

**Health and Social Care Committee
Human Transplantation (Wales) Bill
HT(Ind)77 - Dr R J Clearkin**



Sarah Sargent,
Deputy Clerk
Health and Social Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA.

HSCCommittee@wales.gov.uk

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Re: Consultation on the Human Transplantation (Wales) Bill

Dear Ms Sargent

I am grateful for the opportunity to reply to this consultation on the Human Transplantation (Wales) Bill' (the 'Bill'), and hope that my observations might be of some assistance to the Health and Social Committee in its deliberations on this important subject. In making my response I have read the Bill and its Explanatory Memorandum², and additionally examined the Summary of Responses³ on the Draft Bill.

The stated purposes of the Bill⁴ are to:

1. increase the number of organs donated in Wales;
2. to address the relatively low rate of consent to organ/ tissue ('organ') donation through "clarifying the wishes of more people" and by "effecting changes to public attitudes and awareness about the issue".

Nothing is stated in the Introduction to the Bill quoted above, concerning the introduction of 'deemed consent' for organ donation, though it quickly becomes clear that this is not only central to the proposed legislation, but has been a key concept informing the background to the Bill since 2008⁵.

Specific points of uncertainty arising in my reading of the Bill are:

1. Section (S) 5 Subsection (ss) 3 - it is not clear whether this is a transitional arrangement applying only to the first years after the introduction of the Bill, and that following this period, 'deemed consent' will potentially apply to all those who lose capacity in Wales;
2. S 7 ss 10 part (b) - the nature of the proscription of certain persons as acting as a potential donor's representative is not clarified in the Bill, but is to be addressed in regulations if the

Bill is passed into law. The reason for giving such a power to the Welsh ministers is not explained though it seems remarkable;

3. S 8 ss 2 part (b) - the sole assumption in 'deeming consent' in this section is to present the person lacking capacity only as a donor of transplant material, but not as a recipient, though Equality legislation would surely require that a person lacking capacity should not be excluded by law from the potential benefits of transplantation. It is also highly debatable whether there are more than a handful of cases where the risks of what is normally major surgery and the loss of at least one major organ could reasonably be described as being in the donor's as opposed to the recipient's 'best interests';
4. S 9 ss 1 & 4 + S 10 - describe the punishments under this Bill for carrying out a transplantation activity unlawfully, for example without consent. Given that such activity is technically an assault, may seriously impair the mental &/ or physical health of the 'donor', or cause their death, the penalties seem remarkably lenient, being set at a fine &/ or a maximum term of 3 years imprisonment. This suggests to the world at large that such acts are not to be taken seriously;
5. S 12 - is there a limit to the time a body may be held in an institution after death while consent to transplantation is sought? Will there a limit to the length of time transplant activity is deferred while relatives or representatives of the potential donor are sought, and could some clarity be given to this issue before enactment proceeds?;
5. S 13 - might this mean in practice that if for instance the cause of a person's death is uncertain, and a Coroner's post-mortem might therefore be required, that this would effectively prevent the authority from holding the body (see S 12 ss 1) or using the body for donation at all?;
6. S14 ss 4 - it seems as if there is to be 'deemed authorisation' as well as 'deemed consent'. The employment of 'negative resolution', and the power to make subordinate legislation by regulation or order by to the Welsh ministers alone, suggests a lack of democratic oversight at the least.

It is clear that a lot of thought has gone into the drafting of this Bill. There are however some matters which are not addressed in the materials I have examined, some of these being fundamental. It might be clearer if these were set out in a list form:

- (i) The Explanatory Memorandum presents the figures on the relatively low rate of consent to in the organ donation UK, and the summary of the University of York study⁶ suggests that the impact of presumed consent on organ donation rates is complex and that good evidence in favour of presumed consent appears to be lacking at this time. Furthermore, the EU (2007) survey⁷ suggested 63% of relatives in the UK would consent to organ donation from a deceased close family member, and the 'Organ Donation Task Force' (ODTF)⁸ stated that about 60% of the UK population surveyed would accept a well-implemented opt-out system ie. a presumed consent system like the one proposed for Wales in this Bill. The figures are so close for the opt-in and opt-out schemes that one has to wonder why, if they are a key part of the evidence for this Bill, a move to a potentially very contentious system like 'deemed consent' has been preferred above efforts to improve the current opt-in system?;
- (ii) infrastructure and healthcare costs are considerable, particularly for Heart and Lung transplants, as the initial surgery is so highly expensive. At a time when healthcare expenditure is being cut, and there is a widely publicised reluctance in central government to fund better care for the elderly in the UK for example, what is the opportunity cost for the healthcare system of this move to 'deemed consent'? Are the elderly going to receive better care in Wales in the future than elsewhere in the UK?;

