensual organ retrieval then we would consider the ethical dimension of that prohibition to apply equally to a system of "deemed consent". No one whose organs have been retrieved will be in a position to mount any complaint or litigation. But to misquote Jonathan Glover, it should be no consolation at all that he can have no second thoughts, because ours will come too late.

Dr Idris Baker (Chair, Clinical Ethics Committee, ABM University Health Board)

18<sup>th</sup> January 2013



## **Deemed consent is not consent.**

The explanatory notes to the Bill make clear that “consent is required in order to carry out a transplantation activity.” The Bill and the EM claim that deemed consent is a form of consent.

Proper definition of consent is not only important in organ donation; its importance applies anywhere where consent to treatment is required and we should not redefine it lightly. Giving consent is not the same as failing to object. A range of definitions of consent is available but we refer to that given in a standard British text of medical ethics which concurs with our understanding of the common law on consent:

For medical interventions it is widely accepted that consent means a voluntary, uncoerced decision, made by a sufficiently competent or autonomous person and the basis of adequate information and deliberation, to accept rather than reject some proposed course of action that will affect him or her.<sup>1</sup>

“Deemed consent”, newly introduced in this Bill, does not satisfy this definition. It is further from the meaning of consent than the previously used term “presumed consent” was. We have previously argued in writing<sup>2</sup> and in person<sup>3</sup> that there could be no “presumed consent”. In earlier Welsh Government consultations on an opt-out system we were given verbal assurances<sup>4</sup> that the concept and term were no longer a part of the proposals. We therefore see the pivotal role for “deemed consent” in the draft Bill and in the EM (explained in para 2) as a backward step in addressing the ethical concerns around an opt-out system. We object to “deemed consent” on principle, because it is a misuse of the word consent. Although it has been pointed out in a consultation event<sup>5</sup> that, in other jurisdictions, opt-out systems have not been seen to damage public confidence in consent, we know of no such evidence from a system called deemed or presumed consent. We therefore retain our concern about the practical risks of this misuse of the word consent for what is in fact non-consensual organ retrieval. In holding this position we do not argue that non-consensual retrieval in an opt-out system is inherently wrong. It may well be right if done properly. We think that this proposal, which has in some respects been improved in response to previous consultations, could lead to it being done properly. Non-consensual treatments are justified when they are in the best interests of the patient or consistent with respect for the former wishes of the deceased. But we think that it is better on ethical grounds not only to do it properly but to call it what it is and to stick to the Government’s previous intention not to presume (or implicitly to deem) consent.

In holding this position we recognise that it conflicts with section requiring consent to transplantation activities. We think that the Bill could be amended to remove this conflict by adding provisions for non-consensual transplantation activities that, as under the present system, are in a person’s best interests. Any legal barriers

outside of this proposal to non-consensual organ retrieval would lend support to our reluctance to redefine consent.

Requiring that donation is decided to be in the person's best interests raises particular concerns with donation following circulatory death (DCD), which we have previously<sup>2,3</sup> argued should be excluded from an opt-out system. In the case of DCD the person may in life have non-therapeutic interventions, so as to facilitate organ retrieval after they die, that would otherwise have been contrary to their best interests. For instance, their life support may be continued for longer than it would have been, or they may be moved to an intensive care unit when their life support would instead have been withdrawn without such a move, or they may have additional and potentially painful procedures such as additional cannulations to facilitate the additional life support while the decision to allow them to fulfil their donation potential is being acted on. All of these things have the potential to cause distress. We know that those caring for such potential donors would as now act to minimise any consequent distress arising from these additional actions and we accept that, for someone with a positive wish to donate organs in the event of their death, these actions can be in their best interests. It is in their best interests to fulfil their wishes so long as this can be done without undue distress, and to that extent the intervention may be therapeutic. It is far from clear that this is so for someone whose former wishes are unknown and, given our strong argument on "deemed consent", we hold that it is not in the best interests of someone (who has merely failed to object) that we subject her to additional distressing non-therapeutic interventions in the last hours of life so as to fulfil wishes that she may or may not have had. As well as the strong evidence from our argument that this is harmful to the dying donor, there is arguably a wider harm that arises from using this dying person merely as a means for the benefit of others. This wider harm arguably extends to society as a whole, including any potential recipients of organs. This wider harm is precisely why there are legitimate limits on whether and how a person can become an organ donor in life. Following our earlier argument, we therefore strongly suggest either that DCD is excluded from these proposals entirely or at the very least that any additional intervention in life intended to facilitate retrieval after death that in the reasonable judgment of the clinical team has any potential to cause distress is specifically prohibited without express consent.

***In summary, the Bill cannot introduce a new form of consent called deemed consent. It is not consent. Calling it consent will not help. Legislating to call something consent that is not consent risks widespread harm by damaging what we have worked hard to achieve in protecting patients by requiring consent to medical treatment.***

## **The proposals may not work and may be harmful**

The EM puts in various forms of words the intention to give real weight to the family's view and rightly makes clear that in the present system, as in that which would be created by the Bill, the family wield no formal veto. But there is real concern on three fronts about this part of what is proposed.

The first is that if in reality family members are still given a practical veto, then this Bill will achieve very little. EM paras 41-42 say

41. ... In practice, families are presented with information about organ donation, including whether the deceased person had expressed a wish, and asked whether they are prepared to agree to donation taking place.

42. Under the new arrangements, very little will change in practice...

The improvements in organ donation in recent years in Wales are grounded partly in a reduced rate of family refusal. Given this reduction there are likely to be relatively few refusals that would no longer happen under the soft opt out.

The second concern assumes that there is in fact some further reduction in family refusal (a prerequisite for the Bill achieving the Government's laudable intention of increasing transplantation rates) because families no longer have a practical veto. Because this is a new and controversial extension to the law on transplantation, there is a risk that the absence of a family veto would damage confidence in the system among people in Wales. If the Bill's implementation shakes confidence in the system, it will fail to do so and may have the wholly unintended consequence of reducing transplantation rates.

Finally, it is not clear what should be done in the likely event of disagreement between people with qualifying relationships. Such disagreements are common and there is often uncertainty about who knows best. It is not uncommon to find that a person has an estranged spouse and also a current partner and they can be relied on to disagree about most things. A formal hierarchy or ranking of kinds of qualifying relationship might make things clearer. We note that the lack of ranking is intentional but nonetheless we think that having one would reduce clinicians' uncertainty. We see no argument for not ranking those relationships; the EM says that the intention is for anyone on the list to be able to provide the necessary information about the person's former wishes, but ranking them would not obstruct that intention. It would merely strengthen the guidance for clinicians and transplant teams in the likely event that those with qualifying relationships disagree about the person's former wishes.

***This set of concerns about the role of families means, in summary, that the Bill is likely at best to achieve little or at worst to compromise the current high transplantation rate.***

## Other comments

- 1 Public awareness. We applaud the commitment (although we are not clear how the duties are to be enforced) to educate the people of Wales about organ donation and about any new arrangements. But we know that the need for this reflects a lack of awareness and understanding about it at present. We are therefore sceptical about the significance of current opinion polls such as those cited.
- 2 Altruism. We recognise the importance of the UK as a whole sharing a transplant list but we think that there are legitimate concerns about much of the benefit of the proposed change not being in Wales. We think that these concerns should not be so easily played down. The thrust of the justification for a change is that there are people in Wales needlessly suffering and dying while waiting for organs. This justification is weak given that only a proportion, probably a minority, of any increase in donation rates will lead to the increase in transplantation rates for the people of Wales to which the Welsh Government is committed. Altruism is morally praiseworthy but we think that informed public support for the change would have to rest on a clear understanding that it was a matter of unilateral cross-border altruism more than of interpersonal altruism within Wales.
- 3 Consent & DCD. We have a further comment about consent. It relates to the possibility of deemed consent to donation following circulatory death (DCD). Table 1 in the Bill says that if a person is alive then it is their consent, rather than “deemed consent”, that will apply. When a decision on DCD is taken, the patient is alive but may lack capacity to decide on organ donation. The proposals do not make clear on what basis a decision would then be made for a person who has neither expressly consented nor objected to donation. The only sensible reading of the Table would suggest that interventions in support of DCD would not be covered by “deemed consent” because the person is alive. The Draft Explanatory Notes in Annex 1 to the EM say that “deemed consent can never apply when an adult is alive.” We have argued above that DCD should be excluded from these proposals and we restate that argument here. In DCD, a decision has already been reached to withdraw life-sustaining treatment because it is no longer in the person’s best interests. It must therefore be contrary to her best interests to continue the relevant interventions if there is any remote risk of consequent distress. Intervention which is otherwise contrary to a (dying) person’s best interests can be in her best interests on the basis of her express consent because it allows her wishes to be fulfilled and promotes her former autonomy. It cannot be in her best interests on the basis of “deemed consent” which does not relate to any autonomously expressed wish, intention, goal, aim or value. The donor, and arguably society as a whole including any potential recipient, are harmed by such interventions. If, as we infer, the intention is to exclude DCD from these

proposals then we would welcome an explicit comment to that effect to reduce uncertainty in this important area of clinical decision-making.

