



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,¹ 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

¹ 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.² 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*

² 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/120307organdonationssummaryen.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.³ 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%⁴ of people supported presumed consent, a very significant drop from 63% earlier in the year.⁵

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.⁶ Gone was any reference to waiting for ‘very strong

³ 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>

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

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

⁶ 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."⁷

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.⁸ 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.*

⁷ 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

⁸ '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".⁹ (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".*¹⁰ (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

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

¹⁰ 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.¹¹ 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.'¹² 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 24.9¹³ is better than that of most presumed consent countries (16) and similar to that of two.¹⁴ 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.

¹¹ 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).

¹² http://www.hopkinsmedicine.org/news/media/releases/presumed_consent_not_answer_to_solving_organ_shortage_in_us_researchers_say

¹³ See page 10

http://www.organdonation.nhs.uk/statistics/transplant_activity_report/current_activity_reports/uk_t/activity_report_2011_12.pdf

¹⁴ 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".¹⁵

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.

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