Submission to the Welsh Assembly Health and Social Care Committee Consultation on Presumed Consent to Organ Donation

1 Introduction

This submission is concerned primarily with the general principles underlying the proposed legislation. Brief comment is also offered on the constraints imposed by the terms of reference of this consultation and two specific aspects of the proposals.

2 The terms of reference of your consultation

2.1 The terms of reference for your consultation seem to require you to start by accepting the premise that there is a need for legislation "to increase the number of organ and tissues available for transplantation by introducing a soft opt out system ..". This premise is challengeable since evidence suggests that such a proposal would not necessarily have the effect of increasing the number of such organs and tissues available (see below). The terms of reference therefore inhibit your consultation from offering a fully objective assessment of the proposed legislation. This is contrary to the public interest.

3 The general principles

3.1 The proposal to move to a system of "deemed consent" should be rejected on the following grounds:

1) It is objectionable in principle.

2) There is a lack of evidence that it will achieve the desired result.

3) It compounds an existing and serious wrong.

4) There is potential for significant and adverse unintended consequences.

It is objectionable in principle

3.2 The principle of informed consent underpins good medical practice. This is central to respect for the individual and his personal autonomy. It must not be compromised.

3.3 In keeping with this and while recognising the real and significant benefits of organ donation it is an important point of principle that organs should never be removed without clear evidence of the fully informed consent of the person from whom they are taken. Without this there is no donation, merely harvesting. 'Deemed' consent is no consent at all in the absence of absolute certainty that the person's failure to opt out was both intentional and fully informed. It is for those who support this proposal to demonstrate how this can be achieved.

There is a lack of evidence that it will achieve the desired result

3.4 This was the conclusion of the UK Organ Donation Taskforce following their 2008 Inquiry on this matter[1].

It compounds an existing and serious wrong: brain death is not death

3.5 It is clearly fundamental to public understanding and acceptance of vital organ donation that such organs are only harvested after the death of the patient. The 'dead donor rule' was adopted in principle from the early days of vital organ donation and potential donors are offered this assurance. It is on this understanding that the donor system is accepted, trusted and supported. Yet the criteria used to establish death in the context of organ donation are characteristically different from those used traditionally and in other contexts..

The whole brain criterion:

3.6 On the previously widely-accepted definition of death as 'cessation of the functioning of the body as an integrated whole'[2] the death of the whole brain does not mark but rather heralds death in the absence of further interventions. Outside the context of organ donation a certain diagnosis of brain death may reasonably justify the removal of life support. On this definition, however, the person does not die until after the life support is removed since it is only subsequently that the body ceases to function as an integrated whole. This is well understood by those who will keep vigil at the bedside until the point of subsequent 'clinical death'.

3.7 The use of the death of the whole brain as marking the point of death has been subject to serious and strong evidence-based challenge in other jurisdictions since it evidently fails to mark the moment of death on this definition. Even following diagnosis of the death of the whole brain patients may still have beating hearts, maintain integrative bodily functions with limited support, heal wounds, pass through puberty or gestate a baby. The start of the process of harvesting in such patients may prompt a rise in blood pressure and an increase in heart rate.

3.8 In the light of this and other, more technical, challenges some argue that organ retrieval on this basis should stop.

3.9 For others, however, the continued retrieval of vital organs from those now tacitly acknowledged not to be dead encourages a widening of the criteria to encompass other non-dead donors[3].

3.10 Yet others argue that death itself should be re-defined to encompass some not previously regarded as dead[4].

3.11 There is honest disagreement as to whether the concern regarding the use of whole brain death as a valid criterion for death is one of principle or of unreliable diagnosis. Nonetheless it is clearly the case that the principle of informed consent requires that the potential donor should fully understand and accept the implications as a condition of his

consent. The failure to provide this information prior to consent has prompted considerable concern and challenge[5].

The UK 'brain stem' criterion:

"Conceptually suspect and clinically dangerous"

The US President's Council on Bioethics in December 2008[6]

3.12 While the death of the whole brain as a valid criterion for death is increasingly challenged and prompted calls for a higher standard of information to validate consent, the weaker criterion of the death of the brain stem alone is almost universally rejected and in most jurisdictions harvesting on this criteria would be a serious criminal offence.

3.13 In the UK, however, the brain stem criterion is used without warning to potential donors or their relations of the implications: In distributed leaflets they are invited to "Register now" simply on the basis that the organs will be taken after 'death' without elaboration or qualification. On the organ donation website the information provided is highly challengeable and, in failing to acknowledge this controversy, misleading[7]. In observing, for example, that "when the ventilator is switched off the heart will stop beating" a prognosis is presented as if it were a diagnosis without offering any philosophical basis for this approach or acknowledging its controversial nature. This is a grievous, ongoing abuse which, regardless of the current proposal, is long overdue for challenge and review.

3.14 There is nothing in the proposed legislation which obliges those responsible to ensure that all Welsh citizens are given full knowledge of the criteria used to establish death for the purpose of harvesting organs, the challenges to this, the difference between the UK in this regard and other countries and the implications of this for the process of harvesting. Without this the Assembly cannot reasonably claim that 'consent', whether 'deemed' or actual, has any validity and any attempt to do so amounts to state-sanctioned deceit.

There is potential for significant and adverse unintended consequences.

3.15 After examining the 'opt out' proposal in 2008 the Organ Donation Task Force observed that "such a system has the potential to undermine the concept of donation as a gift, to undermine trust in doctors and negatively impact on organ donation numbers".

3.16 This must be particularly so in the absence of full prior knowledge of the death criterion issues already outlined[8].