- 4 Registration partnerships. The EM says that the existing partnership arrangements (DVLA, Boots and Facebook) will continue to allow an opt in but not an opt out. This asymmetry is ethically problematic because it could lead people who consider registering in those ways to believe that by not opting in they are implying that they do not wish to donate. This arrangement undermines the intended assumption that someone who has expressed no wish did not object. The partnership arrangements should be changed so as to allow access to the Welsh register either to opt in or opt out.
- 5 Previous consultation outcomes.
  - a. In our response to the Welsh Government's 2011-2012 consultation we worked within its stated remit and did not offer a 'yes'/'no' opinion on the opt-out system but rather commented on the ethics of its implementation. We therefore strongly object to the use in the EM and in earlier publicity of statistics about respondents' views on whether the opt-out system should go ahead. It is clear that there are strong views for and against the opt-out system. We share the concerns that those who are strongly against are a significant proportion of the population and that their opposition could contribute to a higher than expected proportion of opt-outs, undermining the Welsh Government's laudable intention of increasing donation and transplantation rates. We do not accept that opposition can easily be written off on the basis of the number of identical responses to the Summer 2012 consultation. We note that a significant proportion of responses supporting an opt out system in earlier consultations were similarly identical and that less weight has been given to that by the Government's presentation of public opinion.
  - b. Regarding the focus groups, we are not surprised that participants "found it easier to argue for [the] opt-out proposals than against". It is easier, and arguing against is not easy; but we hold that ease of arguing has little relevance because the difficult arguments on both sides are pivotal to the rightness of the detail and implementation of the proposals.
  - c. We are surprised and concerned that among the comments on responses to Welsh Government consultations, there are none on the concerns raised about the term deemed consent. We and other respondents known to us did raise detailed concerns on this point which we believe to be of fundamental importance.
- 6 Hospital resources. We have significant concerns about the need for a shift of resources to provide the additional theatre and critical care capacity required to deliver an increase in transplantation rates. It may be that this internal redistribution may be an ethically just form of mesoallocation but this needs more explicit analysis. The likely small proportion of donated organs that will be transplanted into residents of

the same LHB area, or of Wales, means that savings from the post-transplantation reduction in medical care (such as dialysis) will not be released locally. So on what should each LHB spend less to allow for the increase in local theatre and critical care time?

## References

- 1 Gillon R (1985): *Philosophical Medical Ethics*. Chichester, John Wiley & sons.
- 2 Baker JI *et al* for the Clinical Ethics Committee of ABM University Health Board: written submission to the Welsh Government's consultation on organ donation, January 2012.
- 3 Idris Baker & Richard Hain, meeting with John Abraham, HSCC, Cathays Park, 6<sup>th</sup> February 2012.
- 4 Dr Chris Jones, public meeting at St John's Church, Cardiff, 21<sup>st</sup> January 2012.
- 5 Grant Duncan, Swansea, 9<sup>th</sup> July 2012.

## 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 Regulations<sup>1</sup> 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.

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<sup>1</sup> <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 Assembly<sup>2</sup> 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.

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<sup>2</sup> <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.

**Health and Social Care Committee**  
**Human Transplantation (Wales) Bill**  
**HT(Org)28 – Professor John Saunders**

**Draft Human Transplantation (Wales) Bill**

This paper is offered as a guide to issues raised by the Bill (& its memorandum of explanation) ahead of the meeting at the National Assembly on February 7.

The Welsh Assembly Government has bent over backwards to consult on these proposals: with its specialist advisory groups, its public consultation and its active programme of local opinion finding. (The latter was well intentioned, but the numbers too small to be reliable. As its report makes clear some of the findings were contradictory. Nevertheless, it was a good effort).

On the central issue, let me reiterate that I strongly support the intention of the Bill. Transplants save lives; transplants enhance lives. They are also cost effective: transplantation is cheaper than dialysis, for example.

The draft Bill and its explanatory memorandum are, in the main, well written and understandable. The term ‘presumed consent’ has, mercifully, been expunged. What now appears is ‘deemed consent’. I interpret this to mean that the person from whom organs will be removed has not consented but will be treated as if they have. (It might be helpful to acknowledge that in the Memorandum). That is now correct; ‘presumed consent’ (despite its previous use in the Health, Well Being and Local Government Report) was wrong. Consent, to repeat, can never be presumed: that is definitional of consent. Similarly the term ‘donation’ or ‘donor’ implies giving. Giving is voluntary. If there is no knowledge that someone wanted to give, then it is not a gift. It is something removed, not donated. That does not make it morally objectionable, merely inappropriate and – in an extreme view – coercive use of language.

The chief problem with this Bill remains its underlying justification. Organ donation has risen by about 50% since the UK Organ Donation Task Force Report. In Wales 37% are now on the register, an achievement of which Wales should be proud. It is not “only” 37%. There is nothing in the Explanatory Memorandum to the Bill to suggest that a further significant improvement can be achieved by this legislation. We know that Spain, in particular, has the best record in Europe for transplants and we also know that it is not the result of its opt out system.

Para 13 of the Explanatory Memorandum states that “nothing could be further from the truth” that organs will be taken compulsorily or automatically. If there are no family members available to act as advocates against, then the organs will be taken. I have no moral difficulty with that: but I also don’t think it is ‘nothing further from the truth’. It strikes me as pretty close to the truth! The problem with soft opt out is that it is very close to what currently happens when consulting the potential source patient’s family. Insofar as the possible patient’s wishes are downgraded, it is not difficult to understand how some will construe this as the person’s body becoming the property of government: even though it doesn’t. It is legitimate for the state to act on the basis of the best interests of society while protecting minority beliefs. Given the balance of benefit, perhaps the memorandum should make the case for the Bill with greater moral force about the contrast between organs transforming lives, on the one hand; and organs being eaten by worms or burned to ashes on the other. Failure to maximise benefit when the personal cost (i.e. by the

source patient) is so minimal (actually nil, as they are then dead) and the potential for good so high makes the moral calculus, in my view, clear.

The problems with the Bill are the hazards it creates for damaging the present programme of transplantation. That damage will be contingent on certain practicalities and how they are handled. A single mishandled opportunity in the hands of a critical media could create havoc with donation numbers; a vociferous opposition could prime the public in a negative manner if practical issues are not addressed. Among these are the way the modified Register is operated. There is a substantial potential for confusion in the single opt in/opt out register. 'Opting in' could fall, while 'opting out' would take us little further on than where matters stand at present. The practicalities of constant reminders of the system will be challenging. It will require different materials compared to England and Scotland: for example, the invitation on Boots Advantage Card membership may require amending. In principle this represents no problem, but practice may be more difficult.

The biggest single problem with the Bill is the lack of data to predict (or even make probable) its success. The Bill has been introduced in the face of two expert inquiries: one UK wide which was unanimous despite starting with divided opinions; and one in Wales with a 2:1 majority against. It is nowhere adequately explained why these two expert groups got it wrong. After all, the Task Force's other recommendations have surely been responsible for rising rates of donation across the UK. The track record of the Task Force has been good so far on the other issues.

Given the manifesto commitment and the advanced stage of planning, this point may be considered a battle lost for opponents of the Bill; and I would tend to agree with that. However it does emphasise the importance of agreeing what would constitute success. Politicians do not have a high place in public esteem. (I personally think that is overall rather unfair, but that is beside the point). The risk is that if donation continues to rise at the same rate as it is currently rising, there will be a political incentive to now claim that it results from the Bill, when it would have happened anyway. Whether we like it or not, Wales is a pilot project for the rest of the UK. If it can be clearly demonstrated that the Bill really has made a difference, then England and Scotland and Northern Ireland will follow suit, to the great benefit of thousands of patients. If the numbers transplanted falls then the reverse applies. It is therefore critical that what constitutes success is set out in advance and not the subject of argument afterwards. I appreciate the difficulties of creating 'counterfactuals' as discussed at paragraph 93 and the section on Regulatory Impact Assessment is short on detail. It would be helpful to discuss how this might be improved.

This paper emphasises issues previously articulated in the paper submitted by the Royal College of Physicians of London. I declare an interest as the main contributor to that paper and continue to hold the views in it. You may wish to consider queries and opinions arising from it alongside this briefer submission.

John Saunders

Chair, Committee for Ethical Issues in Medicine, Royal College of Physicians of London.  
Consultant physician, Nevill Hall Hospital, Aneurin Bevan Health Board.  
Chair, Donation Committee ABHB (the views above do not represent the views of ABHB)



**Health and Social Care Committee**  
**Human Transplantation (Wales) Bill**  
**HT(Org)29 – Aberystwyth Quaker Meeting Religious Society of Friends**

Human Transplantation (Wales) Bill

We have, as a local Quaker meeting, considered the ethical and practical implications of this Bill which has been introduced to the National Assembly.

We appreciate that our comments may reach the committee too late for its consideration, but nevertheless hope that our response may have some bearing on discussions.

We have arranged for this minute to be sent to Cytun, the ecumenical body with which we are in membership.

We realise that not everyone will support the intentions of the Bill feeling that an 'opt-in method', as currently available, best protects individual and communal sensibilities.

However, overall, we feel that there is nothing to impede support for the Bill, given the finality of our physical being and the possibility that our remains might assist others to lead fuller, longer lives. This is then a matter of showing compassion with those who are in ill-health, where the availability of organ transplantation is a solution to their predicament, giving them and their families hope, in that light it will offer consolation to many. The offering of an organ is both a gift and a legacy

This Bill gives truth to the fact that we all belong to the one society of which we are part, and its outcome should not be seen as a desecration of long held views, and may lead to people gaining a clearer understanding of their own deaths and mortality.

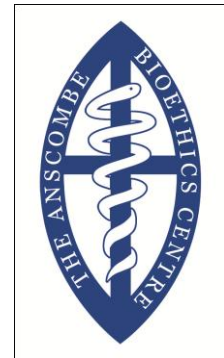
We are concerned that in certain cases, keeping people alive so that their organs can be harvested at a suitable time for medical purposes should be safeguarded. We cannot support any intention that sees organs having a commercial value, and it is therefore essential that control of the procedures and processes be always in the hands of the National Health Service.

It is essential to give people time to come to terms with the legislation if it is passed, so that the concept is familiar to everyone. The needs of those moving to live into Wales is worthy of close attention.

We are particularly sensitive to the demands and challenges that the legislation may give to some professionals, especially those on grounds of conscience who do not support its intentions.

Gethin Evans  
Clerk for this time.

Submission by the Anscombe Bioethics Centre to  
The Health and Social Care Committee  
Inquiry into the general principles of  
The Human Transplantation (Wales) Bill)<sup>1</sup>



**Main points:**

- **The evidence submitted to the previous consultations demonstrates that the case for a change in the law to a ‘soft opt out’ system is very weak**
- **The Anscombe Centre strongly urges the Welsh Government not to change the law on consent but to encourage donation via protocols which are ethically sound**
- **The Human Transplantation (Wales) Bill reflects not a ‘soft opt out’ but a ‘hard opt out’**
- **Several amendments are required if it is to reflect a ‘soft opt out’ system**
- **These amendments include an explicit requirement to consult relatives and a right for relatives to object where there is no evidence of prior express consent by the deceased**

**The Anscombe Bioethics Centre**

The Anscombe Bioethics Centre is the oldest national bioethics centre in the United Kingdom, established in 1977 by the Roman Catholic Archbishops of England and Wales. It was originally known as The Linacre Centre for Healthcare Ethics and was situated in London before moving to Oxford. The Centre engages with the moral questions arising in clinical practice and biomedical research. It brings to bear on those questions principles of natural law, virtue ethics, and the teaching of the Catholic Church, and seeks to develop the implications of that teaching for emerging fields of practice. The Centre engages in scholarly dialogue with academics and practitioners of other traditions. It contributes to public policy debates as well as to debates and consultations within the Church.

