Human Tissue Authority

Responses to the Consultation on the Code of Practice for the Human Transplantation (Wales) Act

May 2014

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Please note: All responses start at Question 5, as the first four questions were asking respondents to provide the HTA with some details about themselves. All responses are published as they were received.

Response 1: Gloria Owens

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No. There is already a code of practice that must be adhered to under the current opt in system. SNODS are experienced in seeking information concerning people who lack mental capacity under this code. I trust the SNODS and other appropriate NHS staff involved in the organ transplantation/ donation process will also work with the same integrity and compassion under this code of practice when assessing whether or not a potential donor lacks capacity; and in their approach to the relatives of those potential donors who lack mental capacity.

17. Please provide any further comments you have on the Code here:

I read the code thoroughly and found the flow charts extremely useful to help understand and clarify the issues and points raised in the code. I believe that the SNODS and other NHS staff involved in the current opt in system have a wealth of experience and act with compassion and integrity when speaking with bereaved relatives. There is no reason why they will not be able to undertake the same professional and compassionate approach when seeking consent from a family of a potential donor whether it be by deemed or expressed consent. I am sure that if there is evidence provided by relatives that a prospective donor, who had not opted out, did not wish to be an organ donor, the SNODs would recognise the family's wishes and not proceed with the organ donation. I think the fact that there will be an opt out register is very important. In addition, the two year interim period will give the Welsh Government ample time to inform and educate the Welsh people of the new law and how it will work in Wales. I am a transplant patient and have been blessed with a functioning kidney for nearly 32 years. I believe that the soft opt out system will be of benefit to all people in the UK. I am sure that the two year information/publicity campaign will inform people of the changes. It is important that all those who wish to opt out of the new system are given an efficient and uncomplicated method to do so. I hope too that the NHS will employ and train more SNODs; and ensure that all potential donors are recognised by the relevant NHS staff.

Response 2: Anonymous

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No. Obviously this is an extremely emotive issue and agreement between parties should be confirmed before progressing to removal of organs.
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No
17. Please provide any further comments you have on the Code here:
I am reassured that there appears to be caution applied where families/friends are concerned. My husband probably won’t get round to opting out but I could never give consent for removal of organs because he would not. I hope he would give consent for my organs to be removed as he knows I’ve been for it for years since I worked in an ITU. Even so, I am not sure that legislation is the way forward on this issue.

Response 3: Anonymous

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No response
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No response
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. I am particularly concerned about the lack of a provision to be registered as a "non-beating heart" donor. There is a segment of the population who would be willing to be “non-beating heart” donors but not donors on the basis of brain death, whilst the heart continues to provide an effective circulatory system. The needs of this group are currently not adequately addressed.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No response
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. I am particularly concerned about the lack of a provision to be registered as a "non-beating heart" donor. There is a segment of the population who would be willing to be “non-beating heart” donors but not donors on the basis of brain death, whilst the heart continues to provide an effective circulatory system. The needs of this group are currently not adequately addressed.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No response
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No response
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response
13. Do you agree that this approach is in line with other professional advice and guidance?

No. I am particularly concerned about the lack of a provision to be registered as a "non-beating heart" donor. There is a segment of the population who would be willing to be “non-beating heart” donors but not donors on the basis of brain death, whilst the heart continues to provide an effective circulatory system. The needs of this group are currently not adequately addressed.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
Yes. I think that staff should have the right to opt out of participating in organ removal.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No response
17. Please provide any further comments you have on the Code here:
I think that staff should have the right to opt out of participating in organ removal.

Response 4: Anonymous

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No
17. Please provide any further comments you have on the Code here:
No response

Response 5: Pauline Elliott, Gynaecological Nurse Practitioner

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No response
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No
17. Please provide any further comments you have on the Code here:
a necessary step forward welcomed by those waiting for transplants.

Response 6: Dr Nigel Page, Human Tissue Representative, School of Life Sciences, Kingston University

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes. Although, I have found the document understandable, I have also found this draft more detailed and lengthy than previous Codes of Practice published by the HTA.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes. Nonetheless, the draft is entitled 'living and deceased organ and tissue donation' those legislative parts relating to living organ donation have been relegated to Annex A. Living organ donation should be given just as much prominence in the ordering, if this is to be an all inclusive code for Wales. I do understand that no material amendments may have been made to the regulatory framework for living organ donation but this does not mean they should be dismissed to an annex, otherwise, Code of Practice 2 should have as much standing as the current proposed draft for health professional in Wales.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes. On the whole, yes, note there is slightly different wording in the same example given in paragraph 119 b and d for some reason.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. May be to consider better ways to link with Codes of Practice 2 and 6 for living tissue donations. Code of practice 6 on Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation is not mentioned. Do you want this draft to be read independently from the other codes of practice or should it be used in conjunction?
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes. They are quite lengthy and from this sense a lot of checking may need to be done. Can a simplified check list be produced, although the flowcharts may go some way to resolving this.
Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes.
13. Do you agree that this approach is in line with other professional advice and guidance?
No. I would have more confident if paragraph 34 read (SHOULD rather than RECOMMENDED) ‘However, if the person seeking consent is not a SNOD, they should meet the criteria in recommendations 1.1.30 and 1.1.31 of the NICE guidelines on consent and be competent in understanding the legislation and this code of practice.‘ This would be in line with other professional guidance provided in for example Code of Practice 1 (Consent) that the persons seeking consent ARE suitably trained’.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes although I can foresee issues with those working part time or as students.
15. Do you consider that any information is missing? If so, what?
Yes. This code will need to be read by Welsh health professionals along with the existing code of practice 2. Code of practice 2 should be updated to reflect the changes in the Human Transplantation Act (Wales).
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No
17. Please provide any further comments you have on the Code here:
Overall, it is quite lengthy compared to other HTA codes of practice, for example, bearing in mind the existing code of practice 2 (157 paragraphs). The living donations regulatory framework paragraphs are relegated to an annex, and the HTA will need to consider whether this is a standalone code of practice or whether code of practice 2 that covers existing living donation should be given just as much prominence.

Response 7: Zoe Goodacre, Critical Care Network Manager, Llanfrechfa Grange Hospital

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No response
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No response
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No response
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No response
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No response
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No response
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response
13. Do you agree that this approach is in line with other professional advice and guidance?
No response
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
No response
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain

your answer.
No response
17. Please provide any further comments you have on the Code here:
No response

Response 8: Clare Small

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No response
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. The code should make clear what the role of the SNOD is. I don't think this is clearly explained enough.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No. could be clearer in section c, where a non welsh person has been living for 12 months or more in wales but this is not their ordinary residence. Who does this apply too; students/people who work away from home/? is there a maximum time i.e 12months -10 years
15. Do you consider that any information is missing? If so, what?

Yes. how do you suggest educating this out to the welsh population?
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
Yes. There are already concerns with this taking away the gift element of organ donation and lack of education suggests that the general public don't know enough about donation to respect and understand the code and what it actually means.
17. Please provide any further comments you have on the Code here:
this will work effectivly if Welsh residents are educated properly on what organ donation is and means. This is missing from the code, there is little about which organs can be used, time frames, how donation proceeds etc.

Response 9: Shelley Jones

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No
17. Please provide any further comments you have on the Code here:
I think, as a member of a family which has benefitted from a transplanted organ in the past, that this is long overdue. Patients shouldn't have to wait for a "lucky death" to be able to live a healthier life.

Response 10: John Biggs

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No
15. Do you consider that any information is missing? If so, what?
Yes
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes
17. Please provide any further comments you have on the Code here:
No response

Response 11: Nicola Ruck, Community Health Council Member, Wales

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes. But on page 39 "The reasonable person test is an objective one ..." is not clear. the test is not clearly referenced.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. Not completely. Maybe there are other areas of nursing which could be used as a comparison. What would make evidence stronger or weaker - some more examples are needed.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?

No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No. I do not have relevant experience
17. Please provide any further comments you have on the Code here:
Good policy and well thought out. The point about deemed consent meaning that donation is legal, but not compulsory is an important one.

Response 12: Dr Peter C Matthews on behalf of Faculty of Intensive Care Medicine (FICM), the Welsh Intensive Care Society (WICS) and the Royal College of Anaesthetists Advisory Board (Wales)

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No. It needs to clarify absolutely that an appointed representative has a higher authority with respect to consent than family members, especially when children are involved (see paragraphs 89 and 90).
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. Clarification is needed in paragraph 125. "...when they did not make a decision in life," could be rephrased for clarity to something like "...when they did not register their express consent (or non-refusal)."
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes.
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?

Yes.
15. Do you consider that any information is missing? If so, what?
Yes. Not missing as such but it appears that Paragraph 139 should be "then donation should go ahead," not "then donation should not go ahead."
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No.
17. Please provide any further comments you have on the Code here:
Primarily the Code is concerned with the practical implementation of the new legislative changes that will come into effect in December 2015 and as such primarily affects the work of the SNODs and transplant clinicians especially with regard to consent issues. It does not ask for further comment about legislation and practice that we have already made representations about in previous consultations, either in written or oral form. On the whole I can't find much to comment about. It does seem that concerns that we have raised in the past have been taken to account to a varying degree, and it doesn't force the SNOD into a position where donation will go ahead in circumstances which could greatly upset families or staff (and even undermine the transplantation programme as a whole). The language used is less temperament than previous WAG guidance. I have reviewed Annex A - Living Organ Donation guidance but it isn't applicable to ICM and so I don't think it is necessary for us to comment on that section.

Response 13: Dr Alex Manara on behalf of the Faculty of Intensive Care Medicine

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain

your answer.
No
17. Please provide any further comments you have on the Code here:
Clear and well written. I am pleased to see that the end of the day the family will still have the final say in difficult cases.

Response 14: Dr Alison Ingham, Clinical Lead in Organ Donation, Betsi Cadwaladr University Health Board (West)

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. In point 142 it may be useful to have some reference to "Gillick competence" or the relevant document / reference, in terms of a child appointing a representative
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes. Although I must stress this is my personal opinion and I am not a SNOD.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes. Re point 142 see previous comment.
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?

No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No
17. Please provide any further comments you have on the Code here:
Fairly clear. Paragraph 57 could be reworded. The sentence regarding DCD could be interpreted by a lay person as allowing organ donation before the patient is dead. There are (unless I have misinterpreted) 3 unintentional errors: 1) Paragraph 139 should read "then donation should go ahead" not "then donation should not go ahead" 2) Paragraph 68. Table 2. Point 4 should read "adult" instead of "child" 3) Paragraph 164 should read "the reasonable person test"

Response 15: Fiona Loud, Policy Director, British Kidney Patient Association

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. Will there be a shorter, lay version available other than the FAQ? Point 17 could be clearer. "It is unlikely that this could be done to a high standard without input from a friend or relative. Therefore, it is highly unlikely organ donation would be considered for such a person." It could say ..'if a risk assessment is not possible...it is highly unlikely' etc. Point 66. Novel transplants - if a lay version of this is produced, an example would be helpful. Point 106c 'The person’s residency in Wales supported the regular order of their life for the time being' would benefit from clarification as 'the time being' is rather vague.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No. Suggest that the 'express and deemed consent' section, 74 onwards, should be before the 'novel transplants' section.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. They are helpful, but could a case where the only family member is in another country be discussed also?
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. There is nothing in the code about BME or other communities, language needs etc - other than a mention of 'language' in a sub paragraph. It will be very important for awareness and understanding of the new code to be clear for Welsh residents who do not have English or Welsh as their first language.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes

13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No. The guidance on the armed forces needs clarification: it does not seem logical that the person serving in the armed forces is not deemed to have given consent if they been posted to Wales, but their family member is deemed to have given consent because they have accompanied that person. The approach needs consistency.
15. Do you consider that any information is missing? If so, what?
Yes. How the SNOD may deal with a request from a family member to make a directed donation, e.g. if another family member is on the organ donor waiting list.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
Yes. The case of a person who expressed a positive desire to donate (but did not give express consent) before their mental capacity was limited (e.g. dementia set in, a road accident etc) is worthy of exploration. How long is 'a significant period before their death'? Families may be disappointed that their relative is unable to donate when they knew that they wanted to.
17. Please provide any further comments you have on the Code here:
There are some specific points which we have made through this consultation, which is a reasonable expression of the advice available. Advice on how this code links with NHSBT guidelines would be helpful.

Response 16: Janet Eleanor Lochain Secluna Thomas

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. It requires a high degree of intellect and education plus a determination to read through some 65 pages which does not include relevant sections of other documents which are referred to in the Code of Practice. While I may consider myself competent and able to tackle this consultation, I think it unfair that those who may be less able but not less concerned by the working of this new law in Wales but have not been given the chance to be given a less demanding document which they can use to express their worries and fears. People who cannot understand complex language are exactly those people who may well be more vulnerable when this Act comes into force and every effort should have been made to ensure that they were consulted in a manner appropriate to their abilities.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No.The order may be logical but there are places where certain statements or information need to be repeated in order to facilitate the ease with which SNODs can remind themselves of all relevant factors.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. The Case Study given in paragraph 41 involved a man who lived in Bristol so, while it shows the problem of disagreement between relatives, it does not throw any light on what would happen if this were a person 'ordinarily resident' in Wales. Surely, the whole point about this new law is the introduction of 'deemed consent' and there should have been numerous case studies examining all the different scenarios. As it is, it is not altogether clear to the ordinary person when 'deemed consent' will be enforced.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. There is a need for it to be made clear that staff should have a clear right to draw attention to and gain action against abuses. Whistleblowers should be regularly informed of easy access to rigorous procedures for the investigation of abuses not only of conscientious objection but of interpretation of the law and the code of practice for instance the improper use of definitions of death as the basis of the taking of organs, failures to give due weight to evidence of the deceased's objections to organ removal, information being passed from those dealing with the deceased to those dealing with possible recipients, undue pressure being put on families and relatives and failures to respect their religious, ethical and moral objections, failures to make efforts to contact relatives and ensure that at least one relative is present. These are only a small selection of possible and even likely abuses which are almost

certain to arise. If those in authority have not realised how easily even the highest standards can be breached then lessons have not been learnt from the Francis Report. There should not be financial incentives, or penalties or promotion or targets attached to the performance of medical personnel; that judgement should remain purely clinical on medical grounds. it should not be a criterion for the recruitment or transfer of staff into or out of ITUs or Transplant Units. Staff contracts must not include any clauses for silence in public on these issues either before, during or after leaving these units; nor should there be any gagging either involving pension benefits or golden handshakes or any other benefits which seek to silence staff.

Specific questions

Evidence that the person would not have wanted to be a donor

10. Do you think the Code provides sufficient information about who can provide this evidence?

Yes

11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?

No. I think that a list of qualifying relationships should be attached to every section because it will be difficult for the family and friends to know who is in this list and whether it is ranked or not. SNODs may be familiar but it would be helpful if the relatives could be given a list to help them. It is also clear that excessive reliance is placed on the SNOD to weigh up evidence etc.; not all SNODs are necessarily so conscientious as to take the time needed to explain to the family why a decision is being made especially in the heat of the moment. It is not a good idea to put such a burden on one individual who may be making a crucial decision which will go against family wishes and cause great distress. This Code of Practice is not just for the early days of the implementation of the Act but must continue when what seems unusual (deeming consent) becomes more routine and less care may be taken over the distress of the family.

Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?

No. I think it less likely to work where the situation involves a sudden event such as a road traffic accident or some other catastrophic accident, a heart attack or stroke; in such circumstances it may well be difficult to find either the representative or family. I am glad to see that in paragraph 17 it is accepted that organ transplantation should not take place because of the risks to the recipient. I would wish for that paragraph to be repeated at this point when dealing with all the possibilities concerning representatives. There will not be time to be turning back to paragraph 17 to remind the SNOD about what to do.

13. Do you agree that this approach is in line with other professional advice and guidance?

No. I do not believe that any earlier professional advice or guidance ever had to deal with a situation where SNODs or clinicians had to decide that where a person has not given express consent they can 'deem' that consent has been given. I think that the Code of practice should err on the side of ensuring the clinicians never find themselves being forced to take a course of action that their conscience tells them is wrong.

Ordinarily resident

14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?

No. Students should not be considered as 'ordinarily resident' because they are absent from mid- June to early October as well as several weeks at both Christmas and Easter. They may have to maintain a base here because of the unfair practice of landlords expecting them to pay for their digs when they are absent for the summer. They do not count Wales as their home and should not be included under the deemed consent provisions.

15. Do you consider that any information is missing? If so, what?

Yes. There is no information for those medical personnel who may have a conscientious objection to deemed consent as to whether they will have any way of withdrawing from transplant operations which involve deemed consent. There are many religious groups inside Wales who reject deemed consent but also many whose ethical principles and whose consciences forbid them from participating in such operations. Their whole experience has been informed by the Human Tissue Act which places such strong emphasis on consent as to make it a criminal offence for the surgeon to carry out a transplant without express consent. It cannot be expected that there will not be many who will find this overturning of the history and ethos of transplant surgery entirely abhorrent. This also involves not only medical staff but also administrative, managerial and ancillary staff who may also have strong conscientious objections. The various scandals which led to the Human Tissue Act show how strongly people feel about this issue of the use of a loved one's organs; the further recent scandals in NHS hospitals highlight the need for principled, conscientious staff. In such a delicate area involving trust, everything must be done to ensure that relatives of possible donors do not feel that the staff with whom they come into contact are anything other than most principled and not just pursuing the goal of increasing the retrieval of organs. It is disingenuous to continue talking about 'donation' which means 'gift' ; only little children greet their guests at a birthday party with the words, " What have you brought me for a present?" A gift must be freely and knowingly given or it is no gift at all.

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. In my experience many adults, especially young adults, pay absolutely no attention to any serious aspects of public life; I have met many people who are unaware that there is a Welsh Assembly and would laugh at the idea that any law that was made could affect them; they will blank out any campaign however widespread because of total lack of interest. They do not read a newspaper except for the sports pages sometimes and their TV viewing is limited to entertainment programmes like Eastenders. Even if they do happen to hear of this change in the law they will not think it applies to them. It is indecent to take their lack of action as being a deemed consent. For many members of the public, they have by their lifestyle made themselves into 'excepted adults' but they will not be judged so in the context of this law. Only their families will know them well enough to be able to judge whether they are likely to be of such a character as to wish to donate. The conditions in which the family's evidence can be accepted are very strict or it will lie with the judgement of the SNOD who is already charged with a great deal and now s/he must be a psychologist as well. Where it is clear that a person is rightly diagnosed as an excepted adult, s/he should be straightaway excluded from consideration as a donor and there should not be a seeking for some way to procure these organs.

17. Please provide any further comments you have on the Code here:

I believe that a valiant effort has been made to try to fit the concept of 'deemed consent' into an earlier framework where it was accepted that only express concept could be trusted or used. You still use terms such as consent and donation when such concepts cannot be used in a system where the only safe course of action is to opt out and leave it to your family to give consent on your behalf. If you don't have a family that you can trust or no family at all then you are in a very difficult position if you wish to be generous and donate your organs. Deemed consent takes away the idea of donation -that's why it is not in the title of the Act. You are an organisation set up to protect the workings of the Human Tissue Act whose principal provision was express consent. How can you write a code of practice which destroys the whole idea of donation and says in effect, " You have said nothing which indicates what your wishes are one way or another, therefore, you must mean that you wish to donate!"? It wouldn't work in a wedding ceremony if either of the participants refused to answer, there would be no continuing the ceremony. No deemed consent for weddings! It's not your fault that the Welsh Assembly went bulldozing ahead with its new law but it behoves you to be very careful that you consider all the pitfalls that a system of deemed consent entails and try to ensure that these dangers do not materialise to the detriment of the dying person. I hear on the news just now that a facial surgeon, Russell Hopkins, has stated that the NHS has been ruined by the interference of politicians. I hope that will not be true of the Welsh transplant service because of this new law.