3.17 The potential for real and ongoing distress to grieving relations who find out too late about the state of the 'donor' at the point of harvesting must be recognised and taken into account in considering this proposal. It is also possible under the terms of this legislation that relations are aware of this, wish to prevent the removal of organs but are over-ruled by the doctors. The psychological implications of both these scenarios must be considered.

4 Comment on specific aspects of this proposal

4.1 Over and above these matters of principle there are two aspects of the proposed legislation which also cause concern.

4.2 Under these proposals the relevant minister would be legally obliged to promote organ transplant on this basis, regardless of any future changes of view or policy arising from concerns such as expressed here or others and despite the misleading presentation arising from the use of the term 'consent' where consent is not evident. It is wrong in principle to so constrain any Minister.

4.2 Under the proposed system the family are no longer permitted to veto the harvesting of their relation's organs. The prior rights of the family are thus usurped. Is it really anticipated that support for organ donation will continue once such a regime is up and running and reports begin to emerge from aggrieved families? It is therefore suggested that the presumption should always be against harvesting in the absence of clear evidence of the fully informed consent of the potential donor and their next of kin.

5 A personal perspective

5.1 I have lost a close friend to kidney failure. I understand the desire to save those who need new organs and would support organ donation in principle. But this must be done both ethically and with due regard for potential donors and their families. My late friend shared this view throughout.

6 Conclusion

6.1 These proposals should be rejected as wrong in principle: The state for the first time takes ownership of its citizens mortal remains. The presumption in favour of protecting the potential donor and respecting their wishes is radically weakened. The term 'deemed consent' is clearly misleading since no consent is involved. The proposal is potentially counter-productive since it radically erodes the basis on which vital organ donation has hitherto enjoyed public support.

6.2 Given that a Government's first duty is to protect its citizens the Assembly should take steps to ensure that organs are not harvested in the absence of clear evidence that the potential organ donor has provided fully informed consent and that such information includes a full understanding of the implications of the criteria used to establish 'death'.

6.3 The information offered here regarding the criteria used to establish 'death' is essential for informed public debate on these proposals. Without this the public interest is not served and the proposed legislation cannot be regarded as enjoying true public support.

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[1] See Taskforce Report, for example §§ 1.5, 1.9, 1.13 and 1.14.

[2] First formulated by Bernat, Culver and Gert and widely adopted subsequently.
Bernat, J. L., Culver C. M. and Gert B. 1981 "On the Definition and Criterion of Death", *Annals of Internal Medicine*, 94, 1981 pp. 389-394
Whole brain death was initially justified on the basis that it satisfied this definition but this was subsequently challenged. In response Bernat reformulated the definition to one which, he argued, better fitted the whole brain criterion. This was also challenged.

[3] For example, writing in the prestigious New England Journal of Medicine Drs. Truog and Miller review relevant research and acknowledge that *"The uncomfortable conclusion to be drawn from this literature is that although it may be perfectly ethical to remove vital organs for transplantation from patients who satisfy the diagnostic criteria of brain death, the reason it is ethical cannot be that we are convinced they are really dead."* They go on to argue that, this being the case, we should abandon the "dead donor rule" and permit potential donors to sanction the removal of their vital organs should they succumb to specified, seriously disabling conditions.

Truog, R D and Miller F G, 2008 "The Dead Donor Rule and Organ Transplantation" New England Journal of Medicine Vol. 359:674-675.
http://www.nejm.org/doi/full/10.1056/NEJMp0804474

[4] An editorial in the influential science journal Nature, for example, argued that the criteria for death should be widened. To support this proposal they observe that *"In practice, unfortunately, physicians know that when they declare that someone on life support is dead, they are usually obeying the spirit, but not the letter, of this law. And many are feeling increasingly uncomfortable about it"*.

They conclude that: *"concerns about the legal details of declaring death in someone who will never again be the person he or she was should be weighed against the value of giving a full and healthy life to someone who will die without a transplant."* They thus imply that death should be redefined to encompass those with a permanent loss of significant prior mental faculties (however that may be defined or determined) apparently regardless of physical prognosis.

"Delimiting death". Nature Vol. 461 1 October 2009.
http://www.nature.com/nature/journal/v461/n7264/full/461570a.html

[5] Dr Alan Shewmon writes:
"Just as cigarette ads are required 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...." 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."
See "Brain Death: Can it be Resuscitated" *Hastings Centre Report* 39.2 (2009): 18-24

[6] The US President's Council on Bioethics in December 2008, while accepting the "whole brain" criterion, was highly critical of the UK "brain stem death" criterion which it described as *"conceptually suspect and clinically dangerous"*.
Washington, D.C.: President's Council on Bioethics, 2008 Pages 66/67
http://bioethics.georgetown.edu/pcbe/reports/death/Controversies%20in%20the%20Determination%20of%20Death%20for%20the%20Web%20%282%29.pdf

[7] See http://www.organdonation.nhs.uk/how_to_become_a_donor/questions/ in particular questions 11 and 12.

[8] Consider one bereaved mother's observations: *" .. I as an individual, an intelligent, articulate mother, did not consider the diagnosis of brain stem death to be final expiration of my son, when in 1987, I offered my son's organs for transplant. I understood my son to be fatally injured, with no hope of recovery. But, despite asking to be present when the ventilator was switched off, I was not aware, nor made aware, that my son would still be ventilated when his organs...his heart, his liver, his kidneys, were removed from his body. Moreover, having discussed organ donation with him, I know that he also was completely unaware of this information."*
Letter to Mr David T.C. Davies MP, Chair, Welsh Affairs Committee from Mrs Eileen Rowlands
http://www.publications.parliament.uk/pa/cm201011/cmselect/cmwelaf/896/896vw23.htm