DRAFT CODE OF PRACTICE ON LIVING AND DECEASED ORGAN AND
TISSUE DONATION FOR TRANSPLANTATION – WALES

Human Tissue Authority

Response from BMA Cymru Wales

INTRODUCTION

BMA Cymru Wales is pleased to give consideration to the Human Tissue Authority’s consultation on a draft code of practice on living and deceased organ and tissue donation for transplantation in Wales.

The British Medical Association represents doctors from all branches of medicine all over the UK; and has a total membership of over 150,000 including more than 3,000 members overseas and over 19,000 medical student members.

The BMA is the largest voluntary professional association of doctors in the UK, which speaks for doctors at home and abroad. It is also an independent trade union.

BMA Cymru Wales represents some 7,000 members in Wales from every branch of the medical profession.

RESPONSE

General comments:

BMA Cymru Wales notes that the guidance has been written in a manner that starts from the viewpoint of when consent cannot be deemed to have been given (from para 9). In considering how the code might operate within a clinical setting, we would suggest that might be better to start from the viewpoint of when deemed consent is irrelevant because a decision to donate, or not to donate, has already been made during life (paras 127–140).

Ideally, in our view, the starting point of the clinical process would first be to ask if a decision has already been made. If not, then the next question for the clinician to consider is whether or not assuming deemed consent would be inappropriate. If the answer to that second question is that it wouldn’t be inappropriate to consider deemed consent, then the clinician knows that they are in the territory of working out whether consent can in fact be assumed.

We therefore consider that, whilst the draft code of practice does contain the right sort of information, it may not be presented in an order that would best help the clinical process. As such, we would suggest that the Human Tissue Authority (HTA) might wish to revise the order in which the paragraphs are presented.

Specific comments:

In addition to the general comments we have listed above, we would wish to submit the following comments on specific sections within the draft code:

Para 11: ‘…made an active decision but neither registered this or shared it with their family or friends, …’ [emphasis added]. This implies that if a family member or friend says the individual informed them that they did not want to donate, then this would be classed as a ‘formal opt-out’ under the legislation and donation
could not lawfully proceed. This cannot be correct or the intention of the National Assembly for Wales. This interpretation would make obsolete the provisions in the Act that allow family and friends to object to consent being deemed, on the grounds that a ‘reasonable person’ would conclude that the family member or friend knows that the most recent view of the individual was not to donate. This part of the paragraph should be amended to read: ‘made an active decision but did not register it, …’. Or, if this is not possible, it should, at least, cross-reference to paras 155-160 which refer to the level of evidence required to judge the veracity of any reported comments.

This paragraph is also rather confusing and so would benefit from some redrafting.

Para 15: in the case of children, the consent of someone with parental responsibility would constitute express consent.

Paras 32–34: the heading and text within these paragraphs refer to the person who ‘seeks consent’. For the avoidance of confusion this should specify that it is referring to cases where consent is not already in place and is not to be deemed (ie where consent is required from an appointed representative, someone with parental responsibility or a person in a qualifying relationship). If this is intended to include deemed consent then ‘seeking consent’ is probably not the best terminology and it should refer to the person who discusses donation with family and friends.

Para 38: it might be helpful to state explicitly here that any relative or friend may provide information and that the list at para 35 does not apply.

Paras 39, 78, 91 and 145: it is strange that information about ranking was not included explicitly in the Human Transplantation (Wales) Act 2013 but rather via amendment to the Human Tissue Act 2004. Nevertheless, given that the ranking, as set out in the 2004 Act, applies, should the reference not be to sections 27(4)-(8) given that all of these sections contribute to the rules on ranking?

Case study: It would be helpful to have a reference, or link, to the NHSBT guidance on dealing with situations in which there is disagreement.

Para 42: point b implies that if a child had not appointed a representative, the ranked qualifying relatives’ list applies. Under the Act, however, someone with parental responsibility, if available, would give consent before moving to the list of qualifying relatives. In most cases the practical impact will be the same but, given that, under the Act, a ‘child’ is someone under the age of 18 it is feasible that a ‘child’ of 17 years old could be married or have a partner. Our understanding is that, in such cases, someone with parental responsibility would still be the first person to consult. It would probably therefore be better to refer only to adults in point b and add in point c, that the child had not appointed someone to make the decision.