Response 17: Anonymous

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No
17. Please provide any further comments you have on the Code here:
Good.

Response 18: Carol Reisman

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
Yes
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes
17. Please provide any further comments you have on the Code here:
Well written.

Response 19: Mair Crouch

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No response
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No response
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No response
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response
13. Do you agree that this approach is in line with other professional advice and guidance?
No response
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
No response
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

No response
17. Please provide any further comments you have on the Code here:
No response

Response 20: Dr A Majid, Islamic Medical Association/UK

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. It should have been simpler to Ethnic Minorities/Asians and Muslims in Wales Some technical and legal matters will not be understood by some Muslim Welsh people Ideally, before the final drafting of any Consultation, some Muslim doctors representatives should attend your meetings in the drafting stage.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No. First: it is not logical for the Human Tissue Authority to get involved in Presumed consent and to support it in many ways? Your Annex A/Consent(adult) in clause 48 in your Code of practice , you say: "FOR CONSENT TO BE VALID, IT MUST BE GIVEN VOLUNTARILY BY AN APPROPRIATE INFORMED PERSON WHO HAS THE CAPACITY TO AGREE TO THE ACTIVITY IN QUESTION"? The Welsh people and the Welsh Muslims have not given voluntarily their free consent in the so called Deemed or Presumed consent? More, you have said This is a complete contradiction to what you preach and say on your website and in your Code of practice? More, you have said also in clause 91:: " A PERSON COMMITS AN OFFENCE UNDER THE HUMAN TRANSPLANTATION(WALES) ACT, IF THEY UNDERTAKE A TRANSPLANTATION ACTIVITY WITHOUT CONSENT"?: Here is another contradiction and another illegality.. Our Welsh Muslims would not have give their consent, to give their organs, when the law is implemented on 1 Dec 2015...but again, you still incist on taking their organs without consent, especially when the majority of the Welsh Muslims will not be aware of the new law when in implemented?
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. They are generally BIASED towards Presumed consent and in support of taking our organs WITHOUT OUR CLEAR CONSENT FROM US?
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No. In practice, it will not be clear as you might think. SNOD will be always BIASED towards to get our organs by using pressure, coercion and perhaps sometimes , in a "dishonest" way? Frequently there will be a problem in communication, explanation or understanding the English language?
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. Whistleblowers of all grades of personnel should be protected when they voice their concerns about any possible abuses throughout the process; there should be no gagging clauses or golden parachutes which are removed if someone is forced to resign because of being a whistleblower or reward those who leave without making allegations or laying complaints · No financial incentives or targets to encourage

retrieval of organs · Nothing to be written into employment contracts to encourage organ retrieval or require compliance against conscience or religious faith · Nothing to be done which penalises conscientious objection Staff in all levels and all areas must be given the highest degree of protection for conscientious objection. It should be recognised that many faith groups have objected strongly to this law , and it should not expected that they will participate. Steps should be taken to establish the faith and ethical position of every patient. If that cannot be done, perhaps of sudden death then no removal under deemed consent can be authorised . Staff in areas outside Wales who are asked to remove or implant organs taken under deemed consent must be given every opportunity to opt out, as the law outside Wales does not authorise the use of Deemed Consent.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. It will not be easy for many Welsh Muslims/Ethnic minority and Asians. It is very inappropriate for SNOD(unknown people) to enter the privacy of a house while all family member are in mourning/bereavement and ask to take the organs of their loved ones? This is very insensitive and is offensive to the Welsh Muslims!
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No. Most of the Welsh Muslims would not know or are aware of the so called: Appointed representatives. In practice this will not work?
13. Do you agree that this approach is in line with other professional advice and guidance?
No. We are not sure about that? We like to see evidences for that.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No. In practice, we do not think this will be simple and clear. It is more complicated with many Muslims/ethnic minority and Asians. We believe that some people, who are considered residents, they are truly non-residents and their organs will be taken BY FORCE AND WITHOUT FREE CLEAR CONSENT?
15. Do you consider that any information is missing? If so, what?
Yes. There are many information which are missing like: -The respect and the

protection of one's CONSCIENCE and RELIGIOUS BELIEF -The PROTECTION of the medical staff(doctors, nurses.....) , who do OBJECT strongly to this new undemocratic/dictatorship law of Presumed consent ,especially when they do object on Conscience and religious reasons to this new inhumane law? -The full respect and the PROTECTION to the FAMILY who should have the right to VETO any decision to take the organs of their loved ones at time of bereavement. We think that intimidation, pressure and coercion will happen to many of them by SNOD? If any Muslim family refuses to consent to the taking of the organs of their deceased one, this SHOULD BE FULLY RESPECTED AND BE ENSHRINED BY LAW? -An important clause should be added: FULL RESPECT OF THE RELIGIOUS AND CULTURAL BELIEFS OF THE MUSLIM COMMUNITY AND THE MUSLIM FAMILIES. -It is missing in the Code of practice: CONSULTING: REPRESENTATIVES OF DIFFERENT RELIGIOUS AUTHORITIES, especially Muslims, Christians and Jews. This should be A MUST when laws and regulations are proposed regarding any Ethical religious or moral issue.

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. Is not simple and practical with some Welsh Muslims and Ethnic minority! Some cultural and religious factors should be explored first! The Welsh Office and the HTA have not considered the wide WELSH MUSLIM OPPOSITION to the new law on Presumed/Deemed consent; In the last two years there were a lot of activities in the mosques in Wales against this unethical inhumane law; -Over 17000 Welsh Muslims in many mosques in Wales have SIGNED THE PETITION against this proposed new law -Many Islamic Rulings/Fatawas were published regarding the Islamic view on Presumed consent.(Islamic Sharia Council, Hizbul Ulamas,and others) Muslim organisations, especially the big official representative of the Muslims: THE MUSLIM COUNCIL OF BRITAIN have declared their opposition to this new proposed law...and many other organisations like: the Islamic Medical Association.in the UK. Many written submissions by Muslims were sent too to the Welsh Office. -Not only that but many Christian and Jewish organisations OPPOSED too this new proposed law. There have been many Multifaith statements which explained well the opposition. -We have also many doctors who opposed too. Finally, we like to explain a little bit about Islam and the issue of organ transplantation: In the Muslim world there are two views on Organ transplantation and donation. Many did approve it but with strict conditions, others oppose it for religious and medical reasons. The organs in the human body are "HOLY" in Islam. One thing more: It is an order to BURY QUICKLY THE DEAD PERSON...within few hours or in same day... So the issue of SNOD and other hospital procedures will take TIME and this is CONTRADICTORY to our Islamic beliefs and practices. The issue is more serious when the organs are taken from a dead Muslim who opposed all his life: Organ donation and transplantation. Also one thing to add: Some Muslims can donate any of their organs during their lives after their free official consent. It is forbidden in Islam to take the ovary or testis as organ donation because these two specific organs are linked to lineage and legitimacy. Finally is very important to emphasize that: A large number of Welsh Muslims are still unaware of the new passed law on Presumed/Deemed consent and almost all will not be aware of the new law on OPTING-OUT? This is very serious practical problem. It is very WRONG and DANGEROUS to take the organs from any dead Muslim when there was no official clarification regarding consent. We believe that when the law is implemented there will be a lot of anger, disharmony, protest, riots and lack of peace among the Welsh Muslims and in many areas in Wales. WE LOVE TO TELL THE WELSH OFFICE AND THE HTA REGARDING THE WELSH MUSLIMS WHO DIE, AT LEAST: KEEP OUT.!... It is wise and safer and is ethical to do that!

17. Please provide any further comments you have on the Code here:

We are not happy with many things regarding your Code: -We did mention some before especially in the missing information. -The Human Tissue Authority has DEVIATED from its "CODE" and philosophy by keeping silent and not defending THE RIGHT OF EVERY ONE/FAMILY FOR FREE CONSENT before the taking of any organ from any one. It looks that HTA did not learn from the many SCANDALS before in Alder Hey hospital and other hospitals when doctors KEPT the organs of patients who died in hospitals WITHOUT THE KNOWLEDGE AND PERMISSION OF THEIR RELATIVES AND FAMILIES? HTA should educate and preach all the times: FREE CONSENT in any medical procedure. It was very wrong for HTA to be associated with this new unethical law on Presumed or deemed consent in Wales? Finally: We like to mention to the Welsh Office and to the HTA that there are many other legal and ethical; ways to increase the number of the organs. More targeted publicity about the need for organ donation, will bring surely more organ donation...

Response 21: Dr Iain Robbé, Medical Educationalist

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No. Problem 1: there is excessive reliance on the accuracy of the Organ Donor Register (ODR) and on the interpretation of the ODR when the ODR is checked to establish whether the dying patient had registered either a decision to, or not to, donate their organs. Even in an organisation as committed to helping people as the NHS, mistakes can occur, for example, prescribing errors including the wrong drug, wrong dose and wrong patient (Dornan, 2009), and wrong patient and wrong site errors for procedures carried out by physician and surgeons (Stahel, 2010). Errors in identifying decisions that have been recorded on the ODR could easily occur. Problem 2: there is confusion about the use of the following words – qualifying relationships, family, friend, present or contactable, et alia hence the Specialist Nurse for Organ Donation (SNOD) will not be clear from whom consent must be sought. Consequently he/she will be more subject to management pressures to obtain organs in order to achieve Welsh assembly government targets.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. Requiring the presentation of "…all the evidence to support the assertion that the person would not have consented…" (paragraph 165) is asking too much of people who are grieving for the dying patient. All that should be requested from these distressed people is that they are able to state orally in clear conscience that the dying patient did not wish to donate her/his organs after death. This paragraph and related paragraphs should be rewritten to lower the burden of proof on the grieving people facing great stress at the side of the dying patient.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?

Yes. Requiring the presentation of "…all the evidence to support the assertion that the person would not have consented…" (paragraph 165) is asking too much of people who are grieving for the dying patient. All that should be requested from these distressed people is that they are able to state orally in clear conscience that the dying patient did not wish to donate her/his organs after death. This paragraph and related paragraphs should be rewritten to lower the burden of proof on the grieving people facing great stress at the side of the dying patient.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No. The approach appears to be a recipe for confusion – excessive reliance on the ODR as detailed above, finding a representative in a timely way, oral or written appointment, roles of "people" (qualifying relations, family, relatives, et alia).
13. Do you agree that this approach is in line with other professional advice and guidance?
No. It is not in line with the GMC's Good Medical Practice as I interpret it.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No
17. Please provide any further comments you have on the Code here:
A collaborative United Kingdom strategy for organ transplantation was recently published by the NHS Blood and Transplant organisation with the apparent support of the Health Departments of all four nations in the UK. The strategy is entitled "Taking Organ Transplantation to 2020" and the key point based on the evidence is that organ donation requires individuals to change their behaviours. Informed consent is central to behaviour change and the Code will have significant problems confirming whether the dying patient has given her/his informed consent.

Response 22: David Brynley Webb, Chairman of the Abertawe Bro Morgannwg University Health Board Organ Donation Committee

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No response
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No response
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No response
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No response
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
At our last committee meeting concern was expressed as to lack of clarity around translation services bearing in mind that the need may be urgent. Will presumed consent be applied when there is not time to obtain a translator?
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No response
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No response
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response
13. Do you agree that this approach is in line with other professional advice and guidance?
No response
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
No response
Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No response
17. Please provide any further comments you have on the Code here:
I have answered the question above from a professional perspective. From an individual position I consider the whole bill defective. The reasons have been rehearsed over and over again and there is no point in repeating them here but it does make it difficult to comment on the code of practice for a process one thinks is defective. My position is shared by many others but the bill is as it is and we must do our best to make it work. It is not sufficiently recognised that as the apex of the consent process is the interview by the SNOD who will not push ahead against vigorously expressed wishes by the relatives a lot of the code of practice will be academic.

Response 23: Dr Katja Empson, Clinical Lead for Organ Donation, University Hospital of Wales, Cardiff

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain

your answer.
No
17. Please provide any further comments you have on the Code here:
The code seems to rely entirely on SNODs for decision making. whilst they are undoubtedly the most experienced and already used to negotiating the consent process with family members however in my opinion some of the decision making might need to be shared by clinical teams caring for the patients when there are questions about capacity etc.

Response 24: Professor William John Armitage, Director of Tissue Banking, and Professorial Research Fellow, University of Bristol

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. 1. Definition of ‘organ’ on p.10, s.19, conflicts with definition in Glossary. This is confusing and unclear whether parts of the Code refer both to organs and tissues. 2. Assurance is needed about the legality of tissue banks outside Wales processing, storing and distributing tissues procured from donors in Wales with deemed consent. (NB Wales has no eye bank, valve bank, skin bank or bone bank; therefore all these tissues from donors in Wales are send to tissue banks elsewhere in the UK.) Under the Human Tissue Act 2004 and the HTA licensing arrangements for tissue banks, specific consent is needed to store and use tissue for transplantation. Is deemed consent equivalent to consent under the HT Act? 3. The Code's seeming emphasis on organs, in the narrower sense of the definition given in the Glossary, is underlined by lack of reference to the Human Tissue (Quality and Safety for Human Application) Regulations 2006. There should be reference to these Regulations in the section on Licensing Arrangements and the need for an HTA licence is it is intended to process, store and distribute human tissue for transplantation.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. The examples relate to SNODs and concern, eg, disagreement within families over consent, which would be dealt with by SNOD training, so not sure why such examples are needed.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. See answer to Q.1.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes

11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
No response
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No response
17. Please provide any further comments you have on the Code here:
No response

Response 25: Martin A. O'Donnell, Vice Chair - Royal College of General Practitioners Wales - Policy and External Affairs

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain

your answer.
No
17. Please provide any further comments you have on the Code here:
The RCGP Wales welcome the publication of this code and applaud the clear and logical way in which it is laid out for the benefit of Practitioners and patients alike, Clarification over the consent issues is well worded and the explanation of Deemed consent and its safeguards is extremely reassuring. 'means that when a person did not make an active decision in regard to organ donation during their life, or when they made an active decision but neither registered this or shared it with their family or friends, their consent to organ donation will be deemed to have been given, unless a person with a close relationship objects based on what they know of the wishes of the person'.

Response 26: Carol Wardman, Bishops' Adviser for Church and Society, Church in Wales

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. Not easy for non-specialists to understand, but perhaps this is less important than understanding by specialists. There are grammatical errors and clumsy wordings which make it hard to understand and occasionally incorrect. For example, 'they' is commonly used as a pronoun for a single individual whose gender is not specified. As 'they' is plural, confusion results. Eg: p15 para 2 line 1 is nonsensical ('themselves' has no antecedent); p39 para 163 line 2 is misleading: grammatically, 'they' refers to 'relatives or friends' (as it is the only plural antecedent) but presumably refers to 'SNOD'. Using 's/he' (with a note in the Terminology section, p10)would get over the gender problem and make it clear who is being referred to. If this is a document available to the public, grammatical issues MUST be more carefully checked to avoid problems.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No. Definition of 'ordinarily resident' (first mentioned p8, explained p30) should be made clear earlier. This is a crucial issue and has changed since the pre-legislation consultation.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. There are bound to be examples which come up as the Code comes into active use!
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. Re-stating and cross-referencing to particular relationships specified in the Act (eg as mentioned at para 23) would make this clearer. There is no reason not to reiterate this information, as it is of crucial importance.

Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?

No. The process is cumbersome and in practice would surely take so long that donation wold be unable to occur. This is the almost inevitable consequence of introducing 'deemed consent' and then refusing to allow families the final decision in unclear cases.

13. Do you agree that this approach is in line with other professional advice and guidance?

Unable to comment.

Ordinarily resident

14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?

No. The information provided is lengthy and confusing. It is not clear why so much 'explanation' has to be provided (other than to state the case of prisoners, who are uniquely resident here 'against', or at least not in consultation with, their free will). Paras 107-108 seem to provide sufficient over-arching guidance. Again, the confusion appears to be the result of introducing 'deemed consent' legislation.

15. Do you consider that any information is missing? If so, what?

Yes. Surprising and contradictory rather than missing. For example, service personnel posted to Wales are exempt (para 112), even though they may remain for some years, bring families, buy homes etc; whereas employees (moved by their employer) and students (who are likely to maintain an address outside Wales) are not exempt. If service personal are exempt, why are their families not? (para 113) The exemption of service personnel appears to contradict paras 106 and 107. A similar test to that for students (para 110) should be applied to service personnel. Confusion and complexity appears to be the result of introducing 'deemed consent' legislation.

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. Confusion will arise as to the voluntary nature of residence, as noted in Qs 14 and 15. Confusion and distress will arise where there is doubt over expressed consent, and/or the potential donor had done nothing to register any wishes, especially where the family objects.

17. Please provide any further comments you have on the Code here:

It endeavours to cover every eventuality, but it will inevitably be found wanting when it is put into practice. (There will always be unforeseeable cases.) As noted before, it is very long and complex, and not easy for a non-specialist to understand - although it will be in the public domain. Grammatical errors and clumsy wordings in places

make it harder to understand.

Response 27: Professor David Albert Jones, Director, Anscombe Bioethics Centre, Oxford

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. There are many useful examples in the draft Code, but only one case study (after paragraph 41) which concerns someone who is not ordinarily resident in Wales and so could not be subject to the 'deemed consent' provisions. It would be useful to have further case studies, and useful if these involved patients who were resident in Wales. One possible example would be a case to illustrate the issue of what kind of considerations would count as a reasonable objection by a relative 'on the basis of views held by the deceased'. See below in answer to question 11.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. The Code should make clear that the obligations of the SNOD and other members of the healthcare team do not end with death but that professionals have a duty to show respect to the body of the deceased and also have a duty of care for the bereaved. This is explicit in the GMC guidance on Treatment and Care towards the End of Life (2010, paragraph 83-84). While the NMC has not issued specific guidance on end of life care, analogous duties surely also hold for nursing staff as for physicians. Explicit reference to these duties would help clarify the basis of the advice in paragraphs 42, 94 and 174. It would also be helpful if some of the language present in paragraphs 42 and 94 were repeated in 174 so as to highlight 'the emotional impact this would have on family and friends' and the 'needs of all the people' involved.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. The Code of Practice helpfully clarifies that if a person has decided not to donate his or her organs then it would be unlawful to deem consent (paragraph 129) and

rightly draws attention to the fact that the Human Transplantation (Wales) Act 2013 does not restrict how this decision is to be recorded. The Code should clarify that there is no restriction on who could provide evidence that a person had made such a decision. For example, it may be that someone had a discussion with a medical professional about donation and expressed an unwillingness to donate. If such a decision were recorded at the time in the medical notes, and there was no evidence that it had been superseded by a later decision, then this record would constitute evidence of a decision in life and consent to donate could not be deemed. The provision in 4(4) of the HT(W) Act and the guidance provided in paragraph 161 to 170 of the draft Code is for circumstances where there is no clear record of a decision in life, and consent can legally be deemed unless there is a valid objection from a relative of friend of longstanding. This objection is based on knowledge of the person but is not evidence of an overt decision (anyone can provide evidence of this, if such a decision was appropriately recorded), it is rather evidence that, given what is known of the person, he or she would have been opposed to consent being given. It would be helpful to have a case study on this topic, for relevant evidence will not only cover the deceased's attitude to organ transplantation, but also, for example, the way he or she made decisions. Take, for example, the case of someone who, when alive, had been was very concerned about the way that the decision was made to withdraw treatment from his dying father. Let us say that in those circumstances he overtly involved other members of the family, and also, though he was not particularly religious, that he was keen to have consulted a faith community leader about whether this was religiously acceptable. Later, when a resident in Wales, he has an accident such that he is declared dead by brainstem criteria, and there is no record that he had made any decision about transplantation. In these circumstances his consent to organ donation could lawfully be deemed, but a concerned relative might object to the transplant going ahead unless and until it had been declared acceptable by the faith community leader. This objection would be reasonable in that it would be based on the relative's knowledge of views and attitudes of the person. More generally, if a reasonable person would conclude that the deceased was sensitive to the wishes of his relatives and would not have wished to add to the distress of his relatives then, if the prospect of transplantation after 'deemed consent' is a significant potential cause of distress, then the deceased should not be deemed to consent.

Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?

No. We have no suggestions to make as this submission has focused on other aspects of the Code of Practice.

13. Do you agree that this approach is in line with other professional advice and guidance?

Yes.

Ordinarily resident

14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?

No. The draft Code is to be commended for stating explicitly that people are not ordinarily resident if their residence is no voluntary and, in particular, that this applies to prisoners (paragraph 111), to members of the armed forced who have been directed to live in Wales (112), and to those compulsorily detained under mental health legislation (115). However, if this is the case then it unreasonable for the Code to describe the families of servicemen, or indeed the families of prisoners or others detained compulsorily, as ordinarily resident. If the family previously lived in Wales then they are ordinarily resident, but where a family moves only to be close to someone who is in Wales involuntarily, then they also are in Wales due to the involuntary relocation. To say that families have a choice if they wish not to join their spouse does not give due weight to the fundamental human right to family life. This situation is different to choices people make in relation to the requirements of work, because the work itself is voluntary. In contrast here the relocation is premised on an involuntary residency. The current paragraph 113 thus needs to be rethought and also expanded to include the families of other involuntary residents. Families who come only to join those in Wales involuntarily should not be deemed to be ordinarily resident.

15. Do you consider that any information is missing? If so, what?

Yes. See previous question. Also, both in relation to residency and in relation to age, the Code of Practice should make explicit how these requirements interact with the requirement for mental capacity. Thus if someone goes into a coma before their 18th birthday, or before the end of their first year in Wales, and then lives for some time in a coma, it may be that consent for transplantation could lawfully be deemed even though the person did not qualify at a time when they had capacity and did not have capacity at the time they qualified (in relation to age or residence). This mismatch cannot be justified ethically and seems not to have been foreseen in the HT(W) Act 2013. One possible way to address this issue would be for the Code to state that the meaning of lacking capacity for ‘a significant period before dying’ would depend on circumstances and, in the circumstances described above, even a short period without capacity might significantly deprive someone of the opportunity to have opted out.

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. Whereas the HT(W) Act 2013 stipulates twelve months residency as necessary and sufficient (in relation to time) for someone to be ordinarily resident, the law does not give a figure for what constitutes ‘a significant period’ without capacity but give a ‘reasonable person’ test: ‘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’ (Paragraph 5(3)). As the law has deliberately avoided giving a set period of time, it seems the draft Code of Practice is departing from the legislation by giving the figure of twelve months as significant (paragraph 122). This also seems problematic for at least two further reasons, in the first place the significance of the length of time will vary with the circumstances. If a person has not been in Wales for twelve months and then falls into a coma, all the time that the person is subsequently in a coma is depriving him or her of the opportunity to opt out during a period which, for most people, would be a statutory safeguard. In contrast, someone who has lived in Wales for several years after the passing of the act will have had ample opportunity to opt out. Nevertheless, even someone who had been resident in Wales for several years after 2013 would still, by a period of incapacity, be deprived of the opportunity to opt out (or to opt in selectively for certain organs). The relevance of the lost opportunity to opt out is expressed in paragraph 123, but it seems to be implied by that paragraph, taken together with 122, that in this case twelve months would be adequate as a safeguard. On the contrary even three months of incapacity would significantly deprive someone of an opportunity to opt out. Rather than specify a time it would be better to use the phrase such as “in the order of weeks or months” for paragraph 122 and to make explicit in paragraph 123 that the length of time that is significant will depend on the circumstances and, where a person has only recently qualified as a possible subject of deemed consent, even a relatively short time might be significant.

17. Please provide any further comments you have on the Code here:

The Code of Practice is helpful in clarifying a number of issues that are unclear in the legislation, and in drawing attention to professional standards and other requirements of good practice which are needed in order to apply the law appropriately. It is the view of the Anscombe Bioethics Centre that the legal move to ‘deemed consent’ in Wales is retrograde, that it undermines the voluntary ethos of donation, is potentially harmful to grieving relatives and to public trust, and that it will not in itself increase the number of organs available. In the words of the Catholic Bishops of France that we have repeated at different points in this legislative process, ‘It would be inhumane to procure organs in cases where the family is opposed or has expressed strong aversion, acute distress, or has no prior knowledge.’ Now that the law has been passed, the accompanying Code of Practice has a vital role in preventing these potential harms from being realised. In general the draft Code of Practice contains many provisions that are helpful in this regard, not least in setting out the duties of a SNOD to discover whether the person had made a decision in life, and if not, to obtain from the relatives and/or longstanding friends the best available evidence for the view that the person would most likely have expressed. From an ethical perspective, the key paragraphs in the Code are probably paragraphs 42, 94 and 174 which clarify that the legislative change is permissive not compulsive. The HT(W) Act 2013 does not require healthcare professionals to apply ‘deemed consent’ in a way that would cause distress to relatives or undermine public trust. It is essential that these paragraphs (42, 93, and 174) are not weakened and indeed that they are strengthened to draw attention to the requirement to consider the needs and feelings of relatives, which in general is also what the deceased would have wanted. This simultaneous care for families and recipients is well expressed in an online response to the British Journal of Medicine on the issue of presumed letter by a doctor who was also an organ recipient: ‘As both a doctor, a recipient of a double lung transplant and having lost a family member waiting on transplant, I was left feeling very uncomfortable reading this opinion letter. However from all three angles, as both the care giver, the recipient and the professional, my conclusions would be the same. As a recipient I view the donation of organs as a gift - from both the donor and their family. I would be horrified to think that in receiving an organ, another family had been left feeling abused and ignored.’ J. Monaghan ‘Re: We should not let families stop organ donation from their dead relatives’ BMJ Rapid Response http://www.bmj.com/content/345/bmj.e5275/rr/598035

Response 28: Dr Dylan Harris, Consultant in Palliative Medicine, Cwm Taf Health Board, Wales

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes (i) Clearer clarification about the role of a medical Lasting Power of Attorney and rights with regard to decisions about organ/tissue donation after death. (ii) Clarity about tissue donation (the emphasis is on organ donation) and whether every family should be asked about cornea donation, for example. (iii) The definition of a "significant period", in relation to how long a patient has lacked capacity for prior to death (12 months), is clarified later in the current code document, but the term is mentioned frequently prior to that and it would be useful if this clarification was made earlier. (iv) The role of an Independent Mental Capacity Advocate (IMCA) could be made more clear, for people with no close family or friends.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes -The role of an Independent Mental Capacity Advocate (IMCA) could be made more clear, for people with no close family or friends. -Clearer clarification about the role of a medical Lasting Power of Attorney and rights with regard to decisions about organ/tissue donation after death.
13. Do you agree that this approach is in line with other professional advice and

guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
The definition of a "significant period", in relation to how long a patient has lacked capacity for prior to death (12 months), is clarified later in the current code document, but the term is mentioned frequently prior to that and it would be useful if this clarification was made earlier.
17. Please provide any further comments you have on the Code here:
(i) Clearer clarification about the role of a medical Lasting Power of Attorney and rights with regard to decisions about organ/tissue donation after death. (ii) Clarity about tissue donation (the emphasis is on organ donation) and whether every family should be asked about cornea donation, for example. (iii) The definition of a "significant period", in relation to how long a patient has lacked capacity for prior to death (12 months), is clarified later in the current code document, but the term is mentioned frequently prior to that and it would be useful if this clarification was made earlier. (iv) The role of an Independent Mental Capacity Advocate (IMCA) could be made more clear, for people with no close family or friends.

Response 29: Benedict Biddulph

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. All of it is difficult for "Joe Average" to understand, who doesn't have the time to sift through such a large document.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. Not having the policy is much clearer. Willing donors donate, others don't. Simple.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No. By not having the complicated policy to begin with. Organ donation should be from those who wish to donate. Anything else is theft, pure and simple.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. The entire policy should be removed. The people of Wales are not the property of the state and the NAW has exceeded its authority by arrogating to itself the power to dispose of people's remains however they see fit.. The Assembly Members who voted for this should be removed from office and sent to jail, guilty of theft, and in the case of Brain Stem Death (where the victim is actually still alive) also of murder and body-snatching.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No opinion.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No.
13. Do you agree that this approach is in line with other professional advice and guidance?

No. Deemed consent is a blasphemous outrage by its very nature. No fiddling with details can make a bad thing good.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No. If the policy is not enacted this will not be a problem.
15. Do you consider that any information is missing? If so, what?
Yes. How the general public will be kept informed in a way the engages with them, not in wordy documents.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
Yes. There will be a vested interest in acquiring organs, so the benefit of doubt will be skewed towards consent.
17. Please provide any further comments you have on the Code here:
The entire policy is evil, barbaric and reminiscent of Nazi Germany where many people were deemed uebermensch who could be experimented on without their consent. The Assembly has decided to put the entire population of Wales in this category when it knows that apathy will be the dominant factor and in practice nearly everybody will fall into the category where those that wish to do so can help themselves to our remains, or even hasten our deaths to aid this process. As usual it will be the poor, the less well educated and ethnic minority groups who will be disproportionately affected. Government is there to protect the weak against the important and powerful, and prevent such things as body-snatching; instead it is doing the very opposite and allowing the inertia factor to justify the unjustifiable theft. Furthermore, there is no mention anywhere in this policy of any provisions for conscientious objectors. Will this mean that anyone working in the medical profession will be expected to become collaborators with the arrogant fascist regime we appear to now have in Wales?

Response 30: Daniel Boucher, Director of Parliamentary Affairs, CARE

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. It is not easy to understand in the sense that it jars with the Explanatory Memorandum and with Ministerial assurances as set out in our answers to questions 9 and 17.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No response
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No response
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No. It is not really clear what should happen when parents disagree. We explore this in detail in our answers to questions 9 and 17.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. We are very concerned that the Code of Practice does not communicate undertakings made by Ministers which are in the Explanatory Memorandum, which the Code of Practice should reflect. This can be seen both in relation to what should happen when the surviving family objects to donation and in relation to what happens when there is family conflict about what should happen with respect to donation. 1] What Happens When the Family Objects to Donation. We are very concerned that the Code of Practice does not communicate undertakings which were given both by the Explanatory Memorandum (i) and by Ministers (ii), which it should reflect. i) The Explanatory Memorandum. In the Explanatory Memorandum accompanying the Draft Bill it was said: ‘clinical teams will 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.’ This was interesting because it set a very high threshold at which relatives concerns would be taken into account, namely ‘very strong objections’ and the fact that even then it was only ‘unlikely’ that organs would be taken. There was no certainty. Widespread concern was expressed about this after which that section was re-written. It now says: ‘Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families by insisting on donation.’ ii) Ministerial Assurance on the Record of Proceedings Assembly Members pressed on these points as well. We highlight the particularly key parts in bold: On 20 January the Minister said: ‘[279] No doubt, we will discuss in detail the role of the family of the deceased in organ donation, but, at the outset, I wish to be very clear about two guiding principles. First, the Bill starts with the principle that we must clarify and uphold the wishes of the deceased and that we alert everyone to how the legislation works and then they

make a choice, including the choice to do nothing. If a person becomes a potential donor, the family can provide evidence that the deceased wished to opt out. Secondly, I am confident that every clinician in the country wishes to deal with families in an extremely sensitive manner and would not insist that organ donation goes ahead in the face of any strong opposition. This is the practical reality that applies now, even when people have opted in, and that is reported to be the case internationally whatever the law of a particular country. I am very happy to take questions 284] Lesley Griffiths: The situation is as it is now. There is no veto now. So, we are saying that the law is all about the deceased person's wishes and not the family's. However, if a family really objected, because, obviously, the clinicians have a duty of care to the family, the organ donation would not go ahead. 354] Mick Antoniw: In any situation, whether someone has opted in or there is deemed consent, if there is any dispute from family members then, in practice, the donation will not proceed. Is that a correct understanding of the situation? 355] Lesley Griffiths: Yes, that is as it is now. If the family objects strongly, the donation would not go ahead, because the clinicians have a duty of care to the family as well.' Para 174 of the Code contradicts both the Explanatory Memorandum and Ministerial reassurances. '173. It is acknowledged that in some cases where there is express consent, or consent can be deemed, the family/friends will feel very strongly that organ donation should not go ahead. In such circumstances it is recommended that the person's family/friends are given the information they require by the SNOD and sufficient time alone to reach a decision. 174. It should be noted that there is no requirement that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would be lawful for organ donation to take place. It will be a decision for the SNOD as to whether to proceed to donation when deemed consent is in place, but the family/friends object.' Conclusion The last sentence of Para 174 should be amended to adopt the language of the Explanatory Memorandum. 'If friends and family object the SNOD should not add to their distress by insisting on donation.' The clear message has been that as a matter of primary legislation it would be legal to take the organs but that as a matter of practice – which should obviously be reflected in a Code of Practice – organs would not be taken if the family objects. 2] What Happens When there is Family Conflict, especially between parents We are also very concerned that the Code of Practice does not communicate undertakings which were given by the Ministers which it should reflect with respect to what happens when there is a conflict between parents or people of the same order of ranking. In order to demonstrate this commitment it is important to revisit part of the conversation between Mick Antoniw and Lesley Griffiths but to read a bit more of it. '354] Mick Antoniw: In any situation, whether someone has opted in or there is deemed consent, if there is any dispute from family members then, in practice, the donation will not proceed. Is that a correct understanding of the situation? 355] Lesley Griffiths: Yes, that is as it is now. If the family objects strongly, the donation would not go ahead, because the clinicians have a duty of care to the family as well. 356] Mick Antoniw: So, even if one member of the family is keen for the donation to take place, if another member of the family says 'no', or any member of the family disputes it, donation will not proceed. 357] Lesley Griffiths: Yes. Disagreements do take place now, but there is the Human Tissue Authority code of practice. Obviously, the matter would have to be dealt with very sensitively, and we are working now on a new code of practice, ready for the legislation, with the Human Tissue Authority.' Although the Minister mentions the Code of Practice, her answer to the statement 'So, even if one member of the family is keen for the donation to take place, if another member of the family says ‘no’, or any member of the family disputes it, donation will not proceed.’ Is ‘Yes.’ To be sure she goes on to mention the Code of Practice and the need for sensitivity but does not say that the Code would contradict her assurance that in the event of disagreement organs will not be taken. This commitment, however, seems to be contradicted by the Code of Practice in paras 42 and 93. ‘42. In a situation in which the list is ranked: a. when an appointed representative is unwilling or unable to act; or b. when the person is an excepted adult or child and did not appoint a representative/s; or c. when the person is a child who had not made a decision and there was no-one with parental responsibility for them before they died, and agreement cannot be reached between people of the same rank; it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.’ Rather than saying that in the event of conflict organs will not be taken, as suggested by the Minister, this merely suggests that if the SNOD thinks the emotional fallout is sufficiently important they may not process in practice. That is entirely different. It provides far less reassurance to families and burdens the SNOD with responsibility for additional and very difficult judgements. Then there is para 93: ‘93. If there is more than one person with parental responsibility, and they cannot come to agreement on whether donation should go ahead, it is lawful for donation to proceed with the consent of just one person with parental responsibility. However, it is recommended that the SNOD seeks to support those with parental responsibility to reach a consensus.’ In this instance given that we are dealing with a child and deemed consent is not operational we would question whether it would even be lawful of an organ to be taken if in the absence of parental agreement. Even if it was in some sense legal, however, it is wholly at variance with what the Minister said would happen as a matter of practice. Moreover, we would suggest that as a matter of practice it would be unfair to place this on the SNOD. As currently construed it sounds like it would be preferable for the SNOD to get consensus if they can but since it is legal for the organ to be taken the door would be open for the SNOD to insist on donation if after trying to get consensus they fail. If it really is legal in this context, we would suggest rephrasing to the effect. ‘Whilst it would be technically legal to proceed with donation in this situation as a matter of practice SNODs are urged only to do so if consensus can be reached.’

Specific questions

Evidence that the person would not have wanted to be a donor

10. Do you think the Code provides sufficient information about who can provide this evidence?

No response.

11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?

No. At times the burdens placed on the SNOD by the Code are unnecessarily burdensome and result from the Code not reflecting commitments made by the Explanatory Memorandum and by Ministers about what would happen in practice. For details please see our answer to questions 9 and 17.

Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response.
13. Do you agree that this approach is in line with other professional advice and guidance?
No response.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response.
15. Do you consider that any information is missing? If so, what?
No response.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No response.
17. Please provide any further comments you have on the Code here:
We are very concerned that the Code of Practice does not communicate undertakings made by Ministers which are in the Explanatory Memorandum, which the Code of Practice should reflect. This can be seen both in relation to what should happen when the surviving family objects to donation and in relation to what happens when there is family conflict about what should happen with respect to donation. 1] What Happens When the Family Objects to Donation We are very concerned that the Code of Practice does not communicate undertakings which were given both by the Explanatory Memorandum (i) and by Ministers (ii), which it should reflect. i) The Explanatory Memorandum In the Explanatory Memorandum accompanying the Draft Bill it was said: ‘clinical teams will 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.’ This was interesting because it set a very high threshold at which relatives concerns would be taken into account, namely ‘very strong objections’ and the fact that even then it was only ‘unlikely’ that organs would be taken. There was no certainty. Widespread concern was expressed about this after which that section was re-written. It now says: ‘Clinical teams also have a responsibility to be sensitive to the views and beliefs of the surviving relatives in accordance with good practice guidance. This means clinical teams would not add to the distress of families by insisting on donation.’ ii) Ministerial Assurance on the Record of Proceedings Assembly Members pressed on these points as well. We highlight the particularly key parts in bold: On 20 January the Minister said: ‘[279] No doubt, we will discuss in detail the role of the family of the deceased in organ donation, but, at the outset, I wish to be very clear about two guiding principles. First, the Bill starts with the principle that we must clarify and uphold the wishes of the deceased and that we alert everyone to how the legislation works and then they make a choice, including the choice to do nothing. If a person becomes a potential donor, the family can provide evidence that the deceased wished to opt out.

