

Human Transplantation Bill

Briefing Note for the Committee for Health, Social Services and Public Safety (2 December 2015)

1. During the second stage debate on 16 November 2015 the Minister asked Members to think very carefully about giving their support to the Bill, because it proposes that, in future, in Northern Ireland, we will move from a tried and tested voluntary registration system to a statutory soft opt-out system of organ donation. That would be a major change in our long-standing approach to organ donation. In doing so, the Bill raises important issues of ethical, legal, medical and social significance that require careful consideration by the Assembly. The Minister expressed this caution because there is no clear evidence that a statutory approach will deliver significantly higher rates of donated organs than we have today.
2. Until this year, we have never had a statutory requirement anywhere in the United Kingdom to make clear our wishes about donating our organs after death. While the Bill makes provision for families to have the last say in the clauses covering deemed consent and affirmation, even with those safeguards, the Bill, if enacted, will introduce a fundamental change to our organ donation policy in Northern Ireland. These are radical changes, and the Minister fears that the proposed move to statutory soft opt-out could undermine the achievements of the last 21 years by making organ donation a controversial act rather than the act of generosity that it is today.
3. The Department's policy is to fully implement the NHS Blood and Transplant strategy on organ donation. The strategy does not propose that soft opt-out legislation should be introduced as a UK-wide policy. The strategy aims to raise awareness and increase the number of donors and donated organs through society and individuals, NHS hospitals and staff, NHS Blood and Transplant and commissioners working together to achieve the desired outcomes. The Department is committed to working with our partners in England, Scotland and Wales to achieve NHS Blood and Transplant's overall

aim, which is for the United Kingdom to match world-class performance in organ donation and transplantation.

4. Northern Ireland will have the opportunity to learn from the impact that statutory soft opt-out will have on organ donation when this system comes into operation in Wales in December 2015. Northern Ireland and Wales operate their organ donor awareness and transplantation service under the United Kingdom's NHS Blood and Transplant partnership, as do England and Scotland. Northern Ireland and Wales have been members of this successful partnership, which, in the past 21 years, has enabled 55,000 people across the UK to receive an organ transplant. Northern Ireland and Wales have a similar culture that shapes social attitudes towards organ donation. We also have the opportunity in the months ahead to assess the impact that the NHS organ donor register, launched in July, will have. The new register extends the choices that a person can record when they sign it. Previously, we could register only to be an organ donor: the new register provides options to formally register our wishes to be a donor or not to be a donor and to record the details of two representatives to make the decision for us after death. The new organ donor register has, therefore, given us the ability to voluntarily opt out and to nominate named individuals to make the decision to donate or not to donate our organs.
5. If statutory soft opt-out significantly increases the number of donors and transplants in Wales, many may wish to consider legislation more favourably; if it makes little or no difference, the cautious approach the Minister has advocated will be seen to have been prudent and sensible.
6. The Department's approach is shared by the clinician team at the Regional Transplantation Centre and they have written to the Minister to express their concerns. A copy of this letter is attached.
7. The Department will be developing amendments to ensure that the Bill gives clear direction in a number of key areas. These include:

- a) introducing a mechanism to defer the commencement date of the legislation if experience in Wales would indicate that refinement of the legislation is desirable;
- b) clarity in relation to the nature of a “campaign” under Clause 1 as this would place a duty on the Department to promote organ donation in a campaign at least once a year that informs the public about the circumstances in which consent to transplantation is deemed to be given and the role of relatives and friends in affirming deemed consent. The campaign should also increase awareness about transplantation;
- c) Clause 4 in particular cause concern to the Department because as currently drafted it potentially could introduce a system which would be difficult to operate at the hospital level due to the lack of clarity and detail on the central aspect of the Bill, namely the operation of the proposed new concept of deemed consent. In deemed consent cases, the individual specified through qualifying relationships in clause 10 will be an important reference for the necessary information about the views of the potential donor in order to ensure that the donation does not go ahead if the deceased had a known objection to organ donation. Deemed consent as described in the Bill is at the heart of some of the most difficult conversations that any family might face. We must therefore ensure that the Bill provides appropriate safeguards in that sensitive area;
- d) the regulations to be made by the Department in subordinate legislation. Those regulations are required under clause 7, which deals with express consent to transplantation activities involving excluded material, clause 8, which deals with deemed consent to activities involving material from living adults who lack the capacity to consent, and clause 9, which deals with appointed representatives to express consent for transplant activities. Clause 9 is especially important, where the individual concerned may disagree with the views of appointed representatives on organ donation;

- e) the designation of a "friend of long standing" in clause 10(1) (h). Nowhere in the legislation does it detail what a "friend of long standing" is, what counts as long-standing or what constitutes a friendship;
- f) Clauses 5 and 8 cover issues concerning the capacity of individuals to consent and, again, need to be clear and easily understood. They also need to be considered in the context of the Mental Capacity Bill, currently under consideration by the Assembly, to ensure consistency of approach; and,
- g) the schedule to the Bill proposes extensive amendments to the Human Tissue Act 2004 and the related codes of practice issued by the Human Tissue Authority. The Department will need to consult the authority fully on those amendments, as its codes will provide guidance on the implementation of the Bill's amendments to the 2004 Act.

Department for Health, Social Services and Public Safety