We are grateful for the invitation to submit written evidence to the Welsh Assembly Health and Social Care Committee after the formal deadline for evidence has passed. Having been brought up in Wales, and having relatives currently living in Wales, the director has submitted evidence in a personal capacity to this consultation and to consultations at previous stages of the process. As a Roman Catholic centre of research in bioethics, the Anscombe Centre was also aware of the Joint Response to the White Paper on behalf of The Roman Catholic Church in Wales, The Church in Wales, and the Wales Orthodox Mission<sup>2</sup> and fully endorses that document. The Joint Response is a significant discussion of the ethical principles raised by this Bill, and would merit a fresh consideration by the Health and Social Care Committee. The discussion in the present Anscombe Centre response should be understood as complementary to these previous submissions.

**The Catholic view of organ donation: Organ donation as a profound act of human solidarity**

The Catholic understanding of organ donation is that it is not only of utilitarian value but, when done voluntarily and in an ethical manner, it is an act of generosity that coheres with a true humanism and helps to reinforce positive attitudes of solidarity within society.

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<sup>1</sup> <http://www.senedd.assemblywales.org/mgIssueHistoryHome.aspx?IId=5178>

<sup>2</sup> Please find a copy attached for your convenience.

When solid organ transplants were first being attempted in the 1950s, Pope Pius XII explained to Catholics that this was 'not a violation of the reverence due to the dead'. Rather, it was justified because of 'the merciful charity shown to some suffering brothers and sisters.'<sup>3</sup> More recently Pope John Paul II said that, 'We should rejoice that medicine, in its service of life, has found in organ transplantation a new way of serving humanity'.<sup>4</sup> Far from opposing the use of the dead body in the service of medicine, the Church actively encourages Catholics to offer their organs after death. The Catechism of the Catholic Church states that 'Organ donation after death is a noble and meritorious act and *is to be encouraged* as an expression of generous solidarity.'<sup>5</sup>

### **The need for consent**

The Catechism of the Catholic Church is very clear on the need for consent. It states that organ transplantation 'is not morally acceptable if the donor or his proxy has not given explicit consent.'<sup>6</sup> It is not morally acceptable because it fails to respect the human meaning of the human remains. Indeed if organs are taken without the consent of the 'donor', or that of the relatives speaking on behalf of the donor, then this is not an act of 'donation'. It is taking without asking. It may be 'deemed' a gift but it is not truly a gift unless it is expressly given. The words of Pope John Paul II regarding donation without consent are very clear: 'In such a perspective, organ transplantation and the grafting of tissue would no longer correspond to an act of donation but would amount to the dispossession or plundering of a body.'<sup>7</sup>

### **The alleged benefits of a 'soft opt out system'**

From the beginning, proposals to abandon the principle of express or proxy consent for organ donation have justified the move by claiming that it will increase the number of organs available. For example, in the Written Statement of 3 December 2012, the Minister for Health and Social Services stated that 'Evidence suggests changing to this system can increase organ donation by up to 25 per cent'.<sup>8</sup> However, the evidence that was introduced in favour of this showed no causal relation but rather an association between rates of donation and presumed consent legislation. Indeed the very report written to support the proposals states explicitly that it 'cannot be inferred that this association means that presumed consent causes increased organ donation.'<sup>9</sup> The evidence of a supposed causal link between opt out systems and rates of transplantation is no stronger now than it was when, the Organ Donation Taskforce concluded that it was 'not confident that the introduction of opt-out legislation would increase organ donor numbers', and there was 'evidence that donor numbers may go down'<sup>10</sup>. Similar conclusions have been reached by two independent reviews in peer review journals in 2011<sup>11,12</sup>

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<sup>3</sup> Pius XII, 'Address to the delegates of the Italian Association for Cornea Donors and the Italian Union for the Blind', May 14 1956. For further references see D.A. Jones (2001) *Organ Transplants* London: Catholic Truth Society.

<sup>4</sup> John Paul II 'Address to the participants at the First International Congress on the Transplant of Organs', June 20, 1991.

<sup>5</sup> *Catechism of the Catholic Church* Paragraph 2296, emphasis added.

<sup>6</sup> *Catechism of the Catholic Church* Paragraph 2296.

<sup>7</sup> Ibid.

<sup>8</sup> <http://wales.gov.uk/about/cabinet/cabinetstatements/2012/6808739/?lang=en>

<sup>9</sup> *Opt-out systems of organ donation: International evidence review*, p. 2

<http://wales.gov.uk/docs/caecd/research/121203optoutorgandonationsummaryen.pdf>

<sup>10</sup> Organ Donation Taskforce (2008) *The potential impact of an opt out system for organ donation in the UK*, paragraph 11.2.

<sup>11</sup> McGlade D, Rae G, McClenahan C, et al. 'Regional and temporal variations in organ donation across the UK (secondary analyses of databases)' *BMJ Open* (2011).

The *Explanatory Memorandum* to the Bill also uses statistics in a misleading manner. While welcoming the increase in rates of donation throughout the UK, and most particularly in Wales, the *Memorandum* concludes that 'NHSBT figures provided to the Welsh Government show the UK as a whole still has a relatively low donation rate with 16.4 pmp (2010 figures) compared with 32 pmp in Spain, 30.7 pmp in Croatia and 30.2 in Portugal'.<sup>13</sup> However, it is doubly misleading to quote UK figures when making a case for donation rates in Wales. In the first place, the relative populations of England and Wales mean that significant changes in the donation rate in Wales do not have a significant effect on the overall UK rate. In the second place, the statistic is misrepresentative because the rate of donation in Wales is much higher than it is in the UK as a whole. In 2012 the rate in the UK was 17.4 whereas the rate in Wales was 24.9.<sup>14</sup> This has not yet reached the levels of Spain, Portugal, or Croatia, but it is improving rapidly and this improvement is not due to change in the legislation. Similarly, while Spain has presumed consent legislation, the increase in rates of transplant did not occur when they changed the law, but only later when they developed a new approach to transplantation and the appointment of transplant coordinators.

### **The importance of trust and communication with relatives**

The success of transplant coordinators in Spain has been achieved by building trust with relatives and not by overriding the wishes of relatives. This is not simply the culture of the people, because it is reflected also in the pattern of donation of British people resident in Spain. Thus in 2005, the families of 45 British people who died in Spain were approached for their permission to allow donation. None of these families refused, despite the fact that, in the UK, the family refusal rate is 40%.<sup>15</sup>

In the Written Statement of 3 December 2012, the Minister for Health and Social Services reported that a review of the role of families in organ donation had demonstrated that 'knowledge of the deceased's wishes is perhaps the strongest factor in families' decision to agree, or not, to organ donation'.<sup>16</sup> This supports the conclusions of the Organ Donation Taskforce which found that where the deceased was not on the register, then in more than 40% of cases the family refuses permission for the organs to be removed, whereas if the deceased has expressed a view through the register, the refusal rate falls to 10%.<sup>17</sup> There is reason to think this refusal rate would be lower still had the deceased spoken with relatives about his or her wishes.

It should be emphasised that the legal action of deeming someone to consent because they have not opted out cannot 'reassure families that they know the deceased's wishes'<sup>18</sup> because expressing a view takes a conscious effort and, therefore, *not expressing a view* does not provide good evidence of consent: it is simply not equivalent to express consent epistemologically, even if it is 'deemed' to be so in law.

There is strong evidence in favour of the approach that Wales has adopted thus far in increasing its rates of donation through implementing the recommendations of the Organ Donation Task Force, and through increased public awareness of donation. It is precisely these innovations that have

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<sup>12</sup> Brian J Boyarsky, Erin C Hall, Neha A Deshpande, R Lorie Ros, Robert A Montgomery, Donald M Steinwachs, Dorry L Segev 'Potential Limitations of Presumed Consent Legislation' *Transplantation* 09/2011.

<sup>13</sup> *Explanatory Memorandum to the Human Transplantation (Wales) Bill* (3 December 2012), paragraph 17.

<sup>14</sup> NHS Blood and Transplant *Organ Donation and Transplantation Activity Report 2011/12*, figure 3.2.

<sup>15</sup> <http://news.bbc.co.uk/1/hi/health/7183798.stm>

<sup>16</sup> <http://wales.gov.uk/about/cabinet/cabinetstatements/2012/6808739/?lang=en>

<sup>17</sup> Organ Donation Taskforce *The potential impact of an opt out system*, paragraph 11.3

<sup>18</sup> *Explanatory Memorandum*, paragraph 148.

increased rates of donation in Spain. In contrast the evidence is equivocal, at best, that changing the law away from express consent will in itself have a positive effect on donation rates.

While there is very poor evidence for any causal link between a change in the law to presumed consent and an increase in donation, the danger to public trust is already apparent. Changing the law could further alienate that minority of the population who do not support it. This has been shown in the shift in reaction to the various public consultations. If one discounts identical submissions from one side or the other (which generally reflect campaigns for or against legislation) and look at those who took trouble to write individual responses, it is clear that there is a consistent and increasing majority who are expressing concern. Furthermore, while a plurality of the population continue to express support for a change in the law, when asked in opinion polls, support has fallen below 50% of the population, while those who are opposed seemed to have increased with each further public engagement, and have become more alienated. In matters where public trust is essential the *Government* should consider not only the views of the majority, but also how to avoid disenfranchising a significant minority whose reasons for opposing the change should be taken seriously.

The reasonable concerns voiced during the consultation process in Wales are also reflected in the online responses<sup>19</sup> to a recent article in the *British Journal of Medicine*,<sup>20</sup> which advocated a similar 'opt out' to that proposed in the Bill. One of the respondents, Dr Jurgen De Wispelaere, illustrated the issue using the following example.