Secondly, I am confident that every clinician in the country wishes to deal with families in an extremely sensitive manner and would not insist that organ donation goes ahead in the face of any strong opposition. This is the practical reality that applies now, even when people have opted in, and that is reported to be the case internationally whatever the law of a particular country. I am very happy to take questions 284] Lesley Griffiths: The situation is as it is now. There is no veto now. So, we are saying that the law is all about the deceased person's wishes and not the family's. However, if a family really objected, because, obviously, the clinicians have a duty of care to the family, the organ donation would not go ahead. 354] Mick Antoniw: In any situation, whether someone has opted in or there is deemed consent, if there is any dispute from family members then, in practice, the donation will not proceed. Is that a correct understanding of the situation? 355] Lesley Griffiths: Yes, that is as it is now. If the family objects strongly, the donation would not go ahead, because the clinicians have a duty of care to the family as well.' Para 174 of the Code contradicts both the Explanatory Memorandum and Ministerial reassurances. '173. It is acknowledged that in some cases where there is express consent, or consent can be deemed, the family/friends will feel very strongly that organ donation should not go ahead. In such circumstances it is recommended that the person's family/friends are given the information they require by the SNOD and sufficient time alone to reach a decision. 174. It should be noted that there is no requirement that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would be lawful for organ donation to take place. It will be a decision for the SNOD as to whether to proceed to donation when deemed consent is in place, but the family/friends object.' Conclusion The last sentence of Para 174 should be amended to adopt the language of the Explanatory Memorandum. 'If friends and family object the SNOD should not add to their distress by insisting on donation.' The clear message has been that as a matter of primary legislation it would be legal to take the organs but that as a matter of practice – which should obviously be reflected in a Code of Practice – organs would not be taken if the family objects. 2] What Happens When there is Family Conflict, especially between parents We are also very concerned that the Code of Practice does not communicate undertakings which were given by the Ministers which it should reflect with respect to what happens when there is a conflict between parents or people of the same order of ranking. In order to demonstrate this commitment it is important to revisit part of the conversation between Mick Antoniw and Lesley Griffiths but to read a bit more of it. '354] Mick Antoniw: In any situation, whether someone has opted in or there is deemed consent, if there is any dispute from family members then, in practice, the donation will not proceed. Is that a correct understanding of the situation? 355] Lesley Griffiths: Yes, that is as it is now. If the family objects strongly, the donation would not go ahead, because the clinicians have a duty of care to the family as well. 356] Mick Antoniw: So, even if one member of the family is keen for the donation to take place, if another member of the family says 'no', or any member of the family disputes it, donation will not proceed. 357] Lesley Griffiths: Yes. Disagreements do take place now, but there is the Human Tissue Authority code of practice. Obviously, the matter would have to be dealt with very sensitively, and we are working now on a new code of practice, ready for the legislation, with the Human Tissue Authority.' Although the Minister mentions the Code of Practice, her answer to the statement 'So, even if one member of the family is keen for the donation to take place, if another member of the family says 'no', or any member of the family disputes it, donation will not proceed.' Is 'Yes.' To be sure she goes on to mention the Code of Practice and the need for sensitivity but does not say that the Code would contradict her assurance that in the event of disagreement organs will not be taken. This commitment, however, seems to be contradicted by the Code of Practice in paras 42 and 93. ‘42. In a situation in which the list is ranked: a. when an appointed representative is unwilling or unable to act; or b. when the person is an excepted adult or child and did not appoint a representative/s; or c. when the person is a child who had not made a decision and there was no-one with parental responsibility for them before they died, and agreement cannot be reached between people of the same rank; it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.’ Rather than saying that in the event of conflict organs will not be taken, as suggested by the Minister, this merely suggests that if the SNOD thinks the emotional fallout is sufficiently important they may not process in practice. That is entirely different. It provides far less reassurance to families and burdens the SNOD with responsibility for additional and very difficult judgements. Then there is para 93: ‘93. If there is more than one person with parental responsibility, and they cannot come to agreement on whether donation should go ahead, it is lawful for donation to proceed with the consent of just one person with parental responsibility. However, it is recommended that the SNOD seeks to support those with parental responsibility to reach a consensus.’ In this instance given that we are dealing with a child and deemed consent is not operational we would question whether it would even be lawful of an organ to be taken if in the absence of parental agreement. Even if it was in some sense legal, however, it is wholly at variance with what the Minister said would happen as a matter of practice. Moreover, we would suggest that as a matter of practice it would be unfair to place this on the SNOD. As currently construed it sounds like it would be preferable for the SNOD to get consensus if they can but since it is legal for the organ to be taken the door would be open for the SNOD to insist on donation if after trying to get consensus they fail. If it really is legal in this context, we would suggest rephrasing to the effect. ‘Whilst it would be technically legal to proceed with donation in this situation as a matter of practice SNODs are urged only to do so if consensus can be reached.’

Response 31: Ursula Cunliffe

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. 44. If a person has made an active decision but not registered it
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No. It appears to give an opportunity for people to refuse consent but is not a reality. Their is a massive risk of the homeless and vulnerable being taken advantage of. It's not clear how you have reached this section of the community or the ethnic communities
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. No, it does not cover ethical and religious belief. Withdrawing medical aid when it has been decided that quality of life is no good, and someone else will benefit more. Who decides on quality of life issues? When a person has no one to speak for them? As a catholic I believe all life is worth living and what is poor quality to some is good to others. A good example is a man whose family decided to let him die, but drs found he could communicate and wanted to live, this mans idea of quality of life had changed and he wanted to live despite paralysis. With this, no one will be given a chance
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Not really, if person has not voiced his decision or registered it consent is deemed.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Religious and ethical beliefs should be considered. What safeguards are in place to protect the vulnerable. What safeguards to prevent a horrific opportunity for a misuse and sale of organs.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No. From experience, I know I that opinions in family can differ. Sometimes consent may be obtained from one sibling that favours donation.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what

improvements could be made?
No. Abolish it.
13. Do you agree that this approach is in line with other professional advice and guidance?
No.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Not enough.
15. Do you consider that any information is missing? If so, what?
No response.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
Yes. Total abuse, withdrawing of medical aid sooner than should be. People suffering, being kept alive for organ use. Pain they may feel pain on removal of organs. So many mistakes have been made when people are presumed clinically dead.
17. Please provide any further comments you have on the Code here:
Not in agreement with it at all.

Response 32: Michael W Thomas

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. para 53 . does not deal with cross border complications for deemed consent; does not mention that organs may be and are likely to be removed in Wales under the Wales Act but implanted in England, by staff not employed under the NHS Wales. The staff implications and provisions for objections at least, and whether such implantation is going to be legal is not made clear. para 173 . “sufficient time to reach a decision" this is entirely unclear. It implies that the family can decide, whereas elsewhere the Code makes it clear that the family cannot decide anything, but only provide information on what the deceased previously decided. para 174 . " It should be noted that there is no requirement that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would be lawful for organ donation to take place. It will be a decision for the SNOD as to whether to proceed to donation when deemed consent is in place, but the family/friends object ". Firstly it is inappropriate and deceitful to use the word ' donation;' when no record of the wishes of the deceased is produced. The Wales Act itself does not use the word ' donation’, but refers only to ' transplantation'. The word 'donation' should be removed; it may be replaced by organ removal / implantation, as appropriate. Secondly, it is left unclear how the SNOD should decide; should the SNOD weigh up the benefits of organ implantation to the recipient against the wishes of the family? One could continue, but the demands placed on the SNOD are impossible and very vague. It may even come down to politics and public campaigns. A much better way to proceed is to acknowledge openly that the family wishes will be paramount, as long as no explicit decision of the deceased is available, and leave the SNOD to persuade sensitively towards voluntary organ removal with family approval.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
No response.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No response.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
No response.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No response.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No response.
11. Are the steps that the SNOD would need to take to assess the evidence easy to

follow?
No response.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response.
13. Do you agree that this approach is in line with other professional advice and guidance?
No response.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response.
15. Do you consider that any information is missing? If so, what?
No response.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No response.
17. Please provide any further comments you have on the Code here:
Most of the questions provided are very limited in scope .The usefulness of the conclusions is therefore similarly limited and Question 17 is too broad to direct attention to some important areas . This draft Code is a cynical attempt to support the Wales Government in undermining the basic ethos of the Human Tissue Act 2004 which was set up precisely to entrench protection for the requirement for full informed explicit consent for the taking or retention of organs . It risks undermining the usefulness of the concept of consent in other spheres..It follows on the evidence that the HTA gave to the Wales Health Committee in Feb 2013 which said " If such a person has not registered either a yes or a no, then their consent will be deemed. This means that the starting point of the conversation which will be held with the potential donor's family and friends is that they wished to donate." "the fact that the family will still be involved in the process under the Welsh Government proposals means that this key safeguard remains in place." In the Human Tissue Act , if no explicit consent is given then there is no consent and the removal will not be legal and will not take place. In the Wales Act , on the contrary, the same organ removal will go ahead with the blessing of the Code as expressed by the HTA .That is the key difference, and it is quite wrong of the HTA to pretend that the Wales Act is consistent with the Human Tissue Act. The fact that the Human Tissue Act2004 will have to be amended is proof that this is not so. The HTA evidence in Feb 2013 itself said that “ express consent is identical to the active consent requirement of the HT Act.” This new ' consent' called deemed is a fiction cooked up for political reasons for the benefit of politicians' careers. The HTA should have nothing to do with supporting it but should be strenuously objecting to the corruption of the HTAct. The supposed ' consent' that can be deemed is in no way substantiated; there is a pretence that a

public information campaign can and will deliver knowledge and understanding and actual decision to consent for every resident in Wales. This campaign is an unknown quantity, since it has not happened, and its effectiveness is total unknown. It is surely highly improbable that any such campaign, even funded to an extraordinary extent , will actually deliver any such deep knowledge and implicit decision for EVERY Welsh resident or indefinitely .Lack of action by the deceased does not persuade any reasonable person that an implicit decision has been taken. Because the Wales Act only identifies at the point of death the person whose organs are to be removed all sorts of extra problems will arise, not only the lack of evidence of knowledge and informed consent. The Wales Act misses the extra opportunities to establish in advance those who wish to donate (by making actual registration to donate unnecessary), and the reasons given by those who do not, or the possibility of providing facts or reassurance to those in doubt. It has no foreknowledge of the position of the latter, and it fails to promote discussion either within the family – by undermining respect for family wishes- or with any trusted authority such as the individual's own general practitioner , who might be expected to support organ donation and seek to persuade as well as inform as long as the process respects the individual's wishes, faith and family .. It also misses opportunities to carry out tissue typing in advance, especially for those whose tissue types are rare. It also fails to identify a shortage of organs likely to be donated by those whose organs are especially needed, to match those whose organs are failing, which is a major problem for BAME (Black,Asian, and Minority Ethnic groups) and a major cause of deaths for those on the Organ Waiting List . Fundamentally the Code does not require any evidence that this fundamental consent and cooperation from the deceased has ever actually been obtained. Later on, after the implementation of the Act, studies may be done on the actual level of penetration reached; but no matter how deep there can never be a guarantee that every Wales resident has been reached, and therefore there can never be a guarantee that the specific individual whose death is expected or has occurred did actually give implicit deemed consent. This is the key moral and legal objection:some organs will be inevitably taken under the Wales Act without any real consent. Instances will be revealed which will prove that the individual did NOT consent, did not even know the law, and that his organs were taken against his wishes or decision. That person or his family may be entitled to prosecute the Human Tissue Authority for cooperating with the taking of his organs. The Code puts clinicians involved in organ removal or transplantation in an extremely difficult position; it pretends that organs can be removed under deemed consent without any problem. Then it pretends that if there is a problem the wishes of the family will be considered, but it requires the family to produce proof of the decision of the deceased to donate his organs. The family is put under pressure and it will be up to the clinicians as to how far to press the family to agree, while still being sensitive to their grief at a very stressful time just before ,during and just after death. The HTA pretends that nothing has changed from the previous act because the family will still be involved. But there are three flaws here: firstly there is nothing in the Act to prevent the taking of organs if no family member is involved; in the Code this is not an explicit requirement either. Secondly, that even if a family member is involved the Act does not empower that person to prevent a taking of the organs , and unless evidence can be produced that the deceased expressed a decision to refuse donation, then nothing the family member says will be sufficient to prevent the taking of organs. Thirdly, nowhere does the family have any power to decide the refusal to take the organs if that is what the family wants. In summary it is dishonest to say that “ this key safeguard remains in place” (HTA evidence to the Assembly Health Committee Feb. 2013) . The safe operation of the organ removal requires the cooperation of the family ,for purely medical reasons; but the Act makes the cooperation of the family less likely by treating them as incidental observers with no rights to the body of their relatives, and to approach them and push for cooperation when they do not wish to proceed. This makes the distress of the family likely to undermine wider public trust in the organ transplantation system. By turning the system from a voluntary one to a compulsory one there is a risk , even a likelihood that the goodwill of the public in the previous system , which was the most successful in the United Kingdom and the second most successful in the world, will be undermined . The best way for the Wales Code to proceed is to ensure that deemed consent is never actually used. This is the ethos and practice in Spain and has been since 1989 See Matesanz, Fabre and Murphy BMJ 30 Oct 2010 ‘ Presumed consent is unnecessary’. Spain reached the level of the highest rate of deceased donor in the world (34.1 per million population), and has stayed at that top level ever since. It always relies entirely on the wishes of the family , never on registration of the wishes of the deceased, and it does not even have an opt-out or opt-in register. It never uses the law of presumed consent . The Wales Code of Practice should respect the experience and conclusions of the best experts and design the Wales Code accordingly. The clinicians will be well aware of the expectations of their senior managers to cooperate with the Wales Health Minister to produce more organs to satisfy the political campaign of the present Welsh Government which has made it an election manifesto commitment. Previous practice has been for clinicians never to take organs without express family consent, even where the deceased gave consent. The Code pretends that this tradition does not exist and that a 180 degree turn to start doing the opposite will not matter . It doesn't even comment on the dilemma and distress to staff that this will cause or offer any help on how to deal with it.. Clinicians at the level of SNOD will be required to weigh evidence from the family about the statements of the wishes of the deceased and do so in the face of forceful opposition and distress from the family members present. This is requiring far too much of anyone . The code should say that SNODs will be authorised to accept that the family wishes to refuse organ removal are respected automatically, after sensitively trying to obtain consent . 1. There are no provisions for protection of conscientious objectors, whether for religious, and moral or ethical principles. It is very obvious that many people of deep faith , from several denominations and communities, - from Anglicans to Catholics, to Jews, to Muslims – as well as non –believers of ethical principles are strongly and conscientiously objecting to the Wales Government’s actions. But there is nothing in this Code of Practice which recognises any of this or the expressions of opposition to the proposed use of deemed consent for this purpose. 2a the Code should include clauses to provide that conscientious objection be incorporated explicitly for all these faiths and ethically principled objectors . This should cover 1. all medical staff involved in the removal or transplantation of organs under deemed consent 2. the individual deceased 3. the family of the deceased People should not have their faith and principles disregarded as though the matter was a purely technical one like extraction of teeth.The sanctity of the body is a fundamental principle; Muslims would I know have the strongest objections having had four fatawas from British scholars or authorities on this specific subject. Strong disagreement has been expressed by the Archbishop of Wales, the Jewish Representative Council, the Catholic Bishops, the Orthodox et etc. For Muslims , for example, to have any organs removed and then not implanted , for whatever reason , is particularly objectionable. In this Wales law there is no guarantee that any such organ will be returned; there is no provision for the deceased' s family to request and be entitled to receive such organs.(I know of a specific case where this happened ; I believe it is not unique as the facilities and the highly qualified and specialised staff to remove or implant organs may not be available at the time and place when it arose such as a weekend. 2b There is a specific need for consideration to be given to the organs of those of Arabic origin, or indeed BAME ; the number of organs being donated by such people is far lower than the requirement for organs to be implanted into the same categories. ;the difference is I believe 4% organs donated , 27% required for implantation. If anything is done which will make the refusal of organs by BAME / Muslim people more likely then this will inevitably lead to more of these people dying .This is a very practical reason why faith considerations should play an important role in the processes. Even those Muslims who believe that organ donation (real voluntary informed donation) can be lawful to Islam, it is only in order to save a life. But this law makes no such limitation. In one case last year a single person gave 16 organs or tissues. There is an increasing number of staff from countries that are predominantly Catholic,like the Philippines or Poland, or Muslim who are immigrating to the UK and getting jobs, sometimes highly qualified jobs, in the NHS. The NHS is increasingly reliant on such people of faith. They should not be discriminated against by being expected to trample on their consciences by pretending they don't strongly object. I have been approached by Muslims who have asked for my advice.. There is a serious possibility that a movement to encourage and facilitate the statement and recording of objections to any organ removal will gather way. 3 family objections and involvement should be respected by right. Para 174 should be amended to read ' If close friends or family object to the organ removal the SNOD should not add to their distress by insisting on organ removal.'Also, ' If no family or close friend is involved in the process of preparing for organ removal it should not go ahead' 4a. Protection for conscientious objectors amongst staff should ensure that no bonuses , promotions, withholding of job references or other inducements or penalties are brought to bear on those who cannot follow the rules on the use of deemed consent for conscience reasons. 4b There should be no target set at unit level, and no sidelining of staff who wish to be exempted. 4c The above will not be easily achieved but it should be done explicitly if it is provide effective protection. 5 These same protections should also be provided to cover whistleblowers; also staff should not be given contractual gagging orders, or paid extraordinary payments or threatened with non-payment of their entitlements to obtain their silence. Such brave people are very necessary to identify abuses and lack of good caring practice; no one can deny that this is necessary in the NHS. Even senior managers have highlighted the need for such brave people to ensure that abuses do not take hold and multiply. People of faith and conscience have a vital and important part to play and their position should be respected and protected. Good care grows out of principles, not ambition and huge financial rewards. the NHS has suffered major breakdowns which have been well documented recently; thousands of people are found to have died unnecessarily . The Wales NHS has not been exempt from these problems. Wales has had an excellent organ donation system. The HTA can and should help to protect it The problems have been increasingly recognised by national leaders. The head of the Care Quality Commission, David Prior, said this week: he was alarmed by the "chillingly defensive " culture he encountered, where even the "most alpha male surgeons" felt frightened to speak out, because to do so was career-ending. " Only by reveling the truth can you restore trust in the NHS. That is where we have to be-speaking truth to power." This HTA draft Code seriously risks making this problem even worse unless it is changed.

Response 33: Roy Thomas, Kidney Wales Foundation

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
No. Requires further discussion in focus groups with third sector. Requires welsh language input and translation.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. Public do not understand abbreviations like the unfortunate "SNODS". It should be bilingual in scope.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No. More cases studies. Where discussions should take place. Evidence given to us in one instance in small dimly lit room in a hospital where family refused.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes.
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes.

15. Do you consider that any information is missing? If so, what?
No. See above.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No.
17. Please provide any further comments you have on the Code here:
Needs to incorporate NICE Guidelines.

Response 34: Professor Vivienne Harpwood, Professor of Law, Cardiff Law School

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes. The section dealing with assessing evidence - para 161 et seq is very helpful, as the SNOD is required to make a very difficult decisions at times when there are numerous other pressures.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes. This is a difficult issue, especially where the SNOD needs to assess the veracity and significance of competing claims.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Yes. The Code should perhaps contain some advice to professionals about whether the fact that organs/tissue might be transplanted into a recipient outside Wales would have been regarded as a material consideration.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes. This is a vital section of the Code and the guidance is clear. However, this is an extremely difficult task for the professionals concerned.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No. There will inevitably be many opportunities for relatives and friends etc to impose/present their own wishes rather than stating what they know to have been those of the potential donor. This problem is very difficult to deal with, especially when conflicts arise between relatives and friends.

13. Do you agree that this approach is in line with other professional advice and guidance?
Yes.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No.
15. Do you consider that any information is missing? If so, what?
Yes. This could be an appropriate time at which to explain that the organs may not be transplanted into patients in Wales. This is a factor that might have had a bearing on the wishes of the donor.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
No. More guidance would be helpful on the question of what amounts to "a significant period" of time.
17. Please provide any further comments you have on the Code here:
The Code is clearly written and provides some very sound information on which professionals can rely. The examples are very helpful. One or two possible omissions/problem areas are noted where relevant. In general, it is impossible to offer advice to professionals on the issues concerning the possibility that relatives may subvert what they know to be the true wishes of the potential donor by fabricating evidence which suits their own stance on organ donation. It might helpful to provide explicit advice to professionals that they need to be alert to this possibility.

