

HUMAN TRANSPLANTATION BILL

EXPLANATORY AND FINANCIAL MEMORANDUM

INTRODUCTION

1. This Explanatory and Financial Memorandum has been prepared on behalf of Mrs Jo-Anne Dobson MLA (“the Sponsor”), in order to assist the reader of the Bill and to help inform the debate on it. It does not form part of the Bill and has not been endorsed by the Assembly.

2. The Memorandum should be read in conjunction with the Bill. It is not, and is not meant to be, a comprehensive description of the Bill, and where a clause or part of a clause does not seem to require any explanation or comment, none is given.

BACKGROUND AND POLICY OBJECTIVES

3. By way of context, the Sponsor of the Bill is the mother of a kidney transplant recipient and has been associated with local and national organ donation and transplantation charities for over twenty years.

4. The principal objective of the Bill is to save lives by changing organ donation laws, making the donation of organs the societal norm in Northern Ireland whilst preserving the principle that after death a donated organ is a gift freely given.

5. The Bill seeks to do this by moving away from the current ‘opt-in’ to a new ‘soft opt-out’ system with appropriate family safeguards, a requirement for express consent in certain cases and the ability for people to nominate advocates to affirm their wishes upon death.

6. The Bill places additional duties on the Department of Health, Social Services and Public Safety actively to promote and increase awareness of transplantation through a campaign at least once a year. The Bill is intended to increase the education around, and the understanding and social acceptability of, organ donation in Northern Ireland.

CONSULTATION

7. The Sponsor undertook an extensive public consultation over a sixteen-week period on the policy objectives and proposed approach of the Bill. A total of 1,366

responses were registered, from which it was clear that a sizeable majority agreed with the objectives of the Bill.

8. A majority of respondents stated that they believed that both legislation and the introduction of a soft opt-out system would make a greater number of organs available for transplantation and therefore increase the chance of saving lives.

9. A clear majority of respondents to the consultation also agreed that the family should continue to play a key role in the decision as to whether organs should be donated.

10. At the end of the consultation, the Sponsor made a detailed overview of the responses to each of the questions available to the public. The overview included the number and percentage of each response and an overview of both positive comments made and concerns expressed about each. The Sponsor also briefed the Stormont All-Party Group on Organ Donation as to the findings of the consultation.

OPTIONS CONSIDERED

11. In developing this legislation, the following options were considered:

Option 1: a “status quo” approach whereby the original opt-in approach remains in place and the local charities and organisations are left at the fore-front of promoting the organ donor register as has been the case for decades. This approach was not supported by the majority of respondents to the consultation and would not be the preferred option of the charities of the local transplant forum. The disadvantage of this option is that it does not represent a step forward and retaining the status quo would mean that in all likelihood, and based on past performance, numbers on the organ donation register will not increase beyond 30-35%.

Option 2: that we move to a new ‘soft opt-out system’ using a two stage consent process under which, subject to exceptions, adults with capacity would be presumed to have consented unless they opt out during their lifetime, with safeguards to ensure that further affirmation is sought after death unless the person had already taken their name off the register before death.

12. Option 2 was chosen on the basis that it provides the best means of increasing the supply of organs available for transplantation purposes.

OVERVIEW

13. The Bill contains 22 clauses and 1 Schedule. It seeks to increase the availability of organs for the purpose of transplantation through a consent process requiring affirmation after death unless the person has already taken their name off the organ donor register.

14. At the moment, human transplantation is governed by the Human Tissue Act 2004, a piece of law which applies to England, Wales and Northern Ireland. If this Bill

becomes law it will fit into the general framework already established by that Act. Some parts of this Bill repeat the provisions of that Act and make them apply to transplants under the Bill. In addition, some parts of this Bill follow the approach taken by the Human Transplantation (Wales) Act 2013.

COMMENTARY ON CLAUSES

Clause 1: Duty to promote transplantation

There are two broad duties on the Department for Health, Social Services and Public Safety. The first is to promote transplantation. The second is to provide information about transplantation. Then there is a specific duty to inform the public about deemed consent and the role of friends and family in affirming deemed consent.

Clause 2: Authorisation of transplantation activities

This is a key provision which sets out the overall structure for the rest of the Bill. It states that transplantation activities are lawful only if there is consent. Consent can either be express, e.g. the person donating the organ has explicitly stated that the organ can be donated, or consent can be deemed, e.g. the person hasn't explicitly stated that the organ can be donated, but their consent is assumed (subject to affirmation as explained below). Consent is dealt with further in subsequent clauses.

