

Human Transplantation Bill

CARE Consultation Response

December 2015

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Introduction

1. CARE (Christian Action Research and Education) in Northern Ireland is a well-established mainstream Christian charity providing resources and helping to bring Christian insight and experience to matters of public policy and practical caring initiatives. CARE demonstrates Christ's compassion to people of all faiths and none believing that individuals are of immense value, not because of the circumstances of their birth, their behaviour or achievements, but because of their intrinsic worth as people.

Summary

2. CARE in Northern Ireland believes that organ donation is a positive social good. The donation of an organ is transformative, bringing new life to individuals, families and communities. We commend all those who are on the Organ Donation Register. As an organisation we believe that maintaining the concept of organ donation being a gift of life remains of real importance. We believe, as the Anglican Archbishop of Wales Dr Barry Morgan succinctly argued when the Welsh Government were considering similar proposals, that "*giving organs is the most generous act of self-giving imaginable but it has to be a choice that is freely embraced, not something that the state assumes.*"¹
3. We are concerned that the Human Transplantation Bill, as currently drafted, could negatively impact on the idea of organ donation as gift. Having met the Bill sponsor in person about the Bill, we appreciate that she is cognisant of this concern and is willing to explore amendments which will safeguard the concept of gift. While we retain general misgivings about the introduction of an opt-out model for organ donation in Northern Ireland, we accept the fact that

¹ <http://www.bbc.co.uk/news/uk-wales-14998726>

the Assembly voted in favour of the principle of introducing such a system by supporting the Human Transplantation Bill at its Second Stage. Consequently, in our response we will focus on how the drafting of the Bill could be improved to ensure that the crucial notion of organ donation as a gift could be maintained within an opt-out system. We also have some comments to make about a number of other clauses in the Bill. This response will consider the clauses of the Bill in order.

Clause 1

4. We believe that if an opt-out system is to be introduced in Northern Ireland that clause 1 of this Bill is imperative. It is crucial that if such a system is introduced, that the Department of Health is required to inform the Northern Irish public about the change. However, we have three issues to raise about clause 1 as it currently stands.
5. As we will outline when we consider clause 4 below, the Bill itself as it currently stands remains unclear as to what the “*role of relatives and friends in affirming... deemed consent*” should be. This could make it difficult for the Department to be clear with the public as to what the role of their friends and relatives would be. The last thing that is needed is confusion on this sensitive issue of organ donation when facing the death of a loved one. In the section below on clause 4 we will outline some suggestions on how the clause could be made clearer in this regard.
6. The requirement set out in clause 1(2) states that the Department would be under a duty to “promote a campaign” informing the public at least once a year. The Bill is not clear on what constitutes a “campaign.” We understand that this proposal is coming from a private member and she cannot dictate to the Department of Health what kind of campaign they would run once such legislation made its way through the Assembly. However, from the experience with other pieces of legislation, the definition of what constitutes a “campaign” can be hugely variable. Would a campaign consist of a set of departmental press releases with regard to the new legislation?
7. This leads in to our third issue. For a new opt-out system to be effective, significant financial resources will need to be expended every year to ensure that the Northern Irish public and individuals coming in to Northern Ireland (for example international students) are aware of this law. We note that the EFM says there will be “a limited cost” associated with the requirement to run a promotional campaign,² but we would submit that significant resources would need to be expended on a campaign to ensure that the Northern Irish public understood the legal change that had been introduced and that a minimalist “campaign” would not be sufficient to achieve this. In these financially stringent times, we would ask for an assessment from the Department of Health as to what resources they are able to commit to a “campaign” with regard to the introduction of this new opt-out system.

Clause 4

8. Clause 4 is at the core of the Bill. Our chief objective with regard to clause 4 is ensuring that it maintains the notion of organ donation as a gift. Our major concern is the idea of organs being taken from an individual with no form of affirmative consent being provided by the individual, their relatives or a close friend. In our view, the removal of an organ in such circumstances does

² See para 15 of the EFM, <http://www.niassembly.gov.uk/globalassets/documents/legislation/bills/non-executive-bills/session-2015-2016/human-transplantation-bill/human-transplantation-efm---as-introduced.pdf>

not constitute a gift and actually sees the state overreach its rightful place in effectively taking ownership of a person's organs after death. However, if familial consent is maintained then we believe that the notion of organ donation as gift is maintained.