Response 35: Roger Goss, Co-director, Patient Concern

Your first code of practice on consent to organ donation said:- ‘the absence of refusal is not evidence of consent’. The opposite is implicit in your new draft code.

The failure of your chair and board members to resign en masse in protest at the government requiring the HTA to publish two ethically contradictory codes has destroyed its integrity.

Patient Concern wishes it had never trusted and supported such a self-interested unprincipled organisation.

Response 36: Richard Clements, Chairman, Standing Welsh Committee, Royal College of Radiologists

“Thank you. We discussed the Code of Practice consultation for the new Human Transplantation (Wales) Act at a recent meeting of the Standing Welsh committee of the Royal College of Radiologists held in Swansea.

We did not feel that this was an issue that affected our fields of practice in Clinical Radiology and Clinical Oncology in Wales and that we needed to contribute to the consultation”

Response 37: Kevan Blomley

My quarrel with the legislation - no longer merely a piece of kite-flying/ no longer the boastful "..we-do-things-differently-in-Wales..."

Now 'the law' in Wales! And due to come into effect Dec.1st 2015...... I believe it to be authoritarian, and essentially illiberal to deem to make an assumption that because an individual has not indicated whilst living that she/he does not wish to have their tissue/organs etc used for transplant operations after their death; that it is therefore democratically acceptable for the State to assume/to deem that such materials may be so used after they have died. It is the 'thin end' of a pretty big and authoritarian wedge. It would have been illuminating, I feel; to have had the opportunity to read/listen to the views of George Orwell, Michael Foot and Enoch Powell on just such a proposition.

There will inevitably be situations where aggrieved relatives will subsequently accuse medical staff - SNODs etc- of having cared more for the prospective transplant recipients than was morally right. To the detriment, of course, of the aggrieved relatives husband/wife/son/daughter/brother/sister/mother/father.

The upshot will be that suspicions will grow concerning the moral/ethical position of medical staff appointed to facilitate transplantation.

All of that inevitable suspicion could have been avoided merely by doing more to advertise to the population at large the desirability of signing the consent register, informing kith and kin of the decision, and an expressed/signed/recorded willingness for remains to be used for such purposes after death, however arrived at. With a well-advertised scheme such as that, and more effort made to marry-up the organs etc of those who have given their consent, simplifying and streamlining a system whereby prospective recipients/theatre slots/surgeons etc are part of a properly-organised system to perform such operations.... well, who could have complained about that?

It is deemed consent that causes the difficulty. It will - perhaps deservedly - rebound upon the politicians who have pushed for this legislative change, and less-deservedly upon the medical personnel obliged to implement the legislation. Yet it will be the medical staff facing distraught relatives, and who will later have to defend the decisions they've taken. Accusations of coercion will fly, and be difficult to defend.

With a Welsh Health Service strapped for funds, headline-grabbing such as this will end in tears.

The HTA should .... at the end of all this testing of opinion...... at the very least urge Welsh Government to mount an effective advertising campaign setting out how individuals may sign up for - or against......

Response 38: NHS Blood and Transplant

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes. There are parts of the Code of Practice which are repetitive. More and clearer examples for interpretation of practice would help a general audience. There could be greater clarity around the role of the Code of Practice versus the legislation and operational processes and procedures. In particular, some areas of the code are overly prescriptive and stray into areas which are better addressed via operational procedures; this is different to the Codes of Practice for the Human Tissue Act.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes. Greater prominence should be given to parts relating to Welsh legislation and in particular, when consent may be deemed. More unusual events such as novel transplantation could appear later in the Code.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Not all. The examples are complex and are of less common scenarios. Examples of more frequent practice would be useful, as complex scenarios would be considered on a case by case basis.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes. The Code of Practice should replace ‘SNOD’ with ‘NHSBT’ or, more accurately, ‘the person seeking consent’ as in the case of tissue only donors it may not be the SNOD undertaking this activity. This needs to be done throughout the document. We remain concerned that, in practice, if an Appointed Representative is not recorded in the ODR, it will be very difficult for the SNOD to identify that there is one, other than by asking the family members present at the time.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes (this will be complemented by detailed operational procedures).
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No. In operational context, it is not practical for SNOD to carry out the specified

checks if no appointed representative is recorded in ODR.
13. Do you agree that this approach is in line with other professional advice and guidance?
It is consistent with current practice (it is unclear as to what other professional advice or guidance is being referred to).
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Overall, this is too prescriptive. The specific actions the SNOD should undertake should be specified in NHSBT operating procedures rather than in the Code of Practice (e.g. paragraphs 106a-c).
15. Do you consider that any information is missing? If so, what?
It would be helpful to set out what the principles around the legislation are and use examples to illustrate the principles. Specific actions should be specified in NHSBT Operating Procedures.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
There is a potential communication issue around the fact that for people aged below 18, deem consent is not permissible however they can register on the ODR giving first person consent.
17. Please provide any further comments you have on the Code here:
Overall the Code of Practice is well structured and comprehensive. We do believe, however, that it is too detailed and overly prescriptive in areas. That level of detail would be more suitably in NHSBT operating procedures, which can be changed with greater flexibility and address the practical realities of organ donation in hospitals. Paragraphs 69 and 70, in relation to the Organ Donor Register, are problematic and are very difficult to implement in practice. This was flagged in NHSBT's previous feedback and remains a significant concern. These paragraphs require interpretation of the data in the ODR which is beyond what was intended at the time of registration and would place an obligation on NHSBT to track precisely what form was used for each registration, many of which are issued by partner organisations.

Response 39: Anonymous

It is common knowledge that the Spanish increase in organ transplant was not due to compulsory donation, it was in fact due to a huge increase in critical care beds and staff, then a big donation campaign.

Donations are increasing but Wales has cut critical care beds and staff, so will not be able to increase the transplants by a significant amount and any increase will jeopardise others needing unplanned critical care.

Until we make a significant increase in these facilities there should be no attempt to introduce compulsory donation, we should publicise the intended increase and when it has been achieved, and at the same time to take advantage of the impetus we should run a high profile voluntary donation push.

On the moral side the state has NO RIGHT to assume ownership of my body and harvest organs; if they do they should be morally responsible for all my funeral costs.

I will opt out but make it clear to my family should any of my organs be of use they can agree to donate them as they see fit.

However in opting out it raises the question if hospitalised will the staff know you are an opted out patient and will that be held against you, will you even get admitted for an operation, easy to run a quid pro quo system (off the record of course).

Legally there will without fail be challenges when mistakes occur and the person is not a permanent resident in Wales or the family has not been consulted. What is the point if compulsory donation if you guarantee to ask the family, do you really expect a surgeon to overrule them and if he/she does what is the legal position, ie who has the final say.

A fine idea in principle but in practice a dogsbody and very undemocratic.

Response 40: Peter Meredith-Smith, Acting Director, Royal College of Nursing Wales

The Royal College of Nursing welcomes the opportunity to respond to the above Draft Code of Practice. The Royal College of Nursing was not supportive of a change to the legislative system for organ and tissue donation.

In our response to the Welsh Government White paper in 2012 the RCN stated that if a new system were to come into operation in Wales our pressing concern would be the need for training and education staff. Nurses and Healthcare support workers are the largest staff group in the NHS and the most likely to be in direct daily contact with patients and families.

The RCN Employment Survey 2013 found that 42 per cent of respondents from Wales received no CPD provided or paid for by their employer, compared to 25 per cent in 2011 and 11 per cent in 2009 and respondents in Wales are less likely to receive most types of mandatory training than colleagues in the rest of the UK.

The Code of Practice as it stands clearly lays out the process that the health professional should carry out to ensure that decisions comply with the Human Transplantation (Wales) Act 2013. We are pleased to see that the Code of Practice states that the health professional who seeks consent needs to be met the criteria in recommendations 1.130 and 1.1.31 of the NICE guidelines **AND** be competent in understanding the legislation and this code of practice. In order for this to be achieved the issue of nursing staff being able to access training and Continuous professional development opportunities has to be addressed.

The RCN hope that you find our comments helpful and if you have any queries or wish to discuss the matter further, please do not hesitate to contact me at my office.

Response 41: Meri Huws, Welsh Language Commissioner

The Welsh Language Commissioner welcomes the opportunity to comment on this consultation on the Human Transplantation (Wales) Act's Code of Practice. This comment is submitted as evidence to assist the Human Tissue Authority (the Authority) in producing a Code of Practice in a field where meeting the needs of individuals, including their language needs, is integral to the quality and effectiveness of services.

The principal aim of the Commissioner is to promote and facilitate the use of the Welsh language. This entails raising awareness of the official status of the Welsh language in Wales and imposing standards on organizations. This, in turn, will lead to the establishment of rights for Welsh speakers.

Two principles underpin the Commissioner's work:

- In Wales, the Welsh language should be treated no less favourably than the English language;
- Persons in Wales should be able to live their lives through the medium of the Welsh language if they choose to do so.

In due course, secondary legislation will introduce new powers allowing the setting and imposing of standards on organizations. Until then, the Commissioner will continue to inspect statutory language schemes through the powers inherited under the Welsh Language Act 1993.

The post of Commissioner was created by the Welsh Language Measure (Wales) 2011. The Commissioner may investigate failure to implement a language scheme; interference with the freedom to use Welsh in Wales and, in future, complaints regarding the failure of organizations to meet standards.

One of the Commissioner's strategic objectives is to influence the consideration given to the Welsh language in policy developments. Thus the Commissioner's main role is to provide comments in accordance with this remit, acting as an independent advocate on behalf of Welsh speakers in Wales who might be affected by these proposed developments. This approach is employed to avoid any potential compromise of the Commissioner's regulatory functions and should the Commissioner wish to conduct a formal review of individual bodies' performance or the Authority's performance in accordance with the provisions made in the Measure.

Looking specifically at this consultation, the Commissioner's comments upon it can be summarised as follows:

- In this consultation, there is a section dealing with **mental capacity**. It is noted that deemed consent does not apply to people who for a significant period before dying lacked the capacity to understand the notion that consent to transplantation activities can be deemed to be given. Additionally, in the next section ‘Significant period’, it is noted that the Human Transplantation (Wales) Act requires a person to have lacked capacity to understand the notion of deemed consent for a significant period, to be a person expected from deemed consent.

- The Welsh Government has developed a strategic framework for Welsh language services in Health, Social Services and Social Care, ‘More than just words…’ The framework is based on the values that all users should be treated with dignity and respect and that they should receive correct assessments and appropriate care. The framework also emphasises that language is a core component of care which meets the needs of users. Looking specifically at **mental capacity**, and in order to ensure that any individual can understand the process of consent to transplantation activities, **it should be ensured that it is possible to provide the relevant services in the Welsh language**.

- Further to the recommendation above, in the section on the requirements of the legislation, the consultation mentions the Act’s Regulations that require that all living organ donations for transplantation must be approved by the Authority before the donation can take place. As well as this, the Authority must be satisfied that an Independent Assessor has conducted separate interviews with the donor and the recipient. **It should be ensured that it is possible to conduct such interviews in the chosen language of the individual in question.** Making a decision regarding donating an organ is a sensitive matter, and often, being in such a situation could mean than an individual **needs** a Welsh language service and therefore **the service should be offered from the outset. An extra burden should not be placed on the patient in having to ask, rather it is the responsibility of the health service to ensure a service that is sensitive to the needs of the patient and his/her family.**

I would like to thank you once again for the opportunity to comment on this consultation.

Response 42: National Kidney Federation

The NKF (National Kidney Federation) welcomes the opportunity to comment on the "Human Tissue Authority Draft Code of Practice on living and deceased organ and tissue donation for transplantation – Wales" consultation document.

Over all, the document is well presented although the actual Draft Code of Practice is quite confusing to understand in itself. The following opinions are put forward for your consideration;

Overview

Paragraphs 12 to 14 are unclear. We would suggest a stronger statement. If the person has signed the organ donor registrar this cannot be overridden by the families without a court order.

Qualifying Relationships

Persons with Power of Attorney could be included in this category.

Family involvement – concern that where agreement cannot be reached between people of the same rank on the list of qualifying relationships that is lawful to proceed with the consent of just one of those people as this could cause family division.

Establishing whether Deemed Consent applies

Children

Is it intended that deemed consent should apply to only both parents and not just one? If this is the case how would this relate to estranged/divorced etc parents who may have some kind of visiting order in place to see the children but may not take an active role in their upbringing?

Residency

We am uncomfortable with the tests needed for habitually resident. The lawyers will be versed in the definition but it is an unnecessary burden of our healthcare providers. We would suggest a more practical approach outlined below;

If the resident has been registered at the hospital or GP surgery for a period exceeding 12 months they are deemed normally resident. If Wales is not their normal residence and they are frequent visitors using the health service in Wales then to avoid this practical test the burden is on them to opt out in their lifetime.

Ordinarily Resident

Armed Forces

It must be made clear to families who plan to join armed forces personnel who have been posted to Wales, for the duration of their posting, they will be considered as ordinarily resident and as such consent will be deemed following 12 months residency unless they are a child or an excepted adult.

Evidence which would satisfy a reasonable person that the person would not have given consent (“the reasonable person test”)

Concern that no mention of a person with power of attorney is mentioned in this category but a carer is.

The Role of the family and friends

Concern that where family/friends object it is still lawful for donation to take place, when deemed consent is in place, should the SNOD decide. Again, this could cause family division.

Glossary

A Specialist Nurse for Organ Donation (SNOD) - perhaps expand on the role of the SNOD and include info on training/guidance received in helping them to make decisions.

Annexe B - Flowchart D

This Flowchart is incorrect and needs to be amended. On following the process through consent should not be deemed as;

- The evidence is presented by a relative/close friend
- A “reasonable person” has considered the evidence as credible
- The evidence is the most recent available.

Response 43: Darren Millar Assembly Member and Shadow Minister for Health, Wales

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
On the whole, the code is easy to understand, but there are a few issues that will be identified in my response to later questions.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes, but more reference should be given at the beginning of the document to the Annex flow charts. Flow charts are a useful tool, and more could be done to draw attention to them.
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
The existence of examples is useful as it gives concrete examples for practitioners to use in a complex field. However, the case study on page 15 is not very clear. There is reference to Bristol residency, and in the context of a presumed consent system it is not terribly clear how these two factors interact. The issue of residency is not addressed until a later chapter within the document, and I envisage this causing confusion. I think a separate case study on the issue of residency could be included, and a case study focussing solely on qualifying relationships should remain. On that note, it would be helpful it more examples and case studies were included. The case studies are also not clearly identifiable within the document. They could be made more noticeable within the text including the use of bolding, or boxes to draw the readers' attention.
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Page 14, which covers qualifying relationships and the use of ranked lists, is quite difficult to understand. Further work should be done to ensure it is clear when a ranked list applies, and when it does not.
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
It could be beneficial to include more guidance on how far a SNOD should go in tracing and contacting relatives.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No. A case study or example could be useful here. Also, there needs to be guidance issued on the use of oral anecdotal evidence (e.g. the patient was squeamish) rather than a reliance on more obvious and direct discussions about the topic.
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?

No. In flowchart D (Is there evidence to overturn deemed consent?) there could be further explanation of how deemed consent could be overturned. From the flowchart, it seems that consent may be deemed in every circumstance, this does little to help a practitioner in possession of strong evidence.
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No, it is unlikely that a person would nominate representatives in practice. Discussions with professionals in the sector show that it is very uncommon to come across nominations. However, in the event that there are nominated representatives, there is little advice in the guidance on how to handle a situation where two nominated representatives disagree with each other.
13. Do you agree that this approach is in line with other professional advice and guidance?
No response.
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response.
15. Do you consider that any information is missing? If so, what?
There should be greater information on the role of family and friends (page 41). Family members should have a veto in practice under the provisions of the code, as was indicated would be the case by the Minister for Health and Social Services when this legislation was initially published. Guidance must include information on the consideration to be given to the distress experienced by a person in a qualifying relationship. It would not be appropriate for donation to proceed if it would result in distress to the family. Guidance needs to be provided on this matter to minimise any distress to those in a qualifying relationship. The Code of Practice needs to be clear that due to a duty of care to family and friends, the organ donation would not go ahead if there were strong objections. This would give peace of mind to family and friends who may be concerned that donation activity could go ahead against their wishes.
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.
These paragraphs relate to children and excepted adults and don’t go into detail about mental capacity. Further detail on mental capacity is found in paragraphs 116-119 – and I wonder if this is the section to which this question refers?
17. Please provide any further comments you have on the Code here:
No response.

Response 44: Angela Burns Assembly Member and Shadow Minister for Education, Wales

Following the recent debate at the National Assembly for Wales on the Human Transplantation (Wales) Bill, I have had the opportunity to reflect on the amendments raised during that debate and the assurances that Mark Drakeford AM, Minister for Health & Social Services gave during the debate.

While I may not have been broadly in favour of deemed consent, I am in favour of express consent and my primary concern was to ensure that this very important piece of legislation had been well thought through and that the most vulnerable in society were well protected. That is why I felt so strongly, that I could not vote for the Bill lightly, or in haste, but only when fully satisfied that I had done as much as I could possibly do, to ensure that the legislation would benefit all, not just those who might receive a new organ, as a result of our decision.

My main areas of concern were for those who are approaching age 18, those who might be emotionally vulnerable, but not known to Social Services, and the use of human reproductive tissue.

Prior to the debate, I met with the Welsh Assembly Government's legal team, to try and understand whether the Welsh Government were deemed competent to introduce specific legislation governing reproductive tissue, those who were suffering mental or learning difficulties and children who were being cared for by the State. At that time, it seemed that these issues could only be dealt with by the UK Government under the Human Tissue Act.

However, I was subsequently invited by Baroness Diana Warwick, on behalf of The Human Tissue Authority, to attend an event held at Pierhead, Cardiff. After discussion with staff of the HTA, it seemed that the Welsh Assembly Government did have competency in this area. I understand this was due to the fact that the Human Tissue Act would need to be amended, to reflect the soft opt-out decision taken in Wales.

As a result, I have asked the Minister to seek clarity on the issue. If it is indeed found that the Welsh Government has competency to legislate alongside the provision set out in the Human Tissue Act 2004, then I have asked the Minister to give further consideration to the specific concerns I raised during the debate. Namely that those individuals who may be suffering temporary mental or emotionally health problems, such as depression or an eating disorder, should not be considered competent to make a decision during that period of illness.

In the debate, we touched on the issue of Gillick competence. However, Gillick competence on its own might not be sufficient to deem a person, particularly one under the age of 18, able to make a rational and informed decision. Consequently, I have highlighted to the Minister some of the constituency cases I have dealt with, which make it evident that there is additional pressure on those in the care of the State. Therefore, they need additional protection. For this reason, I have also asked him to give more thought to removing the right of the State to make decisions over the donation of organs of children in care, and vulnerable adults in the care of Social Services, but to extend the rights of extended family members, such as grandparents, who might be caring for the child.

The Minister, Mark Drakeford AM, has made a commitment to ensure that reproductive organs will be dealt with in regulations and that further discussion will take place with non-devolved bodies, in order to understand where the Assembly has competency to legislate, particularly in regard to the Human Tissue Act.
As it is yet unclear whether the issues I have raised above should be addressed to the Human Tissue Authority, or the Welsh Government, I would be grateful if you would ensure that my views are included as part of the Consultation.

Thank you for your kind assistance with this matter.

Response 45: Citizen’s Advice, Wales

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes. In view of the complexity it is fairly easy to understand for people used to following codes of guidance.
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes, could there be more?
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes, for the most part (see comments below Q 17).
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
Please see comments below Q17.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No response
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
No response
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
No response
13. Do you agree that this approach is in line with other professional advice and guidance?
No response
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
No response
15. Do you consider that any information is missing? If so, what?
No response
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain

your answer.