Para 44: see comments on para 11.

Para 46: this should also refer to people with parental responsibility for children (see also comments on para 42).

Paras 54–57: given that this document is primarily aimed at specialist nurses for organ donation (SNODs) and others working within transplantation, it is questionable whether this section is needed.

Para 68, Table Two: in case 4, it should be ‘child’ not ‘adult’.

Paras 69–72: the purpose of this section is unclear. Is it referring to ‘excluded organs’ that will be listed in the Regulations? If so, this should be made explicit. If not, is it referring to organs that are not on the Organ Donor Register (ODR) list and are also not in the Regulations? If so, it is not obvious the circumstances in which it would be proposed to donate an organ that is on neither the ODR list nor in the Regulations. Is this intended to cover the limited period between donation being possible and Regulations being amended?
Para 75: point b contains a typographical error and should read: ‘They appointed a representative/s to make decisions on organ donation on their behalf.’

Para 76: for the sake of clarity should this also state, explicitly, that if the adult registered a decision not to donate after death, donation cannot proceed?

Para 77: the scope of this requirement needs to be narrowed given the serious implications of deeming consent when someone had appointed a representative. The onus should be on individuals who have appointed representatives to make this known by registering it on the ODR. Some additional, reasonable checks are also appropriate, such as asking those relatives/friends who are present or who it is suggested may have information, but requiring the health care team to ask ‘any family/friends present or who are contactable’ [emphases added] places a huge burden on the SNOD or other staff. Surely it is not suggested that ‘any’ friend or family member who could be contacted, should be contacted in case they have information that the individual had appointed a representative.

Para 85: after ‘withdrawn’ there should be a full stop.

Para 87: this should read: ‘express consent (or express refusal).’

Para 88, table 3: in case 2, meaning of expressing consent, this should read ‘a’ person with parental responsibility and not ‘the’ person, as there could be more than one. The Act itself refers to ‘a person’.

Para 91: there is probably no scope to amend this paragraph, because of the wording of the legislation, but there may be circumstances where a person with parental responsibility exists but is unable to give consent (eg because they were both in a car accident and the parent lacks capacity). It is unfortunate that consent cannot be provided, in these cases, by someone in a qualifying relationship. Is there any scope to allow for this situation? Also ‘the child’ becomes ‘they’ and should be ‘he or she’.

Para 94: It might be helpful to provide a bit more guidance here. As worded, the final sentence implies that if one person with parental responsibility objects, donation should not proceed. If one person, although having parental responsibility for the child, was estranged, or had little recent contact with the child, this might affect the weight given to that person’s views when they are opposed to the views of the person with whom the child was living. Also, should there be some emphasis on trying to respect the known or likely wishes of the child? A little more emphasis on the discretion of the SNOD and transplant team to make a judgement based on the individual circumstances might be helpful. (If this is covered in the ‘dealing with disagreement’ guidance from NHSBT referred to in the case study in para 41, then it should be referenced here.)

Para 111: it is bizarre that someone who normally lives in Wales and happens to be in prison in Wales cannot have their consent deemed. Presumably, the purpose of the ‘ordinarily resident’ criteria is to ensure that the individual was aware of, and recognised, the fact that they would be covered by the legislation and, unless they opted out, their consent would be deemed. We can see no justification for extending this exclusion to prisoners who normally live in Wales.

Paras 112 and 113: it is strange that armed forces personnel are not considered to be ‘ordinarily resident’ in Wales but their families are. This could be confusing. Is it possible to have a consistent approach?

Paras 116–123: we have significant problems with these paragraphs and the advice provided within them. This stems largely from our concerns around the wording of the Act. Nevertheless, we believe there is scope for the HTA to interpret this provision more broadly to encompass not only the actual amount of time the individual has lacked capacity but also how that relates to the period of time the individual had capacity since the legislation came into force.