'In February 2007, in Singapore, the kidneys and corneas of Sim Tee Hua were removed under protest from Mr Sim's mother and wider family. Sim had not opted out of Singapore's presumed consent system, so while 20-30 security personnel and police restrained the distressed family, Sim's body was taken away and his organs removed. The incident provoked public outcry, and in the following weeks many people opted out of the organ donor scheme.'<sup>21</sup>

Similarly, Dr Jacqueline Monaghan gave powerful testimony to the importance for a recipient of knowing that the transplant had been carried out in a sensitive and ethical manner.

'As both a doctor, a recipient of a double lung transplant and having lost a family member waiting on transplant, I was left feeling very uncomfortable reading this opinion letter. However from all three angles, as both the care giver, the recipient and the professional, my conclusions would be the same. As a recipient I view the donation of organs as a gift - from both the donor and their family. I would be horrified to think that in receiving an organ, another family had been left feeling abused and ignored.'<sup>22</sup>

It is to be hoped that, even if the Bill contained no safeguards, professionals in Wales would never act in such an insensitive and brutal manner. Nevertheless, the aim of drafting legislation ought to be to support good practice and promote public trust by including *explicit safeguards*. The law should not permit organs to be taken in the face of strong opposition from relatives in circumstances where the deceased had never given express consent to donation.

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<sup>19</sup> 'We should not let families stop organ donation from their dead relatives'. *BMJ Rapid Responses*  
<http://www.bmj.com/content/345/bmj.e5275?tab=responses>

<sup>20</sup> Shaw, D. 'We should not let families stop organ donation from their dead relatives'. *BMJ* 2012; 345; e5275.  
<http://www.bmj.com/content/345/bmj.e5275>

<sup>21</sup> De Wispelaere, J. 'Respecting the family is key in any viable organ procurement policy' *BMJ Rapid Response*  
<http://www.bmj.com/content/345/bmj.e5275/rr/599245>

<sup>22</sup> Re: We should not let families stop organ donation from their dead relatives *BMJ Rapid Response*  
<http://www.bmj.com/content/345/bmj.e5275/rr/598035>

## Ante mortem procedures in relation to post mortem donation

A further flaw with the proposed Bill is that it does not cover ante mortem procedures directed towards post mortem donation. This has some application in regard to donation after death as determined by brainstem criteria (DBD), but it has very wide if not universal application for donation after death as determined by cardiac criteria (DCD).

DCD now accounts for over one third of post mortem transplantation procedures and is increasing.<sup>23</sup> In such cases the decision about transplantation will be made while the person is still alive, and the circumstances of withdrawal of treatment coordinated so as to facilitate post mortem organ retrieval. The success of transplantation post mortem in these cases is therefore dependent of decisions about what is in the best interest of a living patient: decisions that generally fall under the Mental Capacity Act 2005 and cannot be resolved on the basis of 'deemed' consent. Certainly it cannot be presumed that a person who has never expressly consented to donate has consented to procedures in life that would facilitate donation.

An important difference between DBD and DCD is that in the case of DBD the conversation with next of kin will frequently occur after the determination of death, while in the case of DCD the conversation must happen before death and in circumstances where relatives may be unwilling to relinquish hope of recovery. If, prior to DCD, healthcare professionals had to inform relatives that under Welsh law, treatment could be withdrawn from the living in such a way that organs could be taken after death, without express prior consent of the patient, and overruling any objections that the next of kin might have, this would further complicate an already difficult discussion. It is a recipe for irretrievable breakdown of trust, especially in cases where the person belonged to an ethnic, religious or other minority within Wales.

## The Human Transplantation (Wales) Bill reflects a 'hard opt out' system

Throughout the process of consultation on the various iterations of this legislation, the Welsh Government has maintained its preference for a change in the law to a 'soft opt out' system. This is distinguished on the one side from the current model of explicit consent and on the other side from systems (such as that which operates in Austria) where the family are given no role in the process. The *Explanatory Memorandum* on the Bill of December 2012 used the phrase 'soft opt -out' some 35 times and defines this as follows:

'A soft opt-out systems [is] where organs would become available for donation after death if the deceased had not opted out, but where families would retain full involvement in the process.'<sup>24</sup>

Or again:

'A **soft opt-out system** is one where consent to the removal and use of organs and tissues for transplantation is deemed as having been given unless the deceased objected during their lifetime, and where the next of kin will be involved in the decision making process.'<sup>25</sup>

The public support for the Bill, which provides the mandate for the legislation, has been premised on repeated claims that a change in the law would increase availability of organs by up to 25% and by

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<sup>23</sup> NHS Blood and Transplant *Organ Donation and Transplantation Activity Report 2011/12*, figure 3.2.

<sup>24</sup> *Explanatory Memorandum*, paragraph 14, with similar definitions throughout the document.

<sup>25</sup> *Explanatory Memorandum*, paragraph 94, bold in the original.

repeated assurances that the change in the law would be to a 'soft opt out' system and not to a 'hard opt out' system in which bereaved relatives had no place and no say.

It is thus of considerable concern that the Bill, both in its 'Draft' form and 'As Introduced' contains no requirement that the proposed 'opt out' system involve the next of kin in any way. The proposed legislation places no duty on healthcare professionals to identify, inform, consult or otherwise involve the next of kin. If a person in a qualifying relationship comes forward and gives credible evidence that the deceased would have objected, then consent cannot be deemed, and if a person comes forward who has been formally appointed as a proxy for the purpose, then consent cannot be deemed. But there is no requirement to identify people in such qualifying relationship prior to the transplantation. Furthermore, the requirements for the formal appointment of a proxy are such that few would qualify, even in circumstances where there is credible evidence that the deceased wished that person to represent them in medical decision-making.

Thus in the Bill as introduced, if a person had credible evidence that the deceased strongly objected to transplantation, but that person did not stand in a qualifying relationship, then the evidence could be discounted and consent to transplantation could still be 'deemed'. Similarly if the deceased had repeatedly asserted to different people that he wished his spouse to make the decision, but he had not done so before two witnesses at the same time, or in writing before a witness, then the spouse's wishes could be discounted. Similarly if a healthcare team failed to make any enquiries whatsoever about next of kin, and it was subsequently discovered that a person in a qualifying relationship had evidence that the deceased was strongly opposed to donation and/or it was discovered that the deceased had formally appointed a proxy to ensure these wishes were respected, no offence would have been committed under the proposed Bill.

In sum, the proposed Bill reflects a 'hard opt out' system with no legal requirement of elements constitutive of a 'soft' system. Even those very minimal protections which are present in the Bill are vitiated by a lack of any duty on the part of those retrieving organs to take reasonable steps to identify, consult, or otherwise involve one or more people in a qualifying relationship with the deceased person.

### **Changes in the Bill necessary for it to reflect a 'soft opt out' system**

In 1993, during a period of revision of the legislation in France, the Catholic Bishops of that country stated forthrightly that, 'It would be inhumane to procure organs in cases where the family is opposed or has expressed strong aversion, acute distress, or has no prior knowledge.'<sup>26</sup> In this way they gave expression to a popular concern which, it was feared, would undermine the support for transplantation under the presumed consent model then in operation. In response, a new law was introduced which prescribed a duty to consult relatives. In Belgium, which also introduced a 'soft opt out' system, the law explicitly gave relatives a right to object to transplantation, where there was no prior express consent to donation on the part of the deceased. This system relied on presumed consent but effectively acknowledged that presumed consent (or what the Human Transplantation (Wales) Bill terms 'deemed consent') is not evidentially as strong as express consent and therefore is not sufficient (without further evidence of the express wishes of the deceased) to override the objections of relatives.

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<sup>26</sup> Statement by the Permanent Council of the French Bishops' Conference, *Solidarite et Respect des Personnes dans les Greffes de Tissus et d'Organes*, 12 October 1993, Documents-Episcopat, no. 15, October 1993, translation from COMECE *Science and Ethics Opinions elaborated by the Bioethics Discussion Group of the Secretariat of COMECE* (June 2008) <http://www.comece.org/content/site/en/publications/pubsec/index2.html>

If, despite the weakness of the case for changing the law, and the real dangers that might follow, the Welsh Government persists in its plan to change the law, then at the very least the legislation must be modified so that it reflects the 'soft opt out' system rather than the 'hard opt out' currently reflected in the Bill.

This could be done by inserting the following or similar clauses in the Bill:

- [Those in qualifying relationships should also include] *A person named orally or in writing by the deceased as a person to be consulted.*
- [Deemed consent should not apply unless] *reasonable efforts have been made to identify and consult with one or more persons in a qualifying relationship.*
- [Deemed consent should not apply unless] *where there is no information that would lead a reasonable person to conclude that the deceased had chosen to donate, other than the lack of express objection, and where a person who stands in a specified relationship objects, then the deceased cannot be deemed to have given his or her consent.*
- [A person commits an offence if] *the person does a transplantation activity in Wales using organs from a deceased person without taking reasonable steps to identify and consult with one or more persons in a qualifying relationship to the deceased.*

## **Conclusion**

The evidence submitted to the previous consultations by many bodies and individuals, and well summarised in the *Joint Response to the White Paper on behalf of The Roman Catholic Church in Wales, The Church in Wales, and the Wales Orthodox Mission*, demonstrates that the case for a change in the law to a soft opt out system is very weak and based only on correlations, while the break from the principle of express consent would represent a serious and immediate harm.

It is often regarded as a sign of weakness that a government reverses its intention to bring forward legislation, but when that decision is based on reflection on the arguments and the evidence, it should be counted a sign of strength. The Anscombe Centre strongly urges the Welsh Government not to change the law on consent but encourage donation via protocols which are ethically sound and where consent from donors or proxies is obtained. The most ethical and effective course of action is to concentrate efforts on education, communication and restructuring which have led to and continue to lead to dramatic improvements in the rate of donation in Wales.

If the Welsh Government persists with this legislation then there are several amendments that are required if it is to reflect a 'soft opt out' system, and not, as now a 'hard opt out' system in which there is no duty to consult and in which the strong objections of relatives could be overridden even in circumstance where there was no evidence of prior express consent.