No response

17. Please provide any further comments you have on the Code here:

We do not have the experience of working with people in these very difficult circumstances to comment on many of the details in the Code, but we hope the following comments may be helpful from a lay perspective.

The Draft Code says at:
35 A friend of longstanding is not defined in the legislation as having a specified time period attached to the friendship. Whether someone is a friend of long standing will be a question of fact and degree in each case and the SNOD may ask questions and/or request evidence as necessary to establish what degree of friendship existed.

We think there is a difference between 'long standing' and 'degree' of friendship, examples may be helpful

The issue of Ordinary Residence is often fraught with difficulty. The guidance in the DWP Decision Makers' Guide may be useful eg definition of 'Ordinarily resident ' beginning at 070769 on page 155, see: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/260180/dmg-vol2-ch0701.pdf

We also think the question of whether a person has to be 'lawfully present' in Wales to be classed as resident, should be addressed.

The issue of 'residence by choice' was recently considered by the Court of Appeal in London Borough of Wandsworth v NJ [2013] EWCA Civ 1373 http://www.bailii.org/ew/cases/EWCA/Civ/2013/1373.html. This case may be useful as guidance.

We can see no reason from the wording of the Act to why prisoners who usually live in Wales, and are in prison in Wales not within the Act?

Section 19 of the Act says:
(3) The following are qualifying relationships for the purpose of this Act—
(a) spouse, civil partner or partner;
(b) parent or child;
(c) brother or sister;
(d) grandparent or grandchild;
(e) child of a brother or sister;
(f) stepfather or stepmother;
(g) half brother or half sister;
(h) friend of long standing.
(4) For the purposes of this Act, a person is another’s partner if the two of them (whether of different sexes or the same sex) live as partners in an enduring family relationship.

This seems to indicate that for co-habiting couples, there must be an 'enduring' relationship at the time of death. This seems to raise two questions which do not seem to be covered by the guidance:

- What does 'enduring' mean. Presumably it requires that the relationship be continuing at the time, but for how long previously must it have existed?
- For people who are married or in a civil partnership, their spouse/partner seems to remain a qualifying relative for as long as they retain that legal status. Does there need to a legal termination of the relationship to end the qualification?

There does not seem to be any guidance about consent on behalf of young people under 18 who are married.

Frequently asked questions

Q1 says ' Unless a person registers a wish to either be a donor or not be…' Since there is nowhere to 'register' a wish not be a donor, we think this choice of wording is inappropriate.

Q4 says the Code 'aims to give people who will be affected by the new law an indication of what they can expect from health care professionals.' We do not think it will be easily understood by members of the public.

Q5 refers to serving the needs of health care professionals. We think this Code may well be appropriate for their needs. We do not think it achievable to have one document which could meet the needs of professionals and the public.

Response 46: Dr Grant Duncan, Deputy Director - Healthcare Quality Division, on behalf of Welsh officials

I would like to thank you on behalf of the Welsh Government for the priority the Authority has afforded to the development of the Code of Practice, and for the prominence you have given to the document both on your website and in the events you have held across Wales during the consultation period.

The Welsh Government understands that the content of the various Codes of Practice issued by the Human Tissue Authority is a matter for the Authority itself. However, the following observations on the draft Code below are provided on the basis that they may provide further clarity and assurance for the reader in the operation of the new legislation, which is of course our main aim, and in this respect we hope they will be of some assistance.

The overall layout of the document broadly follows the legislation and this is helpful.

Overview

We felt the *Overview* section could be further strengthened by reference to the three choices which the new law will present to the Welsh public and which will be widely communicated, namely:

- If you know you **want to be a donor**, you will either be able to choose:

o To do nothing and have your consent deemed **or**
o To expressly record your decision on the register (opt in)

- If you know you **do not want to be a donor**, you will be able to choose:

o To expressly record your decision on the register (opt out).

The communication of this choice is at the heart of the new legislation and encapsulates the concepts of deemed and express consent in a very straightforward way. In terms of the use of language, it could be helpful, and more in keeping with the legislation, to use the term “express” consent/decision rather than “active” consent/decision, which appears in various places in the document. You may also find it helpful to revisit the content of the factsheet which we developed for healthcare professionals in which a concise summary of the effect of the new law is set out, in case it is of some assistance to you for the overview section. I enclose a further copy for ease of reference. Finally we do not think that to begin the *Overview* section with a statement about England and Northern Ireland sits well with the purpose of the document, which is to describe the arrangements in Wales, although clearly it is necessary to state the legislative position for each country for the sake of clarity.

Who can seek consent

We wonder whether paragraph 32 should simply state that the Act does not specify who should seek consent. As drafted, the sentence may give the impression that the grade or position of the person is of no relevance, when in fact the subsequent paragraphs show that it in fact it is highly relevant.

Qualifying relationships

We think this section could benefit from further clarification or at least a change of heading. Qualifying relationships are relevant to express consent and are ranked for this purpose, whereas in a deemed consent, a relative or friend of long standing may provide information and these people are not specified or ranked. By heading this section as *Qualifying relationships,* we do not feel this distinction is adequately drawn out.

Children

The section relating to children and their ability to appoint a representative may need further detail. It is mentioned at paragraphs 89 and 90 and again at 142, but we wonder whether further amplification is required on how this will work in practice. In addition, it may be helpful if the Code were to address the situation of looked after children, where the local authority may have shared parental responsibility. Even though it may be lawful to proceed with the consent of the local authority in certain circumstances, it is good practice to involve those closest to the child in decisions of this magnitude and it may be helpful to state this in the Code.

The role of family and friends

Paragraph 173 suggests that in a case where there is express consent, or consent can be deemed, but where families feel unhappy about organ donation going ahead, that they are given time alone “to reach a decision”. We appreciate that the Code at this point is attempting to describe the sensitive conversations and processes the SN-OD undertakes with families, however, it is important to be careful in the use of language. The decision in question, i.e. consent, has already been made by the prospective donor, and it is not the family’s decision. Perhaps a more accurate form of words would be to say that family is left alone to reflect on the information they have been given before further discussions are undertaken.

Use of case studies

It would be very useful to have a short description of the case study, followed by the “key points” of relevance to the case, so the reader can see at a glance which issues apply. It would be helpful to have more case studies and ones which reflect common areas of practice as well as more unusual ones. The document would also benefit from the use of shading or text boxes to differentiate these case studies and key points from the rest of text.

Use of flow charts

The flow charts are very helpful to the reader and we wonder if they would be better used within the body of the document to illustrate cases rather than being placed at the back of the document. We would also ask if you would look at Flow Chart C on appointed representatives as it appears to conclude incorrectly and is, in any case, covered by Flow Chart E.

Response 47: Nuffield Council on Bioethics

1 The Nuffield Council on Bioethics is an independent, not-for-profit, UK organisation that explores and reports on ethical issues in science and medicine. This response is based on conclusions and recommendations of the Nuffield Council on Bioethics report ‘Human bodies: donation for medicine and research’’, published in October 2011. The full report is available to download at http://nuffieldbioethics.org/donation

2 In our report, we argue that the taking of bodily material after death should be based on the **clearest possible information as to the person’s wishes**. Only in these circumstances can it be described as ‘donation’ (paragraph 5.61 of the Council’s report). We further strongly emphasise the central role of **trust** in maintaining and developing a donation system (paragraph 5.82), and highlight the importance of any opt-out system being designed in such as way as to minimise the risk of any loss of trust (paragraph 6.50). Finally, we argue for recognition of the **needs of the relatives** of the deceased to be taken into account too: while family refusal to donate may be based on their knowledge of the deceased’s preferences, it may also at times be understood as an expression of their own needs as bereaved family members, and this should be respected (paragraph 6.58).

3 In the light of the approach taken in our report, we therefore strongly endorse the distinction made in paragraph 12: that while the law may permit donation in certain circumstances on the basis of deemed consent, it does not *mandate* donation. This emphasis on professional discretion is very welcome. We similarly welcome the specific emphasis on professionals (such as the SNOD) using their discretion when making a decision about whether to go ahead with donation in cases where there is disagreement between persons with parental responsibility (paragraphs 93-94) or other members of the family or friends (paragraphs 173-174). It seems likely that this will promote trust both in the healthcare system and in professionals involved with donation.

4 We further endorse the CoP’s emphasis on the need for express consent if there is any doubt about whether the legal requirements for deemed consent are met (such as where there is uncertainty whether or not the 12 m*onth re*sidency requirement has been met, as at paragraph 104).

5 In general, the Code seems to us to be clear, helpful and laid out in a logical order. There were, however, two points that we found confusing:

Paragraph 87: “*Organ donation remains a possibility for people under the age of 18 who die in Wales. If the young person had competence and made a decision to donate or not to donate during their life then this constitutes express consent (or express non-refusal)*”.
Should ‘express non-refusal’ in this paragraph be replaced by ‘express refusal’, reflecting the reference to a decision made not to donate during life?

Paragraph 139: “If the SNOD accepts that the person has changed their mind, having previously recorded a decision not to consent on the ODR, then donation should not go ahead”

Following on from paragraph 138, this seems to imply that donation should not go ahead despite the SNOD accepting evidence provided by family indicating that the person wanted to donate (having recorded a wish not to donate, but changed their mind since). If this were the case then it is not clear why the family should be asked to provide evidence. Should the final phrase read “then the donation should go ahead’?

Response 48: Keith Towler, Children’s Commissioner for Wales

I will not be responding formally to the draft code of practice for the Human Transplantation
(Wales) Act but I would like to thank you for the bringing the document to my attention. I have read the document with interest and am pleased to see explicit reference to children and young people and their rights under the Act. I would like to make you aware that my team have also met with civil servants in Welsh Government to discuss the Act and its implications for children and young people. We intend to work closely with Welsh Government in order to ensure that children and young people in Wales are aware of the content of this Act and how it pertains to them.

Response 49: Welsh Kidney Patients Association

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. It is possible that difficulties would arise with excepted adults. However, it is highly probable that difficulties arise under the existing opt in system when the potential donor lacks mental capacity. The WKPA has confidence that health professionals have experience of dealing with excepted adults who lack capacity under the present system. This will enable them to ensure that the correct procedures would be adhered to under the Human Transplantation Act Wales.

17. Please provide any further comments you have on the Code here:

The WKPA has supported the introduction of the ‘soft opt out system’ in Wales from its inception and welcomes The Human Transplantation Act. There is a wealth of evidence which supports that, where a country has an ‘opt out’ system of organ donation, this taken with other factors, led to an increase in organ donation rates. Although open to public consultation, the Code of Practice is primarily aimed at those Health Professionals directly involved with the procedures relating to organ/tissue donation and transplantation. It is therefore difficult for laypersons lacking an expertise in this sphere to fully appreciate the implications and demands for such professionals on a day to day basis. However, as an Association it is important that our members, many of whom are transplant recipients whilst others are on the waiting list, have confidence in the actual implementation of the Human Transplantation Act Wales. To this end, two committee members were delegated to read the Code and report back reflecting an understanding of it from the patients’ perspective, for committee approval.

The WKPA has concentrated mainly on the aspects of deemed and expressed consent from cadaver donors. As there already is a comprehensive living donor programme operating in the NHS, the WKPA feels that this aspect of organ donation is specified by the HTA under the Code currently in place.

Our Association accepts that the Code of Practice provides ample guideline for loved ones, those in qualifying relationships and appointed representatives to be consulted about donation. Over the years our members have trusted NHS staff to advise and oversee their treatment and to act ethically and within the guidelines for organ donation including those categorised as ‘excepted individuals’ under the new Code There is no reason to believe they will not continue to act responsibly and with integrity in implementing this change in procedure here in Wales, to ensure that organs /tissues are not retrieved from anyone who has expressed the wish to opt out. The key role of the SNOD in the whole process of organ /tissue donation is clearly set out in the Code of Practice. It is therefore imperative that sufficient numbers of suitably experienced professionals are fully trained to fulfil this role at each major hospital in Wales to ensure a smooth transition when the new system will be implemented in 2015.

The Code of Practice in this consultation, together with the experienced staff already working in the current organ donation process, the training and awareness of all health professionals working in Wales along with the two year publicity campaign will ensure that all involved will understand the new system when it is actually implemented on 1st December 2015.

Response 50: UK Donation Ethics Committee

I am replying on behalf of UKDEC to Baroness Warwick's e-mail to Sir Peter Simpson of 30 September 2013. Thank you for providing UKDEC with the opportunity to comment on the draft Code of Practice.

The points made below focus on those parts of the Code that raise ethical issues, especially in relation to the advice it gives on establishing the potential donor's wishes by reference to the Organ Donor Register (ODR) or other sources, and involving family and friends in making decisions. I have also set out some thoughts the Committee had on consistency of terminology in relation to the diagnosis and confirmation of death with other guidance, and some general stylistic points which I hope are helpful.

General comments

Whilst we understand that the Code needs to be sufficiently self-contained to provide practitioners with the help they need to meet the requirements of the new legislation, we thought that the document might benefit from a clearer differentiation between new requirements/guidance and where the requirements/guidance have not changed. For example, whilst deciding whether or not deemed consent can apply is clearly new for practitioners, once it is established that consent cannot be deemed for whatever reason, then the process of establishing consent/authorisation (including dealing with family conflicts etc) remains largely the same as before. Greater use of reference to existing HTA Codes or other guidance might help by allowing more prominence to the new things people need to learn.

The issue of dealing with conflicting views of family and friends comes up several times (for example in paragraphs 42 and 94). On these occasions the Code makes the point that the legislation is not "directive" in that consent/authority to proceed with donation does not mean it has to go ahead, and SNODs might decide not to proceed (for example because of the emotional impact on family and friends). Whilst this correctly sets out the legal position, and rightly acknowledges the problems faced by SNODs in these circumstances, this is a complex area and we believe that deciding not to proceed, even though valid consent has been given, should be presented as an exception rather than the rule. This is perhaps an example of where reference to existing, more detailed, guidance might be considered.

Points of detail

Paragraph 42 (a) It would helpful to clarify what "unable to act" means. Some guidance on what to do if a representative is unavailable or uncontactable would be welcome - for example if a representative has left the country, a lot of time might be lost in a fruitless attempt to track them down.

Paragraph 44. The wording is a little confusing – if a person had made a decision but not recorded it or told anyone, how would anyone ever know? It might be clearer just to say “when a person did not record an active decision about organ donation during their life, or share any such decision with their family or friends....”.

Paragraph 55. The concept of brain-stem death is contentious for some people, and we believe it is important that the terminology used to describe the diagnosis and confirmation of death should be consistent in all contexts, to avoid any possible confusion about what “no longer having any brain-stem function” means. The issues around involving families in decisions, and when they should be approached, are also complex, and we would be concerned about any implication that deceased patients would be ventilated in order to facilitate donation without any prior consideration of the evidence about their wishes. We suggest you use the terminology from the Academy of Medical Royal Colleges Code of Practice for the Diagnosis and Confirmation of death:

“..may take place following the diagnosis and confirmation of death by neurological criteria, as laid down in the Academy of Medical Royal Colleges Code of Practice for the Diagnosis and Confirmation of Death. ....The deceased continues to be ventilated to maintain organ function while arrangements for organ donation are put in place”.

Paragraph 57 The reference to “limitation of” life-sustaining treatment sits rather oddly – should this be simply “planned withdrawal of life-sustaining treatment”?

Paragraphs 69-74 and 136-140

As both these sections seem to be about how to interpret entries on the ODR , and how to seek and interpret corroborative evidence about the potential donor’s wishes, it might be helpful to amalgamate them.

In paragraphs 69-74, the text implies that the only option is to agree to “any or all” organs that appear on the NHSBT list, whereas in paragraph 137 the implication is that “some or all organs” might be ticked. We think the Code would benefit from a clear illustration of the options on the ODR, now and in the future. If indeed it will be possible to agree to donate some organs but not others (as some people will have already done on the ODR), then we think the Code should be clear about how to interpret the ODR where people have ticked some organs but left others blank (which in our view represents a conscious decision not to donate those organs left unticked).

Having established that the ODR can represent a person’s consent to donate their organs, or their decision not to donate them, the Code goes on to discuss how to deal with any evidence that the potential donor had changed their mind since making the entry on the ODR. In our view the evidence of a change of mind would need to be strong, especially to overturn a recorded decision not to be a donor, and the Code might benefit from some more detailed help here (for example examples of the types of evidence that might be offered and their relative strengths, and/or perhaps some case studies). The text references paragraphs 161-170 (the “reasonable person test”), but 161-170 relate to the situation where no decision had been recorded in life, and the SNOD is considering evidence about whether to deem consent or not. We believe the situation where consideration is being given to overturning a previously recorded decision based on subsequent evidence is different and warrants more detailed guidance on the strength of evidence required.

I hope these comments are helpful.

Response 51: British Heart Foundation Cymru

British Heart Foundation Cymru (BHF Cymru) is the nation's leading heart charity. For over fifty years we have fought for every heartbeat to achieve our mission of a UK in which no-one dies prematurely of heart disease. Coronary heart disease is the single biggest killer in Wales, killing over 4,000 people each year.1 To fight heart disease we fund ground-breaking medical research as well as provide support and care to people living with heart disease. In order to carry out our life saving work we rely on donations from the public.

BHF Cymru warmly welcomes the opportunity to respond to the draft Code of Practice as we are greatly supportive of the introduction of a soft opt-out system in Wales. Ensuring that the Code of Practice is easy to understand and accessible is paramount to making sure the transition to opt-out is as seamless and smooth as possible, for donors, recipient and the medical teams that will provide service and care.

We welcome the draft as a very comprehensive and useful document. The balance that is crucial between the law and the role that professional judgement of the Specialist Organ Donation nurses (SNODs) play is well balanced. This enables the document to be flexible for the SNODs to apply in real life situations, on a case by case basis.

Following on from this the draft is very content heavy on the role and responsibilities that are expected of SNODs. They clearly have a primary role to play in donation, however the document may benefit from an executive summary that could more succinctly highlight the expectations placed on SNODs in order to make it more reader friendly. More case studies could also be included to show how to bring the legislation into practice in a way that respects the wishes of the deceased and their families and yet still increases more donations.

In the Overview section, we felt it could be made more explicit that the option to expressly consent to organ donation will remain, as people will still be able to sign the Organ Donor Register. This would ensure that health professionals are aware of the differing types of registration that will exist and the necessary steps that must be taken to confirm each type of consent.

Under point 16, BHF Cymru acknowledges in some circumstances it may be possible to ascertain the relevant details needed to secure donation from someone whose identity is unknown at death and has no family. However, we feel that this is an incredibly rare occurrence and the document should acknowledge that in the more likely circumstance where the criteria for donation cannot be ascertained donation will not go ahead. This will also ensure that the elements of personal ownership, personal choice and family involvement which underpin a soft opt-out system would be upheld.

1 British Heart Foundation. (2012) '*Coronary heart disease statistics'*
http://www.bhf.org.uk/publications/view-publication.aspx?ps=1002097

One major concern is that Flowchart D is incorrect as it currently does not state the correct criteria for where ‘consent may not be deemed.’ The box leading off [Yes] from ‘is the evidence the most recent available?’ should read ‘consent cannot be deemed’ as credible recent evidence has been presented by a relative or close friend(s) of the deceased which is contrary to deemed consent. This needs to be amended.

