

Draft Human Transplantation (Wales) Bill and Explanatory Memorandum:

Consent to organ and tissue donation in Wales

Consultation response form

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Are you responding as a (please tick one):

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The closing date for replies is **10 SEPTEMBER 2012**

Please send this completed form to us by post to the Organ Donation Legislation Team, Medical Directorate, 4th Floor, Cathays Park Cardiff, CF10 3NQ or email to organdonation@wales.gsi.gov.uk

If you are sending your response by email, please mark the subject of your email:
Consultation on the Draft Human Transplantation (Wales) Bill

Alternatively, the consultation responses form is available for completion at www.wales.gov.uk/consultations/healthsocialcare/organbill/?lang=en

Consultation questions

Question 1

Have the concepts of deemed consent and express consent been explained clearly enough?

Yes

No

Comments-

The scenarios in the explanatory memorandum are helpful in this regard and we are glad that this section covers individuals who lack capacity and children and young people (paragraph 33 – 38). However more detail is needed about the role of clinicians in determining consent and talking to relatives.

It is particularly important to make clear that, in relation to the deceased wishes; any deemed consent will have legal precedence. Although this is covered in the explanatory memorandum the consultation document is not adequately clear with regards to the fact that families do not have a legal veto over the donation itself. But also that as currently stands, donation will not go ahead in the absence of member(s) of the deceased family - or a person in one of the relationships listed in the Bill - because they are needed to provide details about the deceased residency and lifestyle.

We believe the Bill also needs to be clear on the process that will be followed in a situation when the deceased family provide information about the deceased wishes which is considered to be unreliable / does not meet the criteria of being the 'sort of information any reasonable person could agree with'. There also needs to be supporting guidance for individuals involved in this process.

The role of the UK ODR and how it will work once the Wales register comes into existence needs further detail. This is especially the case for individuals from Wales who die outside of Wales, or individuals who are not from Wales but die in Wales.

There is some confusion regarding the situation of adults who lack capacity which needs to be clarified. There are two issues here. First, in paragraph 25 - it is suggested that adults who lack capacity can register a decision to be a donor or not to be a donor. If they lack capacity to make the decision, they cannot make the decision and consent will be needed from a qualifying relative after death. The situation is a bit clearer in paragraph 29, although it still refers to people who lack capacity registering views. This might be intended to refer to someone who lacks capacity but expressed a wish to donate, or not to donate, before capacity was lost but again care is needed with the wording to ensure that this is clearly explained.

Many patients lose capacity shortly before death - for example following a road traffic accident. These people, who previously had capacity, should not be treated as lacking capacity for the sake of this legislation. The relevant factor, in determining whether 'deemed consent' would apply should be whether the individual has had capacity at any time since the new legislation was introduced. If they had capacity and chose not to opt-out, they should be deemed to have consented and this should apply even where capacity has subsequently been lost. Where an individual has never had capacity, or lost capacity before the change in the law, they should not be deemed to have consented and it should be for the family or a nominated person to consent, or not.

The BMA believes that the opt-out system should apply at the age of 16, given that this is the age at which young people are legally deemed to be competent to make their own decisions. At 16, there is a presumption that young people can make all kinds of very important and complex decisions regarding their care and treatment including the decision to opt-in to organ donation. The BMA can see no reason for setting a different age for young people to opt-out of organ donation than for other important decisions.

Question 2

Is the role of the family clear?

Yes No

Comments-

Despite paragraph 27 being clear that families do not have a legal veto, there is some wider ambiguity within the documentation about the role of the family. In paragraph 23 of the consultation document, it says the family 'will be able to provide information about [the individual's] wishes'. This implies that there would be no presumption in favour of donation. This section should also detail what kind of information would be acceptable.

In an opt-out system, the family should be asked if they were aware of any unregistered objection but would not be expected to try to guess what the individual would have wanted (because under an opt-out system, if individuals had not opted out, the presumption would be that they wished to donate). This may simply be a matter of loose wording but it is important to be absolutely clear on these points so as not to cause confusion.

The role of the family and the importance of talking to relatives and those close to you about donation should be a central message in the publicity surrounding the implementation and ongoing operation of this policy.

We believe that there should be further consideration here about the role of the clinician in talking to families and in determining consent.

On page 11-12 of the draft explanatory memorandum it says:

“Where relations do not produce any information about the wishes of the deceased, then they will be sensitively encouraged to proceed with organ donation. It is the case that 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. Clinical teams will nevertheless, 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.”

The use of the term ‘Duty of Care’ in this context, without definition or reference, causes us some concern. This phrase has adopted a very specific meaning in medicine and is strongly associated with the existence of legal obligations; and therefore may be subject to misinterpretation.

While the BMA takes a pragmatic approach to this – i.e we have previously said that insisting on donation in the face of the family’s strong and sustained opposition is likely to add to their distress as well as, potentially, generate public hostility towards organ donation - we are concerned as to what, in legal terms, this ‘duty of care’ would mean for the healthcare team.

To be clear, BMA Cymru Wales believes that clinicians must be sensitive to the views and beliefs of the family, but that this needs to be expressed appropriately and clearly in the legislation.