The Centre wishes again to express its gratitude for the invitation to submit evidence to The Health and Social Care Committee on this important issue.

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13 February 2013



## Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper

### A joint response on behalf of The Roman Catholic Church in Wales, The Church in Wales, and the Wales Orthodox Mission

#### Summary

1. *This response primarily addresses the proposals in the White Paper at the level of principle. It is based on the conviction that organ donation is a profoundly Christian positive act. Our main concern is that the positive ethos of donation as a free gift is being endangered by an ill-judged if well-intentioned proposal to move from voluntary donation to presumed consent. However, if organs may be taken without consent, this is no longer “donation”. This is not just a health matter but concerns serious human rights issues such as personal autonomy, as well as questions about the relationship of the state and the citizen. At the same time the belief that presumed consent would itself increase the number of organs available for transplantation is not supported by the available evidence, as is shown below (paragraphs 16 – 25).*

*Organ transplantation enjoys a high level of public support but it also involves the sensitive issue of respect for the human body after death, people’s human right to privacy and respect for personal beliefs and religion. These are areas that need to be negotiated with care and, as far as possible, by consensus legislation. We therefore urge the Welsh Government to revisit the process and establish a cross party committee that could consider all the evidence submitted to the previous enquiries of the last three years: the Organ Donation Task Force, the Welsh Assembly Committee, the U.K. Parliament’s Welsh Affairs Committee and also the substantial research conducted by the Universities of Ulster and Johns Hopkins.*

#### Response

2. The Welsh Government has invited responses to the White Paper both “*on particular aspects of the policy proposals*” and “*on the proposals more generally*”.<sup>[1]</sup> This response will primarily address the proposals at the more general level, for it is important to resolve questions of principle before considering how to implement proposals in practice.

#### The value of organ donation

3. The basis of this response is a shared conviction that organ donation is essentially a profoundly Christian act that is positive both in its consequences for the recipient and as an expression of human solidarity across society. Nothing in this submission should be interpreted as a rejection of the practice of donation of organs after death where this is done with due sensitivity to medical, cultural and ethical considerations. On the contrary, the concerns that are raised here are precisely that ill-judged proposals might endanger the ethos of donation.

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<sup>[1]</sup> Welsh Government Consultation Document *Proposals for Legislation on Organ and Tissue Donation: A Welsh Government White Paper* Number: WG13956, p. 18.

4. Taking their starting point from Christ who healed the sick and who gave Himself for the good of others, Christians have welcomed the benefits that have come through organ transplantation. From the very first there have been strong authoritative voices that would encourage donation.<sup>[2]</sup> There is, of course, diversity between and within Christian communities as there is diversity in wider society. There are differences of education, of personal and family experience, and different levels of trust in the establishment. There are also differences of view both about the practice of transplantation and about whether, and if so, how the law should change. This submission therefore cannot and does not presume to represent the views of every member of our respective communities. Nevertheless, precisely for this reason, the submission strongly urges that the law ***should not presume that individuals or their families would consent to donate their organs***. While there is some evidence of a greater level of donation among Christians,<sup>[3]</sup> and this is an activity that all Churches have encouraged,<sup>[4]</sup> it cannot be presumed that all Christians have decided to donate their organs, and still less can this be presumed for the population as a whole.
5. This joint submission also expresses the concern that any change in the law should protect marginalised communities and individuals, especially those who are socially excluded or who have difficulty in making their views heard. As Christians we are particularly aware of the way that minorities, including religious minorities, can be endangered by the majority, as for example when the majority does not adequately respect the need for consent from someone who is a member of a minority community.

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<sup>[2]</sup> For example, in 1956 when solid organ transplantation had yet to become common practice, Pope Pius XII argued that that would not be “a violation of the reverence due to the dead”. Rather, organ donation from the dead was justified because of “the merciful charity shown to some suffering brothers and sisters” (Allocution to Eye Specialists 14 May 1956).

<sup>[3]</sup> Researchers have shown a statistically significant correlation between Catholicism and rate of donation (Parliamentary Office of Science and Technology “Organ Transplants” *Postnote* October 2004 Number 231, page 2, quoting Gimbel et al. 2003. *Progress in Transplantation* 13:15-23). <http://www.parliament.uk/documents/post/postpn231.pdf>, To date researchers have not investigated the relation between rate of donation and Christianity for other Churches, but there is no reason to think it any less.

<sup>[4]</sup> Pope John Paul II said that, “We should rejoice that medicine, in its service of life, has found in organ transplantation a new way of serving humanity”. Hence the Catechism of the Catholic Church states that “Organ donation after death is a noble and meritorious act and is to be encouraged as an expression of generous solidarity.” For further references see UK Transplant leaflet of Christianity and organ donation [http://www.uktransplant.org.uk/ukt/how\\_to\\_become\\_a\\_donor/religious\\_perspectives/leaflets/christianity\\_and\\_organ\\_donation.jsp](http://www.uktransplant.org.uk/ukt/how_to_become_a_donor/religious_perspectives/leaflets/christianity_and_organ_donation.jsp)

## The necessity of consent

6. Pastors, theologians and Church leaders agree that offering organs for donation can be a significant act of charity, and a reflection of God's freely-given love and care for us, including the gift of life. A few examples should suffice:
7. "Above all, this form of treatment is inseparable from a *human act of donation*. In effect, transplantation presupposes a prior, explicit, free and conscious decision on the part of the donor or of someone who legitimately represents the donor, generally the closest relatives. It is a decision to offer, without reward, a part of one's own body for the health and well-being of another person. In this sense, the medical action of transplantation makes possible the donor's act of self-giving, that sincere gift of self which expresses our constitutive calling to love and communion."<sup>[5]</sup>
8. "Christian faith is a positive motivation for organ donation and a powerful incentive for many people to donate."<sup>[6]</sup> Organ donation is "an expression of the faith-based virtue of helping others; you might call it the 'generous gift' approach ... agreeing yourself to donating your own organs is easily understood as one person's generosity towards others."<sup>[7]</sup>
9. From the point of view of Orthodox Christian ethics, organ or tissue donation can be understood as a generous and virtuous act. Organ transplantation "makes it possible to give effective aid to many patients who were earlier doomed to death or severe disability... The transplantation of organs from a living donor can be based only on the voluntary self-sacrifice for the sake of another's life. In this case, the consent to explantation becomes a manifestation of love and compassion". The same principle applies to posthumous donation. "The posthumous giving of organs and tissues can be a manifestation of love spreading also to the other side of death."<sup>[8]</sup>

## What is wrong with "presuming consent"?

10. The fundamental Christian objection to presumed consent is that this contradicts the rationale and ethos of donation. "Presumed consent" is not consent. Silence is not consent. If organs are taken for transplantation without consent there is no giving, there is only taking.
11. It is sometimes said that Christianity has no official position on "opt-in" or "opt-out" systems of organ retrieval.<sup>[9]</sup> However it is difficult to reconcile "opt-out" systems with the clear Christian commitment to voluntary donation. If the organs are taken without

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<sup>[5]</sup> John Paul II *Address to 18th International Congress of the Transplantation Society* (29 August 2000).

<sup>[6]</sup> Church of England Mission and Public Affairs Division: Response to the House of Lords EU Social Policy and Consumer Affairs sub-committee call for evidence (Inquiry into the EU Commission's Communication on organ donation and transplantation: policy actions at EU level), October 2007, paragraph 2.

<sup>[7]</sup> John Davies, Bishop of Swansea and Brecon

<sup>[8]</sup> Russian Orthodox Church's document *The Basis of the Social Concept*, XII.7 Problems of Bioethics.

<sup>[9]</sup> Edwards, S. *Discussion document Introduction of an opt out (presumed consent) system in the context of Organ Transplantation* Welsh Assembly Government, 2008, Handout, <http://wales.gov.uk/topics/health/publications/health/guidance/discussion/?lang=en>

the prior consent of the deceased, or permission of a relative or friend speaking on behalf of the deceased, then the deceased is no longer a *donor* and taking the organs is no longer an act of *donation*. It is taking without asking. From a Christian perspective this fails to respect the enduring human meaning of the body. Instead of transplantation being an act of donation, an expression of solidarity between people, it becomes merely the medical use of a body.

12. Pope John Paul II clearly stated that without consent “organ transplantation and the grafting of tissue would no longer correspond to an act of donation but would amount to the dispossession or plundering of a body.”<sup>[10]</sup> This understanding is also expressed in the Catechism of the Catholic Church which lays down that organ donation “is not morally acceptable if the donor or his proxy has not given *explicit consent*.”<sup>[11]</sup>
13. From an Orthodox perspective, “donation... cannot be considered a duty. Therefore, the voluntary consent of a donor in his lifetime is the condition on which explantation can be legitimate and ethically acceptable”.<sup>[12]</sup> Hence “the so-called presumptive consent of a potential donor to the removal of his organs and tissues, sealed in the legislation of some countries, is considered by the Church to be an inadmissible violation of human freedom”.<sup>[13]</sup>
14. Within the context of the present debate, the Archbishop of Wales has given voice to this same shared Christian understanding of organ donation. “There is another theological argument. Organ donation surely ought to be a matter of gift. If one takes organs without consent, on the assumption that by not opting out, a person is tacitly assenting, then that is no longer a free gift to others. An organ donation ought to be precisely that, a gift, an act of love and generosity. Giving organs is the most generous act of self-giving imaginable but it has to be a choice that is freely embraced, not something that the State assumes. Put more crudely, it turns volunteers into conscripts. Presumed consent is not really consent at all, merely the assumption that there are no objections.”<sup>[14]</sup>
15. The Christian tradition supports the idea that the state may require us to do (or refrain from doing) certain things with regard to our bodies, for our own good or that of others (for example, safety legislation; the smoking ban, even potentially applied to private cars where children are present; illegal drugs; in extreme cases, taking children into state care if parents are unable or unwilling to act in their best interests, or if they refuse essential medical treatment). Some Christians also argue that the state should be able to use organs from dead bodies without our explicit voluntary consent. However, those who argue in this way must acknowledge that taking organs without consent is not “donation”. The call to use organs without consent is no more or less than a call to abandon donation as the basis for organ transplantation.