Response 52: Welsh Jewish Representative Council

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
No. There are many examples in the draft Code, but only one case study (after 41) which concerns someone who is not ordinarily resident in Wales and so could not be subject to the ‘deemed consent’ provisions. Case studies involving patients resident in Wales, including those belonging to faith communities are essential. Furthermore, the NICE guidelines provide both for those who accept brain stem death and those who do not, and thus, even if “deemed consent” is to be implemented, bereaved families cannot be ignored – this notion would best be brought to the fore by a suitable case study. An important case study should illustrate what kind of considerations would count as a reasonable objection by a relative “on the basis of views held by the deceased”
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
The Code needs to explain clearly the obligations of the members of the healthcare team after death. For example, the role of the “SNOD” is questionable: the impression given at present is that this individual will be working in isolation with no unique defined consultation and reporting obligations relating to this particular form of transplantation where the processes differ from previous. Surely it is in the SNOD’s own interest, and pertinent, that the skills of a SNOD and of a bereavement counsellor may be very different, and both types of skill may be required. It is important to note in the Code that – irrespective of organ donation - professionals have a duty of care to respect the body of the deceased and to care for the bereaved [GMC: Treatment and Care towards the End of Life (2010, 83-84)]. Explicit reference to these duties will clarify the advice in 42, 94 and 174. The language used in 42 and 94 needs to be repeated in 174 to highlight “the emotional impact this would have on family and friends” and the “needs of all the people”.
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
No
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?

No. The draft Code of Practice clarifies that if a person has decided not to donate his or her organs then it would be unlawful to deem consent (129). However, the Human Transplantation (Wales) Act 2013 (HTWA) does not define how this decision is to be recorded. The Code must clarify that there is no restriction on who could (or could not) provide evidence that a person had made such a decision. For example, it may be that someone had a discussion with a medical professional about donation and expressed unwillingness to donate. If this decision had been recorded in the medical notes, and there was no evidence that it had been superseded by a later decision, then this would constitute evidence of a decision in life and consent to donate could not be deemed. Furthermore, it may be that the decision in life was an expression of willingness to donate provided specified conditions are fulfilled (see 7 above), and the mode and status of such declarations needs to be defined.

The provision in 4(4) of HTWA and the guidance provided (161-170) relates to circumstances where there is no clear record of a decision in life, and consent can legally be deemed unless there is a valid objection from a relative of friend of longstanding. Again how is this objection documented – how does one prove that it is based on knowledge of the deceased person, even if it has not been an overt decision? Can anyone provide evidence of this? Or can it be based upon purely what is known of the person?

Relevant evidence will not only cover the deceased’s attitude to organ transplantation, but also, for example, the way they made decisions. Extending the example of mode of death diagnosis mentioned above (7) the Code needs to address the case of someone who, when alive, had been very concerned about the way that the decision was made to withdraw treatment from a dying parent, and who involved other family members in the decision. Although not known to be particularly “religious”, there was consultation with a faith community leader about what was religiously acceptable. Later, when resident in Wales, the person has an accident and is declared dead by brain stem criteria. There is no recorded decision about transplantation. In these circumstances consent to organ donation could be deemed lawful, but a concerned relative might object to the transplant going ahead unless and until it had been declared acceptable by the faith community leader. Surely this objection should be deemed reasonable in that it would be based on the concerned relative’s knowledge of views and attitudes of the person?

Taking this further, a deceased individual might have been someone who was sensitive of the wishes of relatives, and would not wish to cause them distress. If the concept of “deemed consent” is a significant potential cause of distress, then should the deceased be deemed to have consented?

Appointed representatives

12. Do you feel confident this approach would work in practice? If no, what improvements could be made?

No. There are so many concerns about HTWA and the Code of Practice in general that it is difficult to express such confidence (see below).

13. Do you agree that this approach is in line with other professional advice and guidance?

No. See reference to GMC guidance as noted above (9) as an example.

Ordinarily resident

14. Does the Code make clear what factors would be explored when considering

whether a person is ordinarily resident?

The Code states that people are not “ordinarily resident” if their residence is involuntary. This applies to prisoners (111), members of the armed forces directed to live in Wales (112), and those detained compulsorily in Wales under mental health legislation (115). The sequel to this is that if the family of such people lived in Wales previously they are “ordinarily resident”. Where a family moves only to be close to someone who is in Wales involuntarily, then they also are in Wales due to involuntary relocation. Thus it is unreasonable for the Code to describe families of prisoners, servicemen, and those detained compulsorily, as “ordinarily resident”. To say that such families have a choice if they wish not to join their spouse does not give due weight to a fundamental human right to family life. This situation is different to other examples of residency choices, such as in relation to the requirements of work, where relocation is voluntary.

Hence, 113 should be rethought and expanded to include the families of a range of involuntary residents. In doing so, the category of those who “voluntarily relocate” in order to act as carers for family members should also be given consideration.

15. Do you consider that any information is missing? If so, what?

Yes. See previous question response. Both in relation to residency and in relation to age, the Code of Practice should make explicit how these requirements interact with the requirement for mental capacity. Thus if someone goes into a coma before their 18th birthday, or before the end of their first year in Wales, and then lives for some time in a coma, it may be that deemed consent for transplantation could be ruled lawful even though the person did not qualify at a time when they had capacity and did not have capacity at the time they qualified (in relation to age or residence). This mismatch cannot be justified ethically and seems not to have been foreseen in HTWA.

One possible way to address this issue would be for the Code to state that the meaning of lacking capacity for ‘a significant period before dying’ would depend on circumstances. In the circumstances described above, even a short period without capacity might deprive someone of the opportunity to opt-out.

Excepted adults

16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. The HTWA stipulates twelve months residency as necessary and sufficient (in relation to time) for someone to be ordinarily resident. The law does not give a figure for what constitutes “a significant period” without capacity but give a “reasonable person” test: “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 [5(3)].

As the law has deliberately avoided giving a set period of time, it seems the draft Code of Practice is departing from the legislation by giving the figure of twelve months as significant (122). This also seems problematic for at least two further reasons. In the first place the significance of the length of time will vary with the circumstances. If a person has not been in Wales for twelve months and then falls into a coma, all the time that the person is subsequently in a coma is depriving him or her of the opportunity to opt out during a period which, for most people, would be a statutory safeguard. In contrast, someone who has lived in Wales for several years after the passing of the act will have had ample opportunity to opt out. Nevertheless, even someone who had been resident in Wales for several years after

2013 would still, by a period of incapacity, be deprived of the opportunity to opt out (or to opt selectively for certain organs).

The relevance of the lost opportunity to opt out is expressed in 123, but it seems to be implied by that paragraph, taken together with 122, that in this case twelve months would be adequate as a safeguard. On the contrary even three months of incapacity would significantly deprive someone of an opportunity to opt out. Rather than specify a time it would be better to use the phrase such as “in the order of weeks or months” for 122 and to make explicit in 123 that the length of time that is significant will depend on the circumstances and, where a person has only recently qualified as a possible subject of deemed consent, even a relatively short time might be significant.

17. Please provide any further comments you have on the Code here:

The HTWA has been passed by the Welsh Assembly, notwithstanding the serious concerns expressed in advance that it is a retrograde step, undermining the voluntary ethos of donation and public trust in health care services, and potentially causing distress and harm to grieving relatives. It seems that the HTWA is not likely to increase the number of organs available. Therefore the accompanying Code of Practice must aim to achieve the increase, but will have a vital role in preventing the potential harms that were envisaged (including by faith leaders) from being realised.

Against this background it is helpful that the draft Code clarifies a number of the key issues that were unclear in the legislation, and draws attention to professional standards and other requirements of good practice which will be needed in order to apply the law appropriately. Many provisions are helpful, not least those which set out the duty to discover whether the person had made a decision in life; and, if not, to obtain from relatives and / or longstanding friends the best available evidence for the view that the person would most likely have expressed. There are, however, several areas of general concern which remain that are not addressed in it. Some of these were reflected in the earlier submissions made by the Jewish community.

The Human Tissue Authority (HTA) seems at present to be “charged with ensuring that appropriate and valid consent is in place”. This appears to conflict with the HTWA; and any Code of Practice will not have a superior status to the HTWA. Thus there is likely to be confusion in public understanding of the status of the family. The HTWA does envisage that the “family will still be involved in the process”, and it would be helpful to have a summary of the role of the family in the Code.

Assuming that this is resolved the HTA appears to rely on the Welsh Government’s statement that there will be a public information campaign that will ensure that every person in Wales is reached. No provision is made to see how the extent of this knowledge and understanding will be established: the Code requires only a probability. This is not satisfactory.

The clause which refers to death with no family or friends, where it can be established that the person lived, was ordinarily resident and died in Wales, was an adult and did not lack capacity, and had no declared wishes in this regard, can be assumed to have lawful deemed consent, does provide a very broad freedom of action for transplantation. Under such circumstances it would be reassuring to know that there are systems in place to evaluate such cases and confirm that all appropriate steps have been and will be taken.

This in turn raises the question of conflict of interest between interested parties whose professional (or charitable) role is to promote transplantation. Staff who wish to defend a Code of Practice may well find themselves under pressure. There is no provision in the Code for conscientious objection. This applies across a wide range of activities, and not to medical staff only. Intensive Care Units are implicated directly; but it is also necessary to protect the interests of those who provide ancillary help, administration, and management if organs are being taken under the deemed consent provision of the HTWA. As in other areas where conscientious objection is invoked, any such staff will have to be protected against discriminatory practices in their employment. This will have to include protection against targets for numbers of organs donated by deemed consent; and protection for "whistle blowers" about unacceptable practices in this field.

From an ethical perspective, the key parts of the Code are probably 42, 94 and 174 which clarify that the legislative change is permissive not compulsive. The HTWA does not require healthcare professionals to apply deemed consent in a way that would cause distress to relatives or undermine public trust.

It is essential that 42, 94, and 174 are not weakened and indeed are strengthened to draw attention to the requirement to consider the needs and feelings of relatives, which in general is also what the deceased would have wanted. The attention of the Jewish community has been drawn to a quotation which reflects the need for simultaneous care for families and recipients, taken from an online response to a British Medical Journal debate on the issue of presumed consent and written by a doctor who was also an organ recipient:

"As both a doctor, a recipient of a double lung transplant and having lost a family member waiting on transplant, I was left feeling very uncomfortable reading this opinion letter. However from all three angles, as both the care giver, the recipient and the professional, my conclusions would be the same. As a recipient I view the donation of organs as a gift - from both the donor and their family. I would be horrified to think that in receiving an organ, another family had been left feeling abused and ignored"

[J. Monaghan 'Re: We should not let families stop organ donation from their dead relatives' http://www.bmj.com/content/345/bmj.e5275/rr/598035

Response 53: Michael Joyce

I was once involved in renal transplantation as a surgeon, in the days when a SNOD was known as a Transplant Coordinator, and the Transplant Surgeons were actively involved in discussions with the donor family.

At the risk of boring you again, I make a few preliminary comments.

1. I attended the public consultation on the organ donation bill in Bangor University 2012, three members of the public attended. The Medical Director for the Welsh Government told us, the for Presumed Consent for Organ Donation Law would be passed because it had been in the Labour Party Manifesto for the last Assembly Election.

2. I attended the public consultation in Venue Cymru on HTA Code of practice, three members of the public attended. At both meetings one person was a friend who came to keep me company. You particularly asked clinical staff in hospitals involved in organ donation to attend. There was one SNOD from North Wales.

3. The SNOD in Venue Cymru, said she did not think the new law would make much difference in practice, because donation was not going to proceed against the wishes of the family.

The Organ Donation Committee repoted to the Betsi Cadwaladr Board November 2013.

The Human Transplantation (Wales) Act received Royal Assent on 10 September 2013 and will be enacted in 2015. It will change the position of patients over the age of 18 who are normally resident in Wales, who have not expressed a preference will be deemed to have consented to organ donation. In practical terms, we feel that it will make very little difference to our clinical practice as it stands at present, because in reality we are unlikely to proceed
with a donation in the face of objection from family members. However, we are hopeful that, because of increased publicity, more families will have discussed organ donation and thus be aware of their loved ones wishes. This in turn may increase consent rates. The committee feels very strongly that the Bill will succeed or fail depending on the publicity that accompanies it. If done badly, it could have catastrophic effects on organ donation within Wales and possibly the UK as a whole. If done well, we may see the increase in consent rates we anticipate, and the Welsh Government's view that Wales is a truly altruistic nation, being proven correct.

4. Prof of Medicine, Baroness Finlay said in Daily Post "The way people are cared for at the end of life lives on in the memories of the bereaved".

5. I wrote the following letter to the Daily Post July 2013, which explains my reaction to the new organ donation law.
"On the UK Transplant website it states, transplant services in the UK are renowned for the honest, open and transparent manner in which they operate. This is due in part to the fact that consent has always been an integral part of the process of

donating organs for transplant.

The BBC website has a Q&A to help public understanding of the new Welsh Law for Organ Donation, from which I quote.

There has been much debate about the role of families in the immensely difficult circumstances in which medical staff are talking to them about what should happen to their loved one's organs.

The relatives or 'friends of long standing' can object if they know the deceased would not have consented. Medical staff would then use their judgement, based on the information provided, to decide whether or not to proceed with using the organs. The information must be 'sufficient to lead a reasonable person to conclude that they knew the deceased would not have consented.

In law the deceased consent will be deemed if that person has not opted out of being a donor. In practice, however, clinicians also have a duty not to add to the distress of relatives. Should there be no information indicating the deceased wanted to donate their organs, it is extremely unlikely that medical teams would remove organs against the clear wishes of family members. The family does not have a legal veto.

As a retired surgeon who was involved in transplantation, my reaction is that it would be difficult to produce a Law which was less open, honest and transparent. The scenario described is more applicable to a court room than a hospital, and completely unsustainable in the "immensely difficult circumstances" around a dead or dying relative who happens to be a potential donor. This new law will undermine and demean the "family", doctors, and organ donation".

Most of my comments on the code of practice from HTA follow from this letter.

There is the impression from this letter and during discussion of the law in the Senedd, that medical staff (doctors and surgeons) would be actively involved in consultation and decisions with the family. In the code of practice this is refuted in para 32.

In the law it states that the family have no legal right to refuse donation, which by definition would be a 'hard opt out process'. Having made this grand positive legal statement, the law attempts to qualify the legal position, on hearsay evidence from family and friends, as to the state of mind of the donor, and then puts the SNOD in the ridiculous position of having to decide if someone in the family is too distressed, to continue with deemed organ donation.

All this assessment and decision making has to be made using the quasi legal, reasonable person test. This whole process is undertaken by one SNOD, trained for the purpose but alone except for telephone advice from NHSBT. The code of conduct should designate who will be a proper person to give advice to the SNOD on the phone. In my opinion any reasonable man reading this code of practice, which is to be applied by one nurse with the family of a dead or dying potential donor, would conclude that it made unreasonable demands on both the family the nurse, and was undeliverable and unsustainable. I stick to my statement that the law and the code of practice will demean the nurse, the family, and the altruistic principle of organ donation. Demean means to lower in dignity, status or character.

Early debate on the proposed new law always involved the concept of presumed consent, which caused much anxiety in parts of the population. Some people talked about the state presuming rights over organs. Gradually those proposing the new law replaced presumed with deemed, which sounds less aggressive and authoritarian. Collins dictionary describes deem as to judge or consider, and presume as to take for granted or assume. I would contend that presume is an accurate word for removal of organs without active consent of the donor or the family. I know you will not do it, but I suggest that deemed should be replaced with presumed in the code of practice.

The third man at Venue Cymru was adamant that consent could never be presumed. The definition of consent is to give assent or permission, which is the antithesis of to take for granted or assume.

It cannot be easy to attempt to write a code of practice for a law which is so intrinsically contradictory and confused, and could never be described as open, honest and transparent.

Comments on code of practice document

Who can seek consent:

I have already mentioned para 32.

Qualifying relationship:

para 37 No definition of friend of longstanding. SNOD has to decide whether friendship was longstanding, and worthy of recognition and note. You cannot claim that this is objective.

At the end of the case study page 15. **If the family cannot come to a decision on how to proceed, "it is for the SNOD to make a decision how to proceed".** The SNOD presumably decides to proceed to donation as the wife out ranks the father. She can seek guidance by phone from NHSBT from some manager who has never met the family. Prof of Medicine, Baroness Finlay said "The way people are cared for at the end of life lives on in the memories of the bereaved". This code of practice and the law, ignores the damage to the family as a unit and relationships between individual members.

The last paragraph of para 42 sums up the contradictory and confused advice of the new law and therefore the code of practice:

In a situation in which the list is ranked and agreement cannot be reached between people of the same rank, it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.

What is meant by in Wales Residency
Ordinarily Resident

para 95 to 103 attempts to define residency in Wales for a period of twelve months.

Para 104,105 **If there is doubt how long the donor has lived in Wales, the express consent process should be followed.**

Para 106, 107, 108
para 106/a **The SNOD will need to gather evidence in such circumstances and make a decision on whether the persons residence had a voluntary quality.**

para 106/c **The person may have had temporary abscences from Wales and still be considered ordinarily resident. The SNOD will need to gather evidence in such circumstances and make a decision on whether the persons residence supported the order of their life.**

para 107 **These qualities must be assessed on a case by case basis, and whether the qualities have been satisfied will primarily be a question of fact and degree. In many cases the SNOD will be able to establish easily whether the persons residence was characterised by the qualities above. When it is not initially clear that this is the case, it is recommended that there is a discussion with family/friends to gain more information about how the person would have characterised their residency in Wales..**

para 108 The ordinarily resident test involves weighing up information, and when **a SNOD is in doubt about whether the person would have been ordinarily resident, the express consent process should be followed.**

Para 112,113.
Soldiers are exempt, but their wifes and children are included because they choose to live in Wales with their partner. This must be challenged in the courts on the basis of infringement of human rights and denial of family life.

Mental Capacity

The SNOD is not qualified to establish whether there was any condition or illness which may have impacted the persons capacity to understand the notion of consent being deemed. The SNOD is not trained to assess mental capacity.

para 119/d **The SNOD should ask the family/friends whether they believe the person had a level of capacity to understand deemed consent, or analogous notions. This may be a detailed discussion, and if at the end of this there is doubt as to whether the person could have understood the notion of deemed consent, then the express consent process should be followed.**

Significant period

para 121 **The sigfnificant period test is an objective one. The significant period must be long enough to make a reasonable person consider that it would be inappropriate for deemed consent to apply.**

para 122/123 Explain the complexities and conclude in the last sentence. **Therefore it would be inappropriate to deem consent and the express consent of an appointed representative/s or qualifying relation should be sought instead.**

Appointed representative

This is a quasi legal discussion which will rarely occur.

Family and friends

para 157 **The SNOD will need to make a decision based on the evidence presented to them, whether they are satisfied that this constitutes the persons decision in lfe. it is considered that written, signed and dated evidence which was witnessed is most likely to satisfy the SNOD that this was the decision of the person in life.**

para158 **This does not mean that other forms of evidence will not satisfy a reasonable person, but rather that the SNOD must make a judgement as to whether it is reliable.**

The reasonable person test

para 168 **Where there is oral evidence, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.**

para 169 **The reasonable person test is an objective one, and involves the person making the assessment (in this case the SNOD), deciding how much weight the evidence has.**

The role of family and friends

para 172 The law says donation cannot go ahead without the family present. The family and friends "will" be asked to provide medical and social background, not "may".

para 173 **It is acknowledged that in some cases where there is express consent, or consent can be deemed, the family/friends will feel very strongly that organ donatiion should not go ahead. In such circumstances it is recommended that the person's family/friends are given the information they require by the SNOD and sufficient time alone to reach a decision.**

para 174 **It should be noted that there is no requiremment that organ donation goes ahead when there is express consent or consent can be deemed, but rather it would lawful for organ donation to take place. It will be a decision for the SNOD as to whether to proceed to donation when deemed consent is in place, but the family/friends object.**

Offences

para 191 **A person commits an offence under the Human Transplantation (Wales) Act if they undertake a transplantation activity without consent.**

It is impossible to commit an offence because no person has to give consent , which is presumed.

