

**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

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### **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

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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.***

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### **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.***

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## 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

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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?

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## 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.