We therefore would recommend, unless there are overwhelming reasons to continue with the phrase ‘duty of care’ to replace it with reference to paragraph 29 of the General Medical Councils Good Medical Practice:

29. ‘You must be considerate to relatives, carers, partners and others close to the patient, and be sensitive and responsive in providing information and support, including after a patient has died. In doing this you must follow the guidance in Confidentiality.’

Question 3

Are the arrangements for the registration of wishes clear Yes No

Comments-

It is important that both the Wales register and the UK Organ Donor Register map across each other effectively. The precise mechanism to ensure this takes place is unclear. It is also not totally clear as to whether a person can be on both the ODR and the Welsh register.

It is disappointing that despite option C (a register containing only opt-out information) being 'by far the most popular option' (page 21 of the explanatory memorandum) this is not what is being proposed. By giving people the option to both opt-in or opt-out using the register in Wales, there is a real risk that families who realise their relatives have not opted-in, when given the opportunity, will assume they did not want to donate and therefore object to donation. In reality many of these people will have wanted to donate and believed (entirely reasonably) that their decision not to opt-out was sufficient to ensure this wish would be acted upon. This introduces confusion and potentially undermines the system.

We can understand why it is desirable to give people in Wales the option to opt-in, in case they die outside Wales (before the rest of the UK has caught up and introduced an opt-out system) but we do not believe that the option chosen is the best way to achieve this. It would, in our view, have been better to keep the Wales register as just opt-out and allow people to sign up to the UK-wide ODR if they want to donate in the event of their death occurring outside Wales. This might lead to a few people being on both registers. In order to reduce the risk of this happening, when people sign up to the opt-out register they could be reminded that if they have already signed up to the ODR they should ask for their name to be removed. Duplication need not be problematic in practical terms. If someone has signed up to the opt-out register in Wales, and dies in Wales, their refusal will be binding and so the fact that they have also, at some stage in their life, given consent for donation is irrelevant. If they are on both registers and die elsewhere in the UK the fact they have opted out in Wales should be discussed with the family. Unless the family has specific information about the individual's intentions, it is likely that the most recent decision would be taken to represent the individual's wishes.

In the Equality Impact Assessment (paragraph 163) it is mentioned that the legislation allows people with strong religious beliefs to opt in to donation, 'thus preserving the concept that organ donation is a gift on an individual level'. This may have been an additional factor in the decision to allow people to actively opt-in using the Welsh register. The BMA believes that organ donation is always an individual gift and should be perceived and presented as such - a decision not to opt out is as much a gift as taking steps to opt in. Making this statement undermines this notion and, as explained above, allowing people to opt-in as well as opt-out using the Welsh register risks undermining the new opt out system.

The BMA strongly believes that:

- o the register in Wales should only record those who wish to opt-out of donation
- o individuals who live in Wales should be able to continue to sign up to the UK-wide ODR in case they die outside Wales

o when people opt-out in Wales they should be reminded that if they have previously signed up to the ODR they should now ask for their name to be removed in order to avoid confusion.

Question 4

Are the arrangements for establishing residency clear? Yes No

Comments-

The three stage residency test, of which all criterion must be met, appears to be satisfactory although we are not best placed to answer this question.

Detail is needed as to whom will be participating in discussions with the next of kin, how they will be supported and the process to follow when uncertainty arises. There also appears to be a number of phrases in this section which require further legal definition such as 'ordinarily resident'.

We do not have any ethical objection for the appropriate use of medical records to assist in determining points two and three of the residency criteria.

We do not know enough about the local 'gazetteer' system for determining an individual's residency to be able to comment fully.

Question 5

Does the Equality Impact Assessment properly set out how legislation will affect different sections of society, including children and people who lack capacity?

Yes No

Comments-

We fully support the content of the EIA, we are especially pleased to see sections on disability, race and religion have been duly considered and feature prominently in the analysis. We have specifically raised the under-representation of the BME communities on the ODR as a concern and are pleased that it is recognised with specific action proposed to ensure that all communities are included in dedicated communication strategies.

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?

Yes No

Comments-

We fully support the need for a comprehensive communications campaign and for a reasonable period of time between the Bill receiving Royal Assent and coming into force – the two years lead in time does seem appropriate. It is essential for the success of this policy that the setting up of the register and informing people in all sections of society of the change, is undertaken openly, publically and seamlessly.

As we stated in previous consultation responses the BMA believes that publicity, dialogue and full public awareness are the biggest factors in the successful move to a system of soft opt-out. We are supportive of the proposed duties placed on the Welsh Ministers in relation to this.

The success of publicity around organ donation since the publication of the first ODTF report – for example the Tell a Loved One campaign - can be seen from the fact that, according to figures from NHS Blood and Transplant there has been a 49% increase in deceased organ donors in Welsh hospitals between 2007/08.

However, there still does need to be 100% public awareness of the change from opt-in to opt-out. This requires the use of every possible resource and communication tool and in multiple languages (including brail and sign) in order to reach all corners of Wales and all sections of society.