The Act’s description of a ‘significant period’ is ‘a sufficiently long period as to lead a reasonable person to conclude that it would be inappropriate for consent to be deemed to be given.’ Consider a man who is 20
when the legislation comes into force and wants to donate, so is happy for his consent to be deemed. He loses capacity at the age of 40 – as a result of an accident – and dies 2 years later. If it is only the amount of time he lacked capacity that was considered, consent would not be deemed, but it is highly questionable whether most people would consider it 'inappropriate for consent to be deemed' given the amount of time he had to opt-out if that had been his wish. The suggestion in para 123 that a prior decision cannot be relied upon because the individual has ‘lacked capacity subsequently for a significant period in which they might have chosen to opt-out’ is meaningless. By definition, if they lack capacity, they cannot make and communicate a choice.

Logically, it is the amount of time the individual had capacity since the legislation came into force that is the relevant factor, in terms of whether their consent should be deemed, not how long they have lacked capacity. It is unclear why the bar should be set higher here than for someone who had opted into donation, who might equally have changed their mind over the intervening period had they retained capacity; in these cases subsequent incapacity is considered irrelevant.

A better approach would be to set out the test as ‘ie a reasonable person would conclude that it would be inappropriate for consent to be deemed to be given’ and set out the type of factors that should be considered in reaching that judgement. This should include both the time the individual has lacked capacity and also the length of time he or she had capacity since the legislation came into force.

Para 125: it is unclear what type of ‘advance statement’ this is referring to and how realistic it is that an individual may have made such a statement (rather than opting in to donation). Where the individual did not opt-in or make an advance statement, the fact that they had chosen not to opt-out of donation is a relevant factor which should be explicitly shared with those who are required to give consent. It would be helpful to add this to the code.

Para 131: it is disappointing that the Act did not specify that an individual’s wish to donate or not donate organs should be formally recorded on the national register. Given that it did not, it is unclear how much discretion there is for the HTA to interpret this. See our comments on para 11.

Para 134: the two examples given here both involve the presentation of the individual’s views in writing, although SNODs may need to decide about the veracity of any reported comments. A cross-reference here to paras 155-160 would be helpful to clarify that some evidence must be provided.

Para 139: this does not make sense. Should it say ‘donation should or could go ahead’?

Para 144: it seems strange to ask the appointed representative about the extent of their authority. Should this not be recorded on the ODR?

Para 147: the paragraph numbers for the cross-reference are missing and should be included.

Para 154: as with the comments on para 77, this may need to be narrowed slightly so it does not imply that SNODs should contact any family/friends who are contactable which could be an onerous and time-consuming task. Also, a small typo; the semi colon should be a comma.

Para 173: this implies that it the right of the family to override the express or deemed consent of the individual. Whilst pragmatically we accept that donation should not proceed if it will cause severe distress to the family, as currently worded it implies it is the family’s decision whether donation goes ahead. We would prefer the wording from the HTA’s code of practice on transplantation to be repeated here which says that relatives ‘should be encouraged to recognise the wishes of the deceased and it should be made clear, if necessary, that they do not have the legal right to veto or overrule their wishes.’

Glossary – deemed consent: see comments on para 11 in relation to sharing information with family or friends.
Glossary – Human Tissue Authority: should be licenses rather than licences.

Annex A: no comments are offered on this as it is a reproduction of existing published material.

Annex B, Flowchart A: the final box should also include express refusal (or another box should be included to cover refusal). It currently suggests that consent can be deemed even where there the individual has opted out.

Annex B, Flowchart B: a similar issue – this says consent may be deemed if no express consent is in place, but says nothing about refusal.

Annex B, Flowchart C: again, references to the decision on the ODR only cover express consent and not express refusal. Also, it is strange to begin with appointed representatives rather than the individual’s own wishes formally recorded on the ODR or elsewhere.

Annex B, Flowchart D: this seems to contain an error. Where there is credible evidence that the person would not have wanted their consent to be deemed, provided by a relative or close friend, and it is the most recent evidence available, it is suggested that consent may be deemed but presumably it should say consent may not be deemed.

Also, is the relevant question here whether they wanted their consent to be deemed or whether they wanted to donate organs? Someone may have objected, in principle, to opt-out but despite that still be willing to donate their organs. Or, they may have had no objection in principle to opt-out but have made clear they did not wish to donate their organs. We had understood this part of the Act to be concerned with individuals’ wishes about donating organs, rather than their views about the system itself.

Annex B, Flowchart E: this should include express consent from someone with parental responsibility on behalf of a child (see comments on para 42).

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