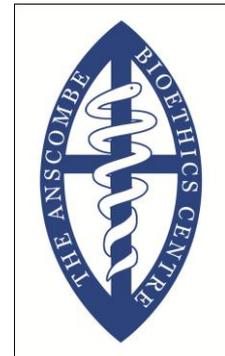


Submission by the Anscombe Bioethics Centre to  
The Health and Social Care Committee  
Inquiry into the general principles of  
The Human Transplantation (Wales) Bill)<sup>1</sup>



**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.

David Albert Jones MA (Cantab), MA, MSt, DPhil (Oxon)  
Director, The Anscombe Bioethics Centre, Oxford  
Research Fellow, Blackfriars Hall, Oxford  
Visiting Professor, St Mary's University College, Twickenham  
[director@bioethics.org.uk](mailto:director@bioethics.org.uk)

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