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<sup>[10]</sup> John Paul II *Address to The Society for Organ Sharing* (20 June 1991).

<sup>[11]</sup> *Catechism of the Catholic Church*, 2296, emphasis added.

<sup>[12]</sup> Russian Orthodox Church’s document *The Basis of the Social Concept*, XII.7.

<sup>[13]</sup> *Ibid.*

<sup>[14]</sup> <http://www.churchinwales.org.uk/structure/bishops/sermons/b43.php>

## Would presumed consent increase rates of transplantation?

16. It should not be taken for granted that changing the law to a system of opt-out / presumed consent would necessarily increase the availability of organs for transplantation. While some studies have shown a higher level of transplantation on average in countries with presumed consent laws,<sup>[15]</sup> it is very difficult to show that this is due to such laws or that a change in the law in itself would necessarily have a positive effect.
17. Changing to a system of presumed consent was rejected by the House of Commons in 2004. The Department of Health, having reviewed the evidence from different countries, stated that “it considers changing legislation to be a high-risk strategy. Without clear public support, presumed consent may be counterproductive, leading to reduced donation rates.”<sup>[16]</sup>
18. In 2008 the Organ Donation Taskforce was asked to consider the case for a change in the law to presumed consent. They commissioned research from the University of York which concluded that “The evidence identified and appraised is not robust enough to provide clear guidance for policy”.<sup>[17]</sup> After the comprehensive review (still perhaps the best to date) the Report concluded that it was “not confident that the introduction of opt-out legislation would increase organ donor numbers, and there is evidence that donor numbers may go down.”<sup>[18]</sup>
19. The country with the highest rate of organ donation is Spain, which has a law which allows organs to be taken with presumed consent. However, when Dr Rafael Matesanz, President of the Spanish National Transplant Organisation, gave evidence to the Organ Donation Taskforce, he was explicit: presumed consent was not the reason for the success of the Spanish system. He reiterated this at a briefing on presumed consent reported in the *British Medical Journal*.<sup>[19]</sup> When asked if a presumed consent law was the reason for the success of the Spanish system, he said:  
  
“Is it because of the law? Not likely. We have always had the same law. The families are always approached. They always have the last decision, and there are great variations from region to region.”<sup>[20]</sup>

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<sup>[15]</sup> E.g. A. Abadie and S. Gay, “The Impact of presumed consent legislation on cadaveric organ donation: a cross-country study,” *J. Health Econ* 25 (2006): 599-620 who suggested that presumed consent countries have roughly 25-30% higher donation rates than informed consent countries.

<sup>[16]</sup> Parliamentary Office of Science and Technology, p. 3.

<sup>[17]</sup> Organ Donation Taskforce (2008) *The potential impact of an opt out system for organ donation in the UK: A report from the Organ Donation Taskforce*, Department of Health, London, paragraph 11.2, [http://www.ics.ac.uk/the\\_potential\\_impact\\_of\\_an\\_opt\\_out\\_system\\_to\\_organ\\_donation\\_in\\_the\\_uk](http://www.ics.ac.uk/the_potential_impact_of_an_opt_out_system_to_organ_donation_in_the_uk)

<sup>[18]</sup> Organ Donation Taskforce 11.5.

<sup>[19]</sup> *British Medical Journal* 2008; 337: a1614.

<sup>[20]</sup> Organ Donation Taskforce 11.3. The fact that in practice Spanish physicians do not take organs without permission has led some studies to characterise Spain as having “presumed consent” legislation with “informed consent” as actual practice, see Parliamentary Office of Science and Technology, p. 2 quoting Council of Europe; National Transplant Organisation.

20. In the light of this evidence it should not be surprising that the cross party committee of the Welsh Assembly which considered presumed consent in 2008 came to a similar conclusion. The majority of the Health, Wellbeing and Local Government Committee judged that “organ donation rates can be improved significantly without introducing presumed consent. More than that, we feel there is a danger that moves to legislate in Wales ahead of the rest of the UK could be a distraction from more productive improvements and could alienate public support for organ donation if not handled properly.”<sup>[21]</sup>

21. The two most recent studies to look at presumed consent are from the University of Ulster and the Johns Hopkins University School of Medicine. In October 2011, a team from the University of Ulster compared donation rates for England, Wales, Scotland and Northern Ireland over two decades and also compared these rates with those of other European countries. They concluded that “Further exploration of underlying regional differences and temporal variations in organ donation, as well as organisational issues, practices and attitudes that may affect organ donation, needs to be undertaken before considering legislation to admit presumed consent.”<sup>[22]</sup>

22. The key paragraph from the Ulster study reviews the evidence from different countries. It is worth quoting in full:

“Hence, though Sweden applies presumed consent, its donation rate in 2009, at 13.8 deceased donors per million population (Scandiatransplant personal communication, 2011), was comparable with that of Germany (14.5 deceased donor per million population) and Denmark (14.0 deceased donors per million population); both of which require informed consent. The figures available for Ireland, where informed consent is needed, were 21.2 deceased donors per million population in 2009. The nation with the highest donor rate (34.4 deceased donors per million population in 2009), is Spain, which operates a ‘soft’ form of presumed consent where next of kin can object to organ donation. Yet, the impact of the legislation has been questioned and the high rate of donor activity attributed to the ‘Spanish Model’ that demands an integrated approach with dedicated transplant coordinators, mainly intensive care physicians, involved in procurement. This highly coordinated network and the respect for autonomy given to the individual and their relatives is credited with improving donation rates of 14.3 deceased donors per million population in 1989 to rates of 33-35 deceased donors per million population in recent years.”<sup>[23]</sup>

23. In November 2011 John Hopkin’s University published the results of in-depth interviews with transplant experts in 13 European nations with presumed consent legislation. They found that, despite the laws, the process of organ donation in those countries did not differ dramatically from the process in countries, such as the United States, that require explicit consent. “Opt-out is not the magic bullet; it will not be the magic answer we have been looking for,” said Dorry L. Segev, an associate professor of surgery at the Johns Hopkins University School of Medicine and leader

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<sup>[21]</sup> National Assembly for Wales, Health, Well-being and Local Government Committee, *Committee Inquiry into Presumed Consent for Organ Donation* (July 2008), p. 32, 10.3. <http://www.assemblywales.org/cr-ld7192-e.pdf>

<sup>[22]</sup> McGlade D, Rae G, McClenahan C, et al. “Regional and temporal variations in organ donation across the UK (secondary analyses of databases)” *BMJ Open* (2011). doi:10.1136/bmjopen-2011-000055, p. 6

<sup>[23]</sup> *Ibid*, p. 6.

of the study published online in the journal *Transplantation*. Implementing presumed consent legislation, Segev argued, would take a huge amount of time and energy with minimal payoff. Many countries with presumed consent have much lower rates of organ donation than the United States, he noted.

“With opt-out the perception becomes, We will take your organs unless you take the time to fill out a form. That’s a dangerous perception to have. We only want to use donated organs from people who intended to donate.”<sup>[24]</sup>

24. It is notable that the latest figures for 2010-2011 show that Wales has already achieved a significant increase in its rate of donation. At 27.7 deceased donors per million<sup>[25]</sup> this is now higher than the United States and is among the highest in Europe. There is every reason to think that further increases can be made through building on this success in public education, communication with relatives and more effective systems of transplant coordination. This real improvement has occurred without changing the law on consent. With high levels of public support, and recent initiatives giving significant improvements in rates of donation, this is no time to abandon the principle of voluntary donation.
25. Some people clearly believe that changing the law from opt-in to opt-out would itself improve the rate of transplantation, and this has been the basis of a very effective media campaign by some groups. However, this belief is simply not justified by the available evidence. It is a myth.

### **Can we reasonably presume that people have consented?**

26. It is frequently stated that “90 per cent of people in the UK say they support organ donation, but to date only 30 per cent have joined the NHS Organ Donor Register”,<sup>[26]</sup> in which case it might seem reasonable to presume that people would consent, if people are given ample opportunity to “opt out”. However, this 90% figure is from a survey by UK Transplant in 2003 which asked if people were “in favour of organ donation in principle”<sup>[27]</sup>. It was not a survey of how many people themselves wished to donate their organs. A more recent survey for Yougov in 2007 found that 62% of

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<sup>[24]</sup> John Hopkins Medicine, News Release 11/29/2011

[http://www.hopkinsmedicine.org/news/media/releases/presumed\\_consent\\_not\\_answer\\_to\\_solving\\_organ\\_s\\_hortage\\_in\\_us\\_researchers\\_say](http://www.hopkinsmedicine.org/news/media/releases/presumed_consent_not_answer_to_solving_organ_s_hortage_in_us_researchers_say) citing Brian J Boyarsky, Erin C Hall, Neha A Deshpande, R Lorie Ros, Robert A Montgomery, Donald M Steinwachs, Dorry L Segev “Potential Limitations of Presumed Consent Legislation” *Transplantation* 09/2011; DOI: 10.1097/TP.0b013e31823173e0.

<sup>[25]</sup> UK Transplant Organ Donation Activity 2011

[http://www.uktransplant.org.uk/ukt/statistics/transplant\\_activity\\_report/current\\_activity\\_reports/ukt/organ\\_donation\\_activity.pdf](http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/organ_donation_activity.pdf)

<sup>[26]</sup> For example, National Assembly for Wales Research Service *Organ and Tissue Donation* Paper number: 11/068, p. 3 <http://assemblywales.org/11-068.pdf> quoting NHS Blood and Transplant, Organ Donation online.