- (iii) transplantation is not a panacea. It is quite frequently fatal within the first year, and it introduces a different form of chronic health condition associated with immune suppression, drug-induced harm to the body and its own range of medical conditions. It is true that health and life expectancy are improved for many people through transplantation however;
- (iv) it would seem that 'deemed' consent simply adds to the ethical and moral difficulties associated with transplantation. As has been widely noted, 'deemed consent' is an oxymoron - consent cannot be 'deemed', and can only be given or withheld. Moreover it creates a dangerous precedent for Medicine, and offers the state a still greater control of the citizen, even to the disposal of their body parts after 'death'.
- (v) it is far from clear that the safety of those lacking mental capacity will be adequately protected by this Bill in its current form. The only unarguable application of 'best interests' to those lacking capacity is the receipt of a donor organ, not its donation. In the very rare cases in which donation from a person lacking capacity might be thought to be in their best interests, for instance to the family member who cares for them, application should be made to the courts in each case. The Bill as it stands gives excessive latitude to those who might be tempted to view those lacking consent as mere organ containers there to benefit others;
- (vi) while it may be true that, solely because of the relative shortage of organs, age is no longer a bar to donation, few recipients would wish to receive organs from a person in their 60s or older. The organ too will be old, and the incidence of undiagnosed malignancies and other pathology is also likely greater than in a young person;
- (vi) given that under the 'Human Tissue Act 2004', consent of a person in a 'qualifying relationship' (or of a representative), in the absence of 'express consent' on the part of the potential donor, is sufficient to permit organ donation to occur (or not to occur), the situation in Wales would be little altered under this Bill if relatives retained anything like the same authority. It is clear that the authority of the relatives of an 'unexcepted adult' will be significantly reduced under the new Bill, and that the burden of providing sufficient evidence such that a 'reasonable person' would agree that the potential donor would not have consented⁹ - may become very hard indeed, particularly if targets for 'donation' are set, or if the Welsh ministers decide to make non-donation more difficult by regulation or order. This is a disturbing prospect, since taking organs from a body without the agreement of relatives, will not only be highly traumatic for them (what is left of their loved one's body may be little more than a shell when every organ and structure to be harvested has been removed), but in quite a short time may also significantly lessen the regard of the population for the law and for the Assembly;
- (vii) the recipients of donated organs may be very uncomfortable with the reality of living with organs taken without the express consent of the deceased or their relatives. This seems likely to increase the risks and prevalence of psychological vulnerability in patients receiving organs in these circumstances;
- (viii) the deeply serious, relevant and ongoing ethical concerns over transplantation are ignored in this Bill. There is in fact no agreement that 'Brain Death' truly represents death, and the profusion of tried and discarded definitions for it over the last 50 years strongly suggests that none is correct. Moreover the 'brain stem tests' or other tests used to diagnose 'brain death' are applied very early and before any brain recovery from its trauma could occur. This means that death cannot safely be diagnosed on 'Brain Death criteria'. This in turn means that many 'organ retrievals' are not the removal of organs from a deceased person, but from one still living, even if possibly dying. Unfortunately, since this is so, 'Donation after Circulatory Death' where circulatory arrest, the universally accepted definition of death, is induced in the operating theatre by clinicians themselves, must place the clinicians involved on very awkward legal and moral ground.

In conclusion I feel obliged to express deep reservations about this Bill. The body does not belong to the state, nor ought the state to assume a power of disposal over it, in any but the most extreme circumstances. Consent is not consent where it has to be 'deemed', nor is there a donation when the state assumes the right to take the person's organs. It is also the case that transplantation unfortunately cannot safely or morally employ such a changing and changeable criterion of 'death' as is offered by so-called 'Brain Death criteria'. These are facts which should be known to, and understood by legislators and the public.

Yours sincerely

Dr R J Clearkin

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Human Transplantation (Wales) Bill: <http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-e.pdf?langoption=3&ttl=PRI-LD9121> - Human Transplantation (Wales) Bill (accessed 17 January 2013)

- 2 Welsh Government, Human Transplantation (Wales) Bill, Explanatory Memorandum: [file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human Transplantation \(Wales\) Bill, Explanatory Memorandum](file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human%20Transplantation%20(Wales)%20Bill,%20Explanatory%20Memorandum) (accessed 16 January 2013)
 - 3 Welsh Government, <http://wales.gov.uk/docs/dhss/consultation/121203responsesen.pdf> (accessed 16 January 2013)
 - 4 Welsh Government, Bill summary Human Transplantation (Wales) Bill January 2013 page 2
 - 5 Welsh Government, Bill summary Human Transplantation (Wales) Bill January 2013 page 1
 - 6 Welsh Government, Human Transplantation (Wales) Bill, Explanatory Memorandum: Part 2: Options; Evidence Base to Establish Impact of Proposed Legislation - Section 105 [file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human Transplantation \(Wales\) Bill, Explanatory Memorandum](file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human%20Transplantation%20(Wales)%20Bill,%20Explanatory%20Memorandum) (accessed 16 January 2013)
 - 7 Welsh Government, Human Transplantation (Wales) Bill, Explanatory Memorandum: Part 2: Options; Evidence Base to Establish Impact of Proposed Legislation - Section 99 [file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human Transplantation \(Wales\) Bill, Explanatory Memorandum](file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human%20Transplantation%20(Wales)%20Bill,%20Explanatory%20Memorandum) (accessed 16 January 2013)
 - 8 Welsh Government, Human Transplantation (Wales) Bill, Explanatory Memorandum: Part 2: Options; Evidence Base to Establish Impact of Proposed Legislation - Section 98 [file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human Transplantation \(Wales\) Bill, Explanatory Memorandum](file:///C:/Users/Ronald/Documents/MyDocuments/Life/OrganDonationPresumedConsentWalesJan2013/Research%20Service%20PresumedConsentOrganDonationWales2013Bill%20Summary.pdf#Human%20Transplantation%20(Wales)%20Bill,%20Explanatory%20Memorandum) (accessed 16 January 2013)
 - 9 Human Transplantation (Wales) Bill: Section 4 Subsection 4 Part (b) <http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-e.pdf?langoption=3&ttl=PRI-LD9121> - Human Transplantation (Wales) Bill (accessed 17 January 2013)
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