9. Clause 4(2) allows a "relative or friend of long standing" to make the deemed consent "effective" if they affirm that "**the person would not have objected**". However, it should be noted that this does not in fact provide the family with the opportunity to affirm consent. Strictly speaking what clause 4(2) proposes is a right for the deceased's family to input what information is available on the deceased views. However, if the family have no explicit information about the views of the deceased regarding donation - perhaps because the matter was never discussed - then the Bill, as currently drafted, provides the family with no role. We are concerned about what may happen in such a situation and we are concerned, like others,³ about the confusion that could be generated if this was the situation.

10. In reading the Official Report of the debate at the Second Stage, we noted that Members from right across the House pointed to the importance of family consent with regard to this matter. Indeed, the Bill sponsor made a number of remarks outlining the importance of familial consent. These include the following:

- "*the role of the family [is] in affirming consent*" (page 9) and "*However, crucially, and I have always said this, consent is subject to family affirmation prior to donation taking place*" (page 10) and the Bill proposes "*deemed consent with family affirmation*" (page 45)
- "*The consultation identified...the crucial role of the family in providing consent for organ donation to proceed, and that is clearly in place at present for express, as it is in the Bill for deemed, consent.*" (page 10)
- ***However, I have said from the beginning that the family will and should maintain the key role in providing consent following the death of a loved one.***⁴ (our emphasis)

11. We fully agree with the Bill sponsor's intention here. However, our concern is that the Bill as drafted does **not** ensure that familial affirmation of consent is required. Having met with the Bill sponsor, we understand that she is actively considering amendments to ensure that active familial consent is legally required. We believe that an amendment to the Bill could help to solve this problem and **recommend that clause 4(2) be reworded so that it reads:**

4(2) But deemed consent is only effective if a person who stood in a qualifying relationship to the person immediately before death consents to that transplantation activity.

12. This change would also remove the terms "relative" and "friend of long-standing", neither of which is defined in the Bill as it stands, while clause 10 defines a "qualified relationship".

13. CARE for Northern Ireland suggests the following amendment:

Clause 4, Page 3, Line 4,

Leave out from 'relative' to 'objected' on line 6 and insert 'person who stood in a qualifying relationship to the person immediately before death consents'

³ We note the letter sent by the Chair of the BMA to members outlining their concern about the potential for confusion due to the current wording of clause 4(2).

⁴ All page numbers here refer to the official report found <http://data.niassembly.gov.uk/HansardXml/plenary-16-11-2015.pdf>

14. This amendment would provide a genuine opportunity for the family to affirm consent. In cases of deemed consent it would ensure that the family is part of the process of gifting organs and would provide clarity to both families and physicians with regard to what should happen in deemed consent cases. The amendment would protect the concept of gift by ensuring that in deemed consent cases someone has to positively affirm the decision that has been made.

Clause 5

15. The Bill proposes to follow the example of the Welsh legislation with regard to “excepted adults” by stating that if an individual dies and has not been “ordinarily resident” in Northern Ireland for a period of at least 12 months before dying that their consent cannot be deemed. The same applies for individuals who are judged to have lacked capacity to understand the notion that consent to transplantation activities can be deemed. However, it is not clear how the law would treat individuals such as international students and armed forces personnel. Would international students who attend university in Northern Ireland for part of the year be deemed to be ordinarily resident and therefore impacted by this legislation? And if so, how will they be informed about the change in the law? A similar issue may impact on members of the armed forces based in Northern Ireland. If a regiment from England or Scotland, where deemed consent does not apply (or yet apply), came to Northern Ireland for a period of time would deemed consent apply to them? And if so, how would they be informed of the change?

Clauses 6 and 7

16. Clause 6 allows children to expressly consent to donation of material covered under clause 2 while they are alive or after they die as a child, either through their own consent if they are considered capable of making such a decision (see clause 18(3)) or by appointing a representative. Clause 7 allows a child to expressly consent to transplants involving excluded material, which will be defined in future regulations.⁵ We note that the current situation allows children aged 14 and over to join the Organ Donor Register.⁶ **Organ donation by children is a controversial subject which needs further discussion.** We are concerned about two issues:

- a) **how a child will be judged to be competent to consent.** Will there be an assumption that if a child is over the age of 14 (as now), they are competent to consent? We note that the test of competency to consent for a child is “if it would appear to a reasonable person that the child has sufficient understanding to make an informed decision” as set out in clause 18(3).
- b) **the ability of a child to appoint a representative.** CARE for Northern Ireland believes that a child’s parent is their natural representative so we question in what circumstances a child should be able to appoint someone outside of their immediate family. We understand that this might be appropriate if the child has no parents caring for them either through death or a situation where a child is in foster care, or that the child is 16 or 17 and married and would wish their spouse to be their representative, but in all other circumstances, **we are concerned that appointment of a representative would be seen as undermining a parent’s responsibility for their child.**

⁵ Note that the Welsh regulations for excluded material were published in 2015.
<http://www.legislation.gov.uk/wsi/2015/1775/contents/made>

⁶ See FAQ on “Who is eligible” and “Can a child donate after death?”