<sup>[27]</sup> UK Transplant Bulletin Issue 47 Summer 2003, p. 11

[http://www.uktransplant.org.uk/ukt/newsroom/bulletin/archive\\_bulletins/bulletin47\\_summer2003/bulletin47.pdf](http://www.uktransplant.org.uk/ukt/newsroom/bulletin/archive_bulletins/bulletin47_summer2003/bulletin47.pdf)

people were willing to donate.<sup>[28]</sup> This is a more realistic figure. There is evidence that people in Wales are more willing to donate,<sup>[29]</sup> but research carried out by the University of Swansea in 2008<sup>[30]</sup> found that, if an opt out system were established in Wales only 60% would “definitely not opt out” with a further 16% saying they would be unlikely to opt out. This leaves 24% who would opt out, might opt out, or who did not know. Interestingly, in the same poll, 24% of people said they strongly disagreed with presumed consent and a further 15% said they tended to disagree with presumed consent.<sup>[31]</sup>

27. These figures show that a significant percentage of people in Wales (between 24% and 39%) disagree with presumed consent and would not be willing for their organs to be taken without their prior consent or permission from those closest to them. As not everyone will get around to making their wishes known, it cannot reasonably be “presumed” that people have not made their wishes clear would have wanted their organs to be used for transplantation. There is a fair chance (perhaps one in four) that they would not have wanted this.

### Improving refusal rates

28. In current practice (both in Wales and in most other countries), whether or not a person has signed the Organ Donation Register (or equivalent), specialist nurses and consultants also ask the relatives whether they would permit organs to be taken. In the United Kingdom around 43% of families refuse permission. This is far higher than in other countries, such as Spain, where the refusal rate is around 9%.<sup>[32]</sup> How can this issue be addressed?

29. The Organ Donation Task Force found that, whereas the overall family refusal rate is around 40%, if the person is on the Organ Donation Register then the refusal rate drops to 10%.<sup>[33]</sup> This shows that families are generally supportive of the removal of the organs *when they know that this is what the person wanted*. The most effective way to increase rates of family permission for donation is therefore to encourage people to sign the Organ Donation Register and to encourage people to talk about the issue with relatives and those close to them. Any move that weakens the Organ

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<sup>[28]</sup> UK Transplant “Support grows for presumed consent” News release 19 October 2007 citing YouGov survey for BMA [http://www.uktransplant.org.uk/ukt/newsroom/news\\_releases/article.jsp?releaseld=190](http://www.uktransplant.org.uk/ukt/newsroom/news_releases/article.jsp?releaseld=190)

<sup>[29]</sup> McGlade et al. “Regional and temporal variations in organ donation”, p. 1.

<sup>[30]</sup> Opinion Research Service, from Swansea University conducted a telephone survey using structured questions to a representative sample of the Welsh population between 14th November and 8th December 2008.

<sup>[31]</sup> Welsh Assembly Government *Consultation Paper on Options for Changes to the Organ Donation System in Wales* (May 2009), p. 27.  
<http://www.wales.nhs.uk/sites3/Documents/773/Organ%20Donation%20consultation%201doc%20-%20English.pdf>

<sup>[32]</sup> Organ Donation Taskforce, 11.3.

<sup>[33]</sup> Organ Donation Taskforce, 1.15.



Donation Register and leaves relatives unsure of what the deceased would have wanted is likely to increase refusal rates among relatives.

30. It should also be noticed that refusal rates in the United Kingdom are significantly higher now than they were in the 1990s. It is likely that there are many causes for this increase, including the Alder Hey scandal in 1999 where organs were kept without consent.<sup>[34]</sup> A number of reports have emphasised the importance of maintaining public trust in the system and the importance of the principle of consent in maintaining this trust.<sup>[35]</sup>

### Consultation with relatives

31. The proposals in the White Paper call for a “soft opt-out” system in which the relatives will always be consulted. It is clearly important for the relatives and those close to the deceased to be consulted. However, the idea of “consultation” or of being “involved in the process” is ambiguous. The law needs to state unambiguously whether, in the absence of an explicit statement of the wishes of the deceased, the relatives will be able to refuse permission for the removal of organs.
32. A duty to consult, as currently proposed in the White Paper, is much weaker than a right to refuse permission. However, if relatives have no right to refuse permission in law, this represents a move of power away from the relatives of the deceased and towards the state. This is not just a matter of health but is about the right of the state to dispose of a body in a certain way even in the face of objections from closest relatives.
33. In practice it seems doubtful that specialist nurses in organ donation in Wales would want the power to overrule relatives so that organs were taken from those who had not given consent in the face of opposition from those who were closest to them. However, if this would not happen in practice, why does the Welsh Government need to create a power that would not be used? ***This power seems unnecessary while at the same time it threatens to undermine the very concept of free donation on which organ transplantation has hitherto relied.***

### The process of public consultation

34. In addition to grave concerns about the central proposal in the White Paper, there are also problems with the way in which this proposal has been brought forward.

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<sup>[34]</sup> According to the Parliamentary Office of Science and Technology (p. 3), in the 1990s the family refusal rate was 30% whereas by 2004 it had reached 42%.

<sup>[35]</sup> “Trust, however, is key to the success of the organ donation system in the UK. If public trust is shaken, organ donor numbers are likely to fall rapidly and could take many years to recover”, Organ Donation Task Force 4.6; “Comments provided highlighted concern that an opt-out system had the potential to damage the relationship of trust between clinicians caring for people at the end of their life.” Welsh Assembly Government Consultation Paper, p. 10; “...and others believe due to the general public’s mistrust for the Government they will resist this type of system being imposed on them.” National Assembly for Wales Research Service, 4.1; “Without clear public support, presumed consent may be counterproductive, leading to reduced donation rates.” Parliamentary Office of Science and Technology, p. 3 emphasis added.

35. Organ transplantation enjoys a high level of public support but it also involves the sensitive issue of respect for the human body after death. It involves people's human right to privacy and respect for personal beliefs and religion.<sup>[36]</sup> This is an area that needs to be pursued with care and, as far as possible, by consensus legislation.
36. It is of extreme concern that while responses are being invited on the proposals in the White Paper, the central proposal, which is the shift from donation to presumed consent, is presented as a *fait accompli*. This approach threatens to polarise debate and to alienate those who have reasonable concerns about this proposal. Whatever the exact shape and scope of the eventual law, this is not the way to secure a broad consensus.
37. We therefore urge the Welsh Government to revisit not only the proposals but also the process. This issue is one that should be resolved as far as possible through open dialogue and consensus building and by a process that can secure the widest possible support. It should not be a party political issue. What is needed to rescue this process is for some independent, academic, or cross-party body to conduct a genuinely open consultation which would consider a range of possibilities without prior commitments to a particular legislative proposal. They might reasonably look at systems that include aspects of opt-in, opt-out and mandated choice. It would also helpfully consider the evidence submitted to the previous enquiries of the last three years: to the Organ Donation Task Force,<sup>[37]</sup> to the Welsh Assembly Committee<sup>[38]</sup> and to the U.K. Parliament's Welsh Affairs Committee<sup>[39]</sup> and to consider the research conducted by the Universities of Ulster<sup>[40]</sup> and John Hopkins<sup>[41]</sup>. For it is not at all clear that the present proposals have benefitted as much as they might from the evidence available.
38. If the proposals in the White Paper are not subject to independent scrutiny then there is a real danger that a change in the law would alienate a significant proportion of the public and undermine the positive image of organ donation and the reputation of Wales. For while a high rate of voluntary donation speaks of a culture of generosity, a system of presumed consent would "turn donation into action by default".<sup>[42]</sup>

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<sup>[36]</sup> Some of these issues were raised in evidence submitted to the Welsh Affairs Committee when it considered Legislative Competence Consent for Organ Transplantation from a deceased adult. However, as the LCO was withdrawn, that Committee was not able to weigh this evidence or explore these human rights issues.

<sup>[37]</sup> Organ Donation Task Force.

<sup>[38]</sup> National Assembly for Wales (July 2008).

<sup>[39]</sup> Welsh Affairs Committee Sixth Special Report into Proposed Legislative Competence Orders relating to Organ Donation and Cycle Paths (HC 896) <http://www.parliament.uk/business/committees/committees-a-z/commons-select/welsh-affairs-committee/inquiries/parliament-2010/organ-donation-lco/>, see in particular Written evidence submitted by the Anscombe Bioethics Centre (which presents a Roman Catholic view) and written evidence submitted by The Wales Orthodox Mission.

<sup>[40]</sup> McGlade et al. "Regional and temporal variations in organ donation"

<sup>[41]</sup> Boyarsky et al. "Potential Limitations of Presumed Consent Legislation"

<sup>[42]</sup> As argued by UK Transplant: National Assembly for Wales, Health, Well-being and Local Government Committee, Committee Inquiry into Presumed Consent for Organ Donation - Evidence from UK Transplant.

## **Signatories**

**The Most Rev George Stack**  
*Archbishop of Cardiff (Roman Catholic)*

**The Most Revd Dr Barry Morgan**  
*Bishop of Llandaff, Archbishop of Wales (Church in Wales)*

**The Very Revd Archimandrite Father Deiniol**  
*Administrator, Wales Orthodox Mission (Eastern Orthodox)*

**The Rt Rev Thomas Burns**  
*Bishop of Menevia (Roman Catholic)*

**The Rt Revd Gregory Cameron**  
*Bishop of St Asaph (Church in Wales)*

**The Rt Revd John Davies**  
*Bishop of Swansea and Brecon (Church in Wales)*

**The Rt Revd Wyn Evans**  
*Bishop of St David's (Church in Wales)*

**The Rt Revd Andrew John**  
*Bishop of Bangor (Church in Wales)*

**The Rt Rev Edwin Regan**  
*Bishop of Wrexham (Roman Catholic)*

**The Rt Revd Dominic Walker**  
*Bishop of Monmouth (Church in Wales)*

**The Rt Revd David Wilbourne**  
*Assistant Bishop of Llandaff (Church in Wales)*

*In the name of Allah, The Beneficent, The merciful*

**We have honoured the progeny of Adam; ... given for them sustenance things good and pure; and conferred on them special favours; above a great part of Our creation.**

[The Glorious Qur'ān, Al-Isrā', 17:70]

This submission should not be interpreted as a rejection of the practice of cadaveric organ donation which, itself, remains a point of contention amongst contemporary Muslim scholarship, but rather it is argued that the Human Transplantation (Wales) Bill does not give due regard to the universal principle of respect for personal autonomy, emaciates the very concept of donation, and assumes what cannot reasonably be assumed. It relegates any notion of donating or giving to simply salvaging and taking - taking without asking at that.