Clause 2 goes on to define what is meant by a transplantation activity. It comprises four types of activity. The most obvious one is what people generally consider as organ donation – removing something from the body of a person for use for transplantation. For example, this could be a heart transplant from the body of a deceased person, or a kidney transplant from the body of a living person. There are three further activities which are also included within the definition of transplantation activities. The first is storing the body of a deceased person for use for transplantation. The second is storing material that came from the body of a person for use for transplantation. The third is using any of that material for the purposes of transplantation.

The final part of clause 2 applies in relation to material from outside Northern Ireland. This material can be stored and used if it was imported from outside Northern Ireland and it was removed from a human body outside Northern Ireland.

Clause 3: Express consent: adults

This clause sets out the default position which will apply in most cases. It applies to most adults (clause 5 applies to “excepted adults”). Under this clause, express consent of the adult is required for a transplantation activity. There are four different cases which may apply.

Case 1 and case 2 are the most common cases. If the adult is alive, then their express consent is required (case 1). If the adult has died, but before their death, they made their views on organ donation known, then their express consent is required (case 2). For

example, they may have signed the organ donation register, or stated in their will that they did (or did not) want their organs to be donated.

If a person has ‘opted out’, i.e. expressly stated that they do not wish their organs to be donated, then this decision is final and the family will not be approached. If someone has ‘opted in’ (e.g. by confirming their wish to be on the organ donor register or making reference to this in a will) then this provides ‘express consent’ but does not require the harvesting of organs. It is understood that health professionals currently engage with families in such circumstances, advise family members of the wishes of the deceased, but do not necessarily harvest organs in all cases. There is nothing in the bill to preclude the continuation of this practice.

Cases 3 and 4 apply where the adult has appointed a representative to deal with the issue of transplantation. Where the adult has died, then the express consent of the appointed representative is required for the transplantation (case 3). Where the adult has died and for some reason the appointed representative is not available to give or refuse consent, then there can only be transplantation if another person in a qualifying relationship with the deceased gives express consent (case 4). Clause 9 sets out in more detail what an appointed representative is. Clause 10 sets out in more detail what a qualifying relationship is.

Clause 3 does not apply if the adult is an excepted adult (see clause 5). Clause 3 does not apply if the material being removed falls within clause 7 (excluded material).

Clause 4: Deemed consent: deceased adults

This clause represents a change from the existing law. If an adult has died and hasn’t made his or her views on transplantation known, then the person is deemed to have consented to transplantation. However, deemed consent is not effective unless it is affirmed by a “qualifying person” (defined in clause 10 as a close relative or friend of long standing) and this requirement for family affirmation is the main safeguard in the Bill.

Reasonable efforts in the circumstances must be made to contact qualifying persons. The affirmation required is that the deceased *would not have objected* to the transplantation activity and the person making the affirmation must have *reasonable grounds* for believing that to be the case. Paragraph 7(d) of the Schedule requires the Code of Practice to include guidance in connection with deemed consent, affirmations, objections to affirmations and the procedure for dealing with an affirmation and an objection to that affirmation.

If there is express consent (or the adult has expressly stated that they do not consent) then clause 4 does not apply. Consent is only deemed if the adult has not expressed their views. Another way of expressing this is that all adults are deemed (or in other words, assumed or implied) to have consented to their organs being donated after their death, unless they have opted out. However, the family must still affirm that the deceased would not have objected to that donation.

Clause 4 does not apply if the adult is an excepted adult (see clause 5). Neither does it apply if the material being removed falls within clause 7 (excluded material).

Clause 5: Express consent: excepted adults

This clause applies to two small subsets of deceased adults. The first subset are adults who haven't lived in Northern Ireland for at least a year before they died. The second subset are adults who for a significant period of time before dying didn't have the capacity to understand the nature of deemed consent to organ donation.

For both these subsets of adults, it would not be fair to deem that they had consented to their organs being donated. Those from outside Northern Ireland may not have been aware that unless they opted out, they would be deemed to have consented. Those lacking mental capacity may likewise be unaware that they unless they opted out, they would be deemed to have consented.

For both these subsets, express consent is required for transplantation. This express consent is similar to that required for other adults. There are four cases.

If, before their death, the adult made their views on organ donation known, then their express consent is required (case 1). For example, they may have signed the organ donation register, or stated in their will that they did (or did not) want their organs to be donated. In this case, express consent is dealt with as above in clause 3.

Cases 2 and 3 apply where the adult has appointed a person to deal with the issue of transplantation. The express consent of the appointed representative is required for the transplantation (case 2). Where for some reason the appointed representative is not available to give or refuse consent, then there can only be transplantation if another person in a qualifying relationship with the deceased gives express consent (case 3). Clause 9 sets out in more detail what an appointed representative is. Clause 10 sets out in more detail what a qualifying relationship is.