The publicity, information and dialogue behind this change needs to be fully and appropriately resourced, there is no doubt this will require dedicated investment.

It is vital that this publicity starts at school to get the issue of donation into the public consciousness and to ensure people – especially young people - know that they have a choice to make; this will also encourage dialogue with parents and families at home.

It is also important that high level publicity across the whole of Wales continues after implementation, to encourage continuing awareness of what will be a permanent system for Wales.

It will need renewed ideas on how to ensure that donation, and the choice individuals have to register their objection, becomes an embedded part of the Welsh identity and part of what it means to live in Wales. The Welsh Government will need to work closely with third sector groups – particularly those working with people new to Wales.

We are pleased that the Welsh Government has adopted the BMAs suggestion of safeguarding the rights of those who lack mental capacity by making every effort to help those lacking capacity to understand the change in law and make a decision along with support and involvement of a nominated or responsible adult.

All publicity requires imagination and new and different ways of communicating – including alongside the traditional mechanisms using concerts, sporting and cultural events, popular culture, social media, industry, agriculture, membership and professional organisations etc.

By no means will this be a small endeavour, and the importance of a sound communications strategy should not be underestimated if the scheme is to succeed and gain the confidence of the public and the professionals.

Question 7

We have asked a number of specific questions. If you have any related issues which we have not specifically addressed, please use this space to report them:

Specific Comments

Page 8, paragraph 30: it is not clear why, if a nominated person is unable to give consent, donation could not proceed with the consent of a qualifying relative. There could be a situation for example, where an individual nominated a partner to make the decision but both were involved in an accident and unable to communicate. In such circumstances, the individual's family may be willing to give consent but, based on the information here, would be unable to do so. It is not clear why that is the case and we would welcome clarity over the legal issues surrounding this.

Under the Human Tissue Act, if the nominated individual is unable to give consent, the nomination is disregarded and the family can give consent. (The HTA's code of practice says: 108. The nomination may be disregarded if no one is able to give consent under it. This includes situations where it is not practicable to communicate with the nominated representative within the time available if the consent is to be acted upon. In the event that a nomination is disregarded, consent may be given by a person in a 'qualifying relationship' (see paragraphs 109–114).) It is unclear why this is being changed.

Page 9, paragraph 31: people actually have four options because they could also nominate someone to make the decision for them, as explained in paragraph 29.

Page 10, paragraph 38: as mentioned in the general comments, it is essential that the legislation is clear that when talking about patients who lack capacity (for whom consent is not to be deemed), it is referring to patients who have not had capacity since the legislation came into force. If not, it could be taken to refer to all patients who lack capacity in the period leading up to their death and, as mentioned previously, most patients, who are being considered for donation, will lack capacity at that time.

Regulatory Impact Assessment

Paragraph 102: the statement about Spain is misleading. Although the law is based on opt-out, in practice consent of the family is always sought and so it operates more in line with an opt-in system than an opt-out one.

Paragraph 153: we are unsure of the meaning of the following statement: "It must be emphasised again that if there is evidence available of the wishes of the deceased, those wishes should be respected with *no judgement regarding mental capacity*". It is stated earlier that when an individual signs up to the ODR there is no check on capacity. This is appropriate and in line with the law under which adults are assumed to have capacity unless there is reason to believe the contrary. This sentence appears to go further, however, and say that capacity is irrelevant, but in some circumstances it may be appropriate to consider capacity. If doubts are raised about the individual's capacity at the time the decision was made, for example, it would be appropriate to make further enquiries before relying on the decision, although the onus will be on those who argue there was a

lack of capacity to provide evidence to support their case.

In the draft Bill

s15(4)(a) we assume this should be 2013 and not 2004?

General

We would welcome more detail on the role of clinicians / the impact the changes may have on healthcare professionals. This would be especially useful, for example, in relation to talking to relatives, and in determining mental capacity as specified in this consultation document.

Detail is needed on the publication of accompanying guidance.

Consideration should also be given to what will happen as new forms of donation are found – such as face or limb donation. For example should an opt-in system continue to operate for these new forms of donation? This is an important consideration in any move to opt-out, especially as complicating the policy may encourage more people to opt-out of donation entirely. We have previously argued that face donation (or other new types of donation) should continue to be based on an opt-in system with consent required from the donor while alive or the family after death. Welsh Government legislation may therefore need to contain provision, such as a Regulation making power, in order to exclude certain organs from the opt-out system.

Importantly - and fundamental to the operation of an opt-out system - the issue of capacity in NHS Wales also needs to be considered. There are a number of questions which need answering in relation to this – can NHS Wales cope with an increased number of donors? Do we have the network, infrastructure and number of healthcare professionals in place to support this policy? Are there enough ITU beds? Are tissue retrieval teams located in the best possible sites to enable access to all hospitals in Wales within one hour? And will performance / success be monitored - and if so, how?

Confidentiality

Responses to consultations may be made public – on the internet or in a report. Normally the name and address (or part of the address) of its author are published along with the response, as this helps to show the consultation exercise was carried out properly.

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