The Qur'ānic verse quoted above is self-evident and comprehensive in its recognition of dignity for all human being without limitations or qualifications. The superiority of mankind discussed here is due to the intellect which is the basis of obligation.<sup>i</sup> The principles of autonomy of the individual, beneficence, non-maleficence and justice are considered established principles of the medical field which govern the ethical practice of medicine and research. Islam too recognises these principles, although their application may differ from a western secular understanding. In the context of the current debate, Islam acknowledges the principle of autonomy conferred upon man as God's viceroy on earth.<sup>ii</sup> This latter principle recognises the rights of individuals to self-determination and is rooted in respect for the individuals' ability to make informed decisions about personal and other matters. However, this requires the full disclosure of information to the individual since one can validly make choices only if one is fully informed.

Informed consent can be described as “a voluntary and explicit agreement made by an individual who is sufficiently competent or autonomous, on the basis of adequate information in a comprehensible form and with adequate deliberation to make an intelligent choice about a proposed action.”<sup>iii</sup>

Thus, basic requirements of informed consent include a discussion and an enumeration of risks, benefits, and alternatives. This discussion should address either serious or frequent risks or both. The individual concerned should be encouraged to ask questions and express concerns. The process should be voluntary and without coercion. It is the existence of such discussion and the transfer of information and decision-making rights that empowers the patient and respects his or her autonomy.

The Human Transplantation (Wales) Bill not only does not meet the basic requirements of informed consent, it actually relies on the individual being either languid or not being informed at all.

Furthermore, the current debate has not taken into account accepted meanings of presumption in Law and science and the consequences for rights of ownership that would arise should the Bill become law. Any action or decision made on a presumption is accepted in Law and science as one based on judgment of a provisional situation. It should therefore allow the possibility of reversing the action or decision. The Bill will not permit such reversal. Once organs are mistakenly removed the deceased cannot be returned to his/original state.

The absence of a positive indication of an individual's wishes cannot be interpreted as a desire to donate organs – to do so would be quite presumptuous! Without express consent it is difficult to be sure that someone would have wanted to be an organ donor. At best, one can maintain a neutral assumption until the wishes of the individual are established one way or the other. Whilst an act to do something should come from an instruction, an omission should not require specific instruction. Under the Bill the burden of ensuring that the respect for the individual's preference has been upheld is shifted on to the individual rather than on to the state. The Bill stipulates that the law will “deem” that someone has consented, but if the only evidence of consent is a lack of evidence of objection then this “deeming” is a legal fiction. It is not real consent.

The Bill places the value of body organ function above the requirement for permission from the individual. It demands moral responsibility – organ donation is the proper thing to do in the case of one's death.

It would also be difficult to establish a system that records an individual's objection to donation and makes the record easily and immediately available to all doctors and health care providers involved in terminal or critical care.

The Bill, as it stands, does not require the state to accept the wishes of relatives should they object to their loved one's organs being removed. Rather, the state may take the organs without the prior free and express consent of the deceased, and without, or even against, the express wishes of relatives. Whilst this is a policy for organ transplantation it is not a policy for organ *donation*. Organ donation must remain a truly altruistic positive action by the individual. A gift – not routine salvage.

The Bill law must state in unambiguous terms that in the absence of an explicit statement of the wishes of the deceased, the relatives will be able to refuse permission for the removal of organs. The Bill lacks effective protection for conscientious objection based on faith or ethical or family reasons.

It is pertinent to note that Islamic bodies, such as the London based Islamic Shariah Council, that gave pioneering edicts in support of organ donation are opposed to the system of 'deemed consent'. It is quite likely that rather than increase the availability of organs from the Muslim community the Bill will reduce the number of organs being donated.

The Bill creates a moral dilemma for even those Muslims who support organ donation but consider the policy of 'deemed consent' to be at odds with their faith. Contemporary Muslim scholars who have decreed organ donation to be a permissible and praiseworthy act have also required the donation to be with the express permission of the deceased or of his/her relatives. Thus, even according to these scholars the Bill does not respect the requirements of donation as per the Muslim faith.

Finally, the above discussion exists in an environment wherein the actual point of death remains a point of contention amongst not only medical practitioners and specialists but also amongst Muslim scholarship. In 1987, the Islamic Fiqh Academy of the Muslim World League based in Mecca decreed that the irreversible cessation of all brain activity was sufficient to remove the life support systems but not to determine that death had indeed occurred. This, decree has found favour amongst the majority of Muslim scholars worldwide.

I would thus urge the political parties in Wales to reconsider their positions on a system of 'deemed consent' and instead increase their efforts to raise awareness under the current system.

Mufti Mohammed Zubair Butt

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<sup>i</sup> Al-Qurṭubī M, Al-Jāmi' li Aḥkām al-Qur'ān, 10:190.

<sup>ii</sup> The Glorious Qur'ān, Al-Baqarah, 2:30.

<sup>iii</sup> Aveyard H. Implied consent prior to nursing care procedures. J Adv Nurs. 2002;39:201-7.

Health and Social Care Committee  
Human Transplantation (Wales) Bill  
HT(Org)32 - Islamic Medical Association

To Mark Drakeford  
Chair:Health and Social Care Committee

Ref: Islamic Medical Response on Presumed Consent

Dear Mark,

We like first to thank you for giving us the chance to send our Islamic responses by 14th Febr/today.

One thing we like to explain first:

The Islamic Medical Association, is a reg charity and is very much involved with Health and medical ethical issues since about 40 years..

We frequently try to respond to the government on many bills and consultations and to give the Muslim view on ethical issues and behalf of the Muslims.

We tried twice before to answer your Consultation/questionnaire on Presumed/Deemed consent(Organ transplantation Bill);

If you allow us to give you now an updated and brief version of our Islamic medical response on the bill and the issue of Organ transplantation:

-The issue of Organ donation and Organ transplantation, is a controversial issue among Muslim scholars and the Muslims generally.

However many Muslim scholars/Muftis allowed Organ donation but under many strict conditions and the most important condition is:

The Consent/Permission of the donor(a religious and a human right)

It is not allowed to take the organs of any Muslim at the time of death without clear written permission or consent before.

To presume that there is a consent.... is out of question and no Muslim or Welsh Muslim will accept it.

Organ donation is a voluntary GIFT ,given after a well informed consent.

-It is important in Islam also:

Not to take any organ while the patient is still alive !

The end of life of every one of us is FIXED in advance by the Creator who is the Owner of life.

Many Muslims have concern today if doctors "delay death or play with the natural moment of death"

The issue of BRAIN DEATH is questionable among many Muslims and theologians today.

It can not be accepted to allow any doctor to do what he/she likes with the organs of the "dead/live body" ?.

-OPTING OUT, is not practical and will not work among the Welsh Muslims for a lot of reasons:

Most Muslims will not be UNAWARE of this clause, many will shy away from doing it because of the language problem or other reasons ,others are lazy to do it like most public today who think they are " living for ever"...?

-The clause on the decision/permission of the FAMILY is also not practical and will not work among the Welsh Muslims for many reasons:

-First we noticed in your Bill that there was no clear VETO and no effective right of the family to say NO to the taking of the organs from their dead relatives.

Many Welsh Muslims have no family around and many of their families are living back home. Almost all Muslim students in Wales have no families.

Besides, some Muslim families might agree to allow the taking of the organs from their dead relatives contrary to the wishes of the dead person himself/herself.

**WELL INFORMED CONSENT AND PERMISSION DURING ONE'S LIFE IS THE ONLY POSITIVE WAY FORWARDS.**

-Finally, as we are having more damaged and failed organs today with more demand for organs and longer waiting list ...we feel it is very important for doctors and scientists to work on finding out the causes of the failure of our organs in order to work on PRIMARY PREVENTION.

British Medical Association  
bma.org.uk/wales

We know also today that some organs do fail for clear reasons:

Liver/Liver Cirrhosis from the consumption of alcohol...so efforts should be directed towards alcohol to prevent any damage to the Liver.

Thus there will be no need for the donation of a Liver.

Similarly: Lung cancer from smoking cigarettes...Proper medical practice is to STOP smoking in order to avoid the damage to the lungs

Thus there will be no need for the donation of a lung..

This is the only way forwards for PRIMARY PREVENTION and to reduce the need for a lot of organs today.

Also,if there is proven need for more organs donation in Wales,as many do not believe that this new bill on Presumed consent will not increase the number of donated organs ,we believe there are many other and simple ways to get organs: BY EDUCATING the public well about organ donation.

NOW ALLOW US TO GIVE YOU AN INTERESTING BRIEF REGARDING THE RESPONSE OF THE MUSLIM SCHOLARS AND THE WELSH MUSLIMS AGAINST PRESUMED CONSENT:

-First : there are 2 Islamic rulings/FATAWAS against Presumed consent :

First by the famous Islamic Sharia Council

Second by the Society of Muslim Scholars(Hizbul Ulama).

-Second: The clear Statement by the big famous Muslim body: The Muslim Council of Britain(MCB) against Presumed consent.

MCB represents over 500 Muslim organisations,mosques and Institutions(affiliates)

You can see all these Fatawas/Statement in the enclosed attachment after been published in the Muslim Weekly newspaper.

-Third: LETTERS SIGNED BY THE WELSH MUSLIMS IN MOSQUES AND ORGANISATIONS WITH THE FULL SUPPORT OF ALL IMAMS

AGAINST PRESUMED CONSENT:

\*Last September,about 2400 signed letters by Welsh Muslims were delivered by hand to the Welsh Assembly

\* In January/February this year,another 7000 signed letters by the Welsh Muslims were delivered by hand to the Welsh Assembly.

\*Today ,you are receiving also separately :A clear Islamic response from a Mufti/scholar in Islam and in Medical ethics:Mufti Mohammed Zubair Butt.

Who put clearly to you the Islamic argument and opposition to Presumed consent.

All were asking to drop this unethical unnecessary unislamic bill on Presumed consent.

We should keep the Status co on organ donation:

Any one can donate his/her organs by choice as a free gift and after a well informed consent and with the clear permission of the donor during his/her life.

We are all asking to drop this unethical unnecessary unislamic( & unchristian) bill on Presumed consent.

Dr A Majid Katme(MBBCh,DPM)

Spokesman: Islamic Medical Association  
Weekly TV broadcaster

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