In Conclusion

•The SNOD is gathering written evidence, and hearsay evidence from relatives and freinds. Collating and recording the evidence. Recieving advice on process and decision from an undefined source at NHSBT.

•making decisions on the mental capacity of the donor, with no qualification.

•The SNOD is then to decide on the reliability and weight to be given to evidence using the reasonable person test. This is a quasi legal process, identical to a court of law where evidence collected by solicitors, presented by barristers, is 'decided' by a judge or twelve reasonable people. The SNOD is to fill all roles, and make an 'objective' decision in 12-24 hours, while 'nursing' a grieving family.

•The SNOD has to decide whether the family is too distressed for donation to proceed even if it is lawful. This decision is totally subjective, and is the decision which should carry most weight. If there is doubt at any stage in the process, the express consent of an appointed representative/s or qualifying relation should be sought instead. This is resorting to the long established principle of nursing and medical care of informed consent freely given.

In practical terms, we feel that it will make very little difference to our clinical practice as it stands at present, because in reality we are unlikely to proceed with a donation in the face of objection from family members.

Response 54: Helen Burt, Living Donor Coordinator, Swansea

Consultation Questions
5. Do you think the Code is easy to understand? If no, which part (s) are difficult to understand and how could they be improved?
Yes
6. Do you think the Code is laid out in a logical order? If no, what improvements could be made?
Yes
7. Are the examples provided in the Code clear and helpful? If no, what improvements could be made?
Yes
8. Does the Code make clear from whom the SNOD would seek consent in cases where consent cannot be deemed? If no, how could this be made clearer?
Yes
9. Is there any information which you consider should be included in the Code which is currently missing, or anything that is included that should not be?
No
Specific questions
Evidence that the person would not have wanted to be a donor
10. Do you think the Code provides sufficient information about who can provide this evidence?
Yes
11. Are the steps that the SNOD would need to take to assess the evidence easy to follow?
Yes
Appointed representatives
12. Do you feel confident this approach would work in practice? If no, what improvements could be made?
Yes
13. Do you agree that this approach is in line with other professional advice and guidance?
Yes
Ordinarily resident
14. Does the Code make clear what factors would be explored when considering whether a person is ordinarily resident?
Yes
15. Do you consider that any information is missing? If so, what?
No
Excepted adults
16. Do you foresee any issues with how this will work in practice? Please explain your answer.

Yes. Excepted adults (lacking capacity/vulnerable adults) in the “Soft Opt Out” situation may well present difficult situations. These individuals often do not have one sole carer or advocate who is able to make a stand alone decision on their behalf and family members may conflict in their representation.

However I would hope that SNODS will have the necessary training, experience and communication skills required to deal with these highly specific situations when faced with them.

I feel similar scenarios may present also themselves with children. Where one parent is for donation and another against, there is a very real potential for family conflict. You state that one parents decision only is required (93), but then seem ambiguous in (94) it will be very difficult to determine that one parents view point will have any more standing than anothers?

17. Please provide any further comments you have on the Code here:

I personally have slight difficulty with the wording “Deemed Consent” because “Deemed” implies consent is assumed and as the HTA is aware, as Live Donor Coordinators, we rely totally on “Informed Consent” and are not allowed by law to proceed with any organ removal unless the Donor has “capacity”, been appropriately informed and been able to assimilate information and make a decision regarding the process and risks involved, prior to any organ removal.

In The “Soft Opt Out” deceased donation process, when a person has not expressed consent to organ removal but has also not actively opted out, it will be difficult to know whether a person had actually watched, read or intelligently considered any of the campaign led information regarding the new Act prior to their Brain or Cardio/ Resp death.

If we are to “Deem” consent we can only Hope we have reached people by ensuring public education is promoted widely and is ongoing in all public arenas; particularly schools, GP Practices; media etc. to ensure there is a free flowing continuum of information at all times, Informed and regularly updated by all religious communities and traditions.

Response 55: British Medical Association (BMA) 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?

Paras116–123: 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).

Response 56: National Institute of Health and Care Excellence (NICE)

We welcome the inclusion of NICE’s clinical guideline on organ donation (CG135) in the list in section 31 of guidance on organ donation, transplantation and other matters.

Section 33 states that the reference to the person seeking consent for deceased organ donation as a SNOD (meaning a specialist nurse for organ donation) reflects the NICE guideline. This is an accurate statement.

Section 34 recommends that, if the person seeking consent is not a SNOD, they should meet criteria set out in sections 1.1.30 and 1.1.31 of the NICE guideline. We support this recommendation. However, it is important to note that these sections in the guideline are about the skills, competencies, and specific knowledge not just of the SNOD but of other members of the multidisciplinary team recommended by NICE in the preceding three sections of the guideline on hospital policy and protocols. We suggest that it might be useful if, somewhere in sections 32 to 34, there were a reference to the need for hospitals to have in place a policy and protocol governing the consent process as a support to the function of the SNOD and other members of the multidisciplinary team. The relevant sections in the NICE guideline are 1.1.27 to 1.1.30.

Response 57: Dr Anna de Lloyd, Acute Physician, Cardiff

I agree entirely with the scheme that provides opportunity for opting out and appropriate regulations are in place to protect people’s decision making. However it will hopefully increase transplantation material available to improve quality of life for those lucky enough to have it. I’d anticipate that if the role reversal scenario was evaluated the majority of people would want this treatment modality should they have clinical need for it. The reality is that the dead will not benefit in anyway from their tissues and I advocate any strategy that favours the living over the dead when they were given opportunity to object if that were their wishes.

Response 58: Stuart Taylor and David Thewlis

We would like to take this opportunity to thank you for the assurance and security that the Human Tissue Act 2004 has provided for the individual and the general public in the establishing and maintaining of Fully Informed Consent. The Human Tissue Act 2004 was safe, secure and all embracive – an outstanding piece of legislation.
We are very anxious that the Human Transplantation (Wales) Act 2013 does not weaken this in any way.

In the HTA 2004 it is not difficult to see that a democratic system of Government has provided for the conscience of the individual. The Human Transplantation (Wales) Act 2013 has assumed a State controlled right to possession which represents a constitutional, fundamental change.

There is an insurmountable, chasm between the two systems.

Before responding to the Consultation in detail we would like to table 2 questions:

1. Has any final decision been made as to the 'stand alone' status of the HTA?
2. Given that the HTA 2004 Act has been amended by section 15 of the Human Transplantation (Wales) Act, is it envisaged that further amendments will be forthcoming which could result in further weakening of the Act and the promotion of 'deemed consent' in other parts of the UK.

In response to the Draft Code of Practice Consultation we would like to offer the following comments and observations:

Page 8, paragraph 11. **Deemed consent means that when a person did not make an active decision in regard to organ donation during their life, or when they made an active decision but neither registered this or shared it with their family or friends, their consent to organ donation will be deemed to have been given, unless a person with a close relationship objects based on what they knew of the wishes of the person.**

Response: Whilst acknowledging this is what the HT(W)Act is all about we view this as a very dangerous precedent, weakening principles established in the 2004 Act. Furthermore we would submit that there should be provision for the allowance of the wishes of the person with a close relationship even if they were not aware of the wishes of the deceased person.

Page 9, paragraph 16. **On occasion a person will die and there will not be any family or friends in existence or available for the SNOD to speak with. Although it is unlikely, it may be possible to establish that the person both lived and died in Wales and was ordinarily resident there, that they were an**

adult and they had not lacked capacity for a significant period prior to their death. In this circumstance it would be lawful for their consent to organ donation to be deemed, if there was no other recorded wish.

Response: We feel this should be altered to: ‘In this circumstance it would **not** be lawful for their consent to organ retention to be deemed’.

Page 9, paragraph 17. **However, under the Quality and Safety of Organs Intended for Transplantation Regulations 2012 a risk assessment must be conducted. This includes gathering information on the deceased person’s lifestyle. It is unlikely that this could be done without input from a friend or relative. Therefore, it is highly unlikely organ donation would be considered for such a person.**

Response: This is good and right, the default position must be **not** to proceed, confirming our response to paragraph 16.

Page 13, paragraph 32. **There is no requirement under the Human transplantation (Wales) Act that the person seeking consent for deceased organ donation is of a specified grade or fulfils a certain role in the given institution.**

Response: We feel this is dangerously open, surely there should be some required status to those seeking consent.

Page 13, paragraph 34. **This does not mean that only a SNOD can seek consent. However if the person seeking consent is not a SNOD, it is recommended that they meet the criteria in recommendations 1.1.30 and 1.1.31 of the NICE guidelines on consent and be competent in understanding the legislation and this code of practice.**

Response: We would suggest that it should read that ‘if the person seeking consent is not a SNOD it is **mandatory** ‘that they meet the criteria’ &c.

Page 15, paragraph 41 (last paragraph). **If a unanimous decision cannot be reached it is for the SNOD to make a decision how to proceed. The SNOD may wish to rely on guidance from NHSBT on how to deal with situations where there is disagreement.**

Response: We feel that if a unanimous decision cannot be reached the decision must always be not to proceed.

Page 15, paragraph 42. **In a situation in which the list is ranked**

a. **when an appointed representative is unwilling or unable to act; or**

b. **when the person is an excepted adult or child and did not appoint a representative/s; or**
c. **when the person is a child who had not made a decision and there was no-one with parental responsibility for them before they died, and agreement cannot be reached between people of the same rank, it is lawful to proceed with the consent of just one of those people. This does not mean that the consent of one person must be acted on, and the SNOD may make the decision not to proceed due to the emotional impact this would have on family and friends.**

Response: We feel this should read ‘and agreement cannot be reached between people of the same rank, it is **not** lawful to proceed with the consent of just one of those people’.

Page 16, paragraph 44. **Deemed consent means that when a person did not make an active decision in regard to organ donation during their life, or when they made an active decision but neither registered this or shared it with their family or friends, their consent to organ donation will be deemed to have been given, unless a person with a close relationship objects based on what they know of the wishes of the person.**

Response: See or answer to paragraph 11 –We feel this is dangerous and undesirable.

Page 17, paragraph 49. **Deemed consent does not apply to the donation of organs for research purposes.**

Response: We are thankful for this clarification.

Page 18, paragraphs 55 and 57.

(55) Donation after Brainstem Death (DBD) may take place following tests that have established that the person no longer has any brainstem function. Patients declared brainstem dead may have suffered head trauma, for example in a car accident, or a stroke. The patient’s organ support, including mechanical ventilation, is maintained while consent is established or sought.
(57) Donation after Circulatory death (DCD) may be either controlled or uncontrolled. Controlled DCD describes organ retrieval which follows the planned limitation or withdrawal of life-sustaining treatment at the end of a critical illness from which the person cannot recover. Uncontrolled DCD occurs following a sudden, irreversible cardiac arrest.

Response: We would like to ask why should it be that in the case of DBD, organ support, including mechanical ventilation, is maintained while consent is established or sought, whilst in the case of DCD there is no mention of consent being established or sought, instead it is deemed. This needs addressing.

Page 28, paragraph 93. **If there is more than one person with parental responsibility, and they cannot come to agreement on whether donation should go ahead, it is lawful for donation to proceed with the consent of just one person with parental responsibility. However, it is recommended that the SNOD seeks to support those with parental responsibility to reach a consensus.**

Response: We would submit that in the event of it not being possible to reach a consensus it should **not** be lawful for donation to proceed.

Page 34, paragraph 125. **A person may have made an advance statement in regard to organ donation prior to losing capacity, and when a person lacked the capacity to understand the notion of deemed consent for a significant period before their death the SNOD should ask family/friends whether such a statement exists. The existence of such a statement may help those in a qualifying relationship make a decision on behalf of the person when they did not make a decision in life, and there is not an appointed representative/s.**

Response: We would insist that in the absence of any such statement deemed consent should not apply.

Page 35, paragraph 130. **When a person had neither made a decision about organ donation nor appointed a representative/s, then their consent may be deemed unless they are a child or an excepted adult.**

Response: We cannot accept this paragraph at face value. Surely the SNOD would have to consult with relatives.

Page 35 , paragraph 132. (including example in paragraph 133 and text of paragraph 134) **(132) If there is more than one recorded decision of the person, and these are contradictory, it is the most recent decision that should be observed.**

Response: These paragraphs obviously refer to written evidence. What weight would oral evidence from family or friends carry?

Page 35, paragraph 135. **The HTA considers the steps at paragraphs 127 to 153 are the minimum to be undertaken by the SNOD when seeking to establish whether a person had made a decision on organ donation in life.**

Response: Whilst we agree with this statement, we would like to ask how effective is it really, bearing in mind our responses, above, to paragraphs 130, 132, 133 & 134.

Page 36, paragraph 142. **Under the human transplantation (Wales) Act a child can appoint a representative to make a decision on their behalf.**

Response: We would add the following words ‘providing they have the written approval of parents or guardian.

Page 37 paragraph 145.   **If the appointed representative on the ODR cannot be contacted in time to make a decision, or is unwilling to make a decision, then a qualifying relation may be approached to make a decision about organ donation. The list of qualifying relations will be ranked in accordance with section 27(4) of the Human Tissue Act.**

Response: We feel that If the appointed representative cannot be contacted in time or is unwilling to make a decision then deemed consent should not be allowed.

Page 37, paragraph 150. **If more than one person has been appointed, the default position is that the appointed representatives can make decisions jointly or separately. This means that the representatives do not have to agree, so one of them can give consent regardless of what the other representatives decide.**

Response: No, the default position has to be that all agree as in paragraph 151.

Page 37, paragraph 152. **It may be the case that a person appointed representative/s But did not record them on the ODR or tell their family/friends about them. It is recognised that it is not practical for the SNOD to make numerous checks to establish whether a person appointed a representative/s. it is therefore considered adequate for a SNOD to check the ODR and to ask family/friends. It is important that a note is made of these checks and any discussions with family/friends.**

Response: Instead of ‘adequate’ insert the word ‘mandatory’.

Page 38, paragraph 160. **If the SNOD is informed by family/friends that the person had not made a decision in life, then their consent to organ donation may be deemed (unless they are a child or an excepted adult).**

Response: The SNOD MUST take account of objections as in paragraphs 162 and 164.

Page 39 paragraph 165. **In order to satisfy the reasonable person test, the SNOD should ask that they are presented with all the evidence to support the assertion that the person would not have consented.**

Response: This must include oral evidence or testimony from family and friends.

Page 39, paragraphs 167 -170 which includes notes are on page 40.

(167) When there is written evidence and this has not been witnessed, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.

(168) Where there is oral evidence, it will be for the SNOD to make the decision whether this is evidence that would satisfy a reasonable person.

(169) The reasonable person test is an objective one, and involves the person making the assessment (in this case the SNOD), deciding how much weight the evidence has.

(170) In order to assess the weight of the evidence presented, the following questions may be considered to aid the SNOD in reaching a decision:
(a) Is the evidence presented as reflecting the views of the person, or the views of those in a qualifying relationship? The test requires that evidence must be presented of the person's view. Therefore, more weight should be given to evidence which is presented as being a reflection of the person's view.
(b) Is the evidence in writing, signed and dated by the person and witnessed? if this is the case, then this is the case, then this is likely to form an express decision of the person.
(c) Is the evidence oral? If so, is it corroborated by more than one person? It is more likely to pass the reasonable person test if more than one person is able to confirm that the person orally stated that they would not have consented to donation.
(d) How recent is the evidence? The Human Transplantation (Wales) Act requires the most recent evidence to be relied on, therefore the SNOD should establish when the record was made or the conversation took place and note this in the person's medical record or other appropriate document.
(e) How well does the person providing the evidence know the person? It is not necessarily always the case that a person knows someone well simply because they are related. For example, a person may have a carer who is not related to them, but spends every day with them.

Response: We would submit that if there is any doubt whatsoever as to the wishes of the deceased then the default position has to be that consent is **not** deemed.

Page 41, paragraph 173. **It is acknowledged that in some cases where there is express consent, or consent can be deemed, the family/friends will feel very strongly that organ donation should not go ahead. In such circumstances it is recommended that the person's family/friends are given the information they require by the SNOD and sufficient time alone to reach a decision.**

Response: This is perhaps one of the most important statements in this Code of Practice and we strongly submit that the last sentence should read ' In such circumstances the feelings of the family/friends should be respected'.

Page 42, paragraph 176. **The Human Transplantation (Wales) Act allows for steps to be taken to preserve part of the body of a deceased person when it is, or may be, suitable for transplantation, but consent or the absence of consent has not yet been established.**

Response: 'Steps to preserve part of the body'. Does this mean that parts can be removed and preserved prior to consent or absence of consent being established. This must not be permitted – remember Alder Hey!

Page 42, paragraphs 179 and 181.
(179) The steps which can be taken to preserve the body part/s for transplantation must be minimal and there is an obligation that the least invasive procedure is used.
(181) If it is established that express consent is not in place, and that consent cannot be deemed for the person, then the steps to preserve for the purpose of transplantation should cease or be withdrawn promptly, as applicable.

Response: Consent must be established before any steps can be undertaken.

Page 44, paragraphs 187 and 188.
(187) Where the person's death is violent or unnatural, or is sudden and the cause is unknown, the matter of organ donation requires referral to the coroner and in such cases agreement (or lack of objection) of the coroner should be sought before any transplantation activities can be undertaken, or steps can be taken to preserve the body part/s of the person.
(188) It is recommended that SNODs and hospital administrations seek to agree a working protocol with the coroner/s in the local area, in order that they are able to establish at an early stage whether the person's body will be under

the coroner's authority, and whether the coroner will agree to steps being taken for preservation, and eventually for organ donation.

Response: The coroner's authority over the body only relates to establishing the cause of death – how, when and where. He or she does not have the authority to give consent for any steps relating to organ donation. Express consent of the deceased to donate must be established to allow any steps to be taken towards preservation for donation.

We appreciate the opportunity to participate in this Consultation exercise.

Response 59: Anne Jones, Assistant Commissioner (Wales)

Thank you for your letter of 27 September inviting the ICO’s comments on the Draft Code of Practice on Living and Deceased Organ & Tissue Donation for Transplantation (Wales).

My colleagues and I have read the Draft Code of Practice with interest, and have no comments or suggestions for improvements as the issues we raised in earlier consultations have been addressed. The current consultation has not raised any further Data Protection or Freedom of Information issues.

Response 60: Hywel Dda University Health Board

As part of the Regional Collaborative meeting of South Wales Organ Donation Team, which included SNODs and CLODs and representatives of the HTA, some responses were put forward, which I will list below. I have also had some feedback from some of the Organ Donation Committee.

Section 4 Q14   Paragraph 113 - Regarding the families of armed forces personnel being considered as ordinarily resident when their relatives are not, due to armed forces personnel not having a choice as to where they live because of their job was questioned. We thought this was odd, as their relatives do not necessarily have a choice as to where they live, as it would seem sensible to think the only reason they may have moved to Wales is so they can be with their family member who is in the armed forces.

Section 2: Paragraph 138 and 139 - For these paragraphs to make sense, it would appear that the last part of the last sentence in paragraph 139 should say "then donation should go ahead", not "then donation should not go ahead".

Flowchart D on page 64 - In the flowchart on the bottom tier, where the box asks "Is the evidence the most recent available?" if Yes then Consent may be deemed, this should say Consent may NOT be deemed.

Apart from this the Code seems to be fairly clear and no other issues were raised.