17. Given the concerns about a child appointing a representative who is not their parent, CARE for Northern Ireland is suggesting that there should be an additional subsection in clause 9 which defines when a child can appoint a representative and proposes the following amendment:

Clause 9, Page 5, Line 34,

At end insert ‘subject to the conditions in subsection (1A).

(1A) If the person is a child, the child may appoint a representative if the child—

- (a) has no living parents;
- (b) is in the care of a Health and Social Care Trust;
- (c) is married.’

Clause 8

18. Clause 5 proposes how to deal with the consent of a person who has died but did not have the capacity to consent to donation before death and requires a third party to provide consent for the person. Clause 8 allows the law to deem consent for such individuals **while they are alive** “in circumstances of a kind specified by regulations made by the Department”. The Explanatory Memorandum says that “*there may circumstances where it may be in the best interests of a person incapable of giving consent, to donate material to a living relative.*”⁷ However, there is no indication of the type of circumstances that might be considered applicable as there is in clause 7(3), nor any explanation as to why this might be in the individual’s best interest and most importantly no safeguard on who can agree to such a donation. **CARE for Northern Ireland is concerned that vulnerable adults who cannot consent should have the full safeguard of the law and it is not clear that they do so under this clause.** CARE for Northern Ireland is not reassured by regulations made under a similar clause in the Welsh legislation which state that the adult who lacks capacity “*is deemed to have consented to the activity where the activity is done by a person who is acting in what they reasonably believe to be [the adult’s] best interests.*”⁸ There is no further clarity about who might be “a person” who can make this decision.

19. CARE for Northern Ireland notes that a similar provision already exists under [Section 6](#) of the Human Tissue Act 2004⁹ and that [Regulation 4](#) of the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 applies in Northern Ireland. In this Regulation, there are three areas where a person without capacity may have ‘deemed to have consented’
- a) Either for obtaining scientific or medical information about a living or deceased person which may be relevant to any other person (including a future person) or for transplant purposes – decision to be made by “a person who is acting in what he reasonably believes to be P’s best interests”;
 - b) For clinical trials; or
 - c) For research.

20. It is not clear if the intention of this Bill is to mirror the 2006 Regulations nor whether these Regulations have really safeguarded vulnerable adults, since the Human Tissue Authority’s

⁷ Explanatory Memorandum, page 7

⁸ See Regulation 2 of The Human Transplantation (Persons who Lack Capacity to Consent) (Wales) Regulations 2015 <http://www.legislation.gov.uk/wsi/2015/1774/contents/made>

⁹ which would be replaced by Paragraph 3 of the Schedule in the Bill

Guidance on consent in these circumstance is very scant, saying only that “*Storage or use of tissue from adults who lack capacity to consent is permitted in certain circumstances specified in the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006*”.¹⁰ **CARE for Northern Ireland advocates that the Committee consider in what circumstances this power should be allowed, if at all.**

Clause 10

21. Clause 10 sets out the type of relationships that can provide express consent to organ donation. This clause is based on Section 27 of the Human Tissue Act 2004 (HTA)¹¹ which sets out detailed instructions as to how this should be interpreted; for instance those at the top of the list are ranked higher than those at the bottom. CARE for Northern Ireland would prefer to see similar detail for how decisions would be made within this list of qualifying relationships and is concerned that the ranking of the order could be made under codes of practice, as proposed in clause 10(4) rather than in statute.

Clause 14

22. The Bill sensibly requires an annual report on transplantation to be introduced. It requires the Department to include in the report at least once in every five financial years “*the opinion of the Department as to whether this Act has been effective in promoting transplantation activities*” and any recommendations for “*amending the law so as to promote transplantation activities.*” We would suggest that consideration should be given to making the interval under clause 13(4) once every three years rather once every five.

Conclusion

23. This response has outlined a number of detailed areas of concern with regard to the Human Transplantation as it stands, in particular the role of the family and how vulnerable individuals – children and adults lacking capacity will be treated under the Bill. We hope that the response is helpful to the Committee in determining its response to the Bill. We are happy to provide oral evidence to the Justice Committee if they would find that helpful in their deliberations.

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¹⁰ Human Tissue Authority, Code of Practice 1, Consent, para 150, page 29

https://www.hta.gov.uk/sites/default/files/Code_of_practice_1_-_Consent.pdf

¹¹ <http://www.legislation.gov.uk/ukpga/2004/30/section/27>