Case 4 applies where the adult hasn't made their wishes known and hasn't appointed a representative. In this case, the express consent of someone in a qualifying relationship is required.

Clause 5 does not apply if the material being removed falls within clause 7 (excluded material).

Clause 6: Express consent: children

A child is never deemed to have consented to transplantation: express consent is always required. In most cases this will mean either the consent of the child or their parents, although there is a limit on what a child can consent to.

There are six cases. If the child is alive and has expressed their wishes, then these wishes prevail (subject, as set out below, to the capacity of the child to express their wishes). So, if the child is alive, their express consent is necessary for transplantation (case 1).

If the child is alive but hasn't expressly consented or refused consent (for example, they don't want to deal with the issue), then the express consent of the parent is required (case 2). If the child has died, but before death they expressed their wishes, then these wishes prevail (case 3). Again, this is subject to the caveat set out below on the capacity of the child to express their wishes).

Cases 4 and 5 apply where the child has died but, before death, the child appointed someone to deal with the issue of consent. The express consent of that representative is required (case 4). Where that representative is not in a position to give consent (for example, they cannot be contacted), then the express consent of a parent is required (case 5). If no parent is available, then the express consent of someone in qualifying relationship is required (see clause 10 for the meaning of qualifying relationship).

Case 6 applies where the child has died, the child hasn't given express consent and hasn't appointed a representative. In this case, the express consent of a parent is required. If no parent is available, then the express consent of someone in qualifying relationship is required.

A child can only consent if he or she is competent to deal with the issue of consent at the time. The meaning of competence is further defined in clause 18(3) – it means that the child has sufficient understanding to make an informed decision. This means that a child can only consent to donating an organ if the child understands what this really means.

This limitation also applies to a child appointing a representative. Therefore, a child can only appoint a representative if he or she understands what this means.

Clause 6 does not apply if the material being removed falls within clause 7 (excluded material).

Clause 7: Express consent: transplantation activities involving excluded material

This clause will only apply in unusual circumstances. It applies if the body part being transplanted is what is termed “excluded relevant material”. This term is not defined in the Bill; instead it will be defined in regulations to be made by the Department. Examples of excluded relevant material are things like composite tissues and other material which would be considered to be novel to be used in transplantations. Faces and limbs are examples of composite material.

Consent will never be deemed for transplants involving excluded relevant material. Express consent is required for both adults and children. Depending upon the circumstances, the express consent can be given by the person, an appointed representative, a parent or person in a qualifying relationship. This follows the general approach in the above clauses on the giving of express consent.

Clause 8: Deemed consent: activities involving material from living adults who lack capacity to consent

This clause governs transplantations from the body of a living adult who lacks the capacity to consent to the transplantation. It only applies where there is no express consent decision in force. The Department may make regulations setting out the circumstances in which consent may be deemed. For example, there may be circumstances where it may be in the best interests of a person incapable of giving consent, to donate material to a living relative.

Clause 9: Appointed representatives

A person may appoint a representative to take a transplant decision on their behalf. The decisions of the representative will constitute express consent to transplantation activities. This clause sets out the procedure for making (and revoking) an appointment. Children cannot act as representatives and the Department may by regulations specify other people who cannot act as representatives. If a representative has been appointed under English or Welsh laws, then they will also be regarded as a representative under this Bill.

Clause 10: Qualifying relationships

In some of the clauses set out above, where the person hasn't given express consent themselves, the express consent of a person in a qualifying relationship is required. This clause sets out the meaning of qualifying relationship. These are essentially either close family members, or a friend of long standing. It also includes unmarried couples. The Code of Practice of the Human Tissue Authority may set out further details on how to handle conflict where different people in a qualifying relationship want different things.

Clause 11: Offences

It is an offence to carry out a transplantation activity if there is not the appropriate consent for it. There are defences to this, for example if the person reasonably believed that there was consent. It is also an offence to falsely represent that there is consent to transplantation, or that consent is not required.

Clause 12: Offences by bodies corporate

Organisations and groups can be guilty of offences under this Bill, not just individuals.

Clause 13: Prosecutions

A person can only be prosecuted for an offence under this Bill if the Director of Public Prosecutions consents to the prosecution.

Clause 14: Annual report on transplantation

This clause sets up a mechanism for post-legislative scrutiny. The Department must produce a report once a year on transplantation activities. The report must be given to the

Assembly. Once every five years, the Department must report on whether this Bill is working, and on any potential ways in which the law could be amended to increase transplantations.

Clause 15: Preservation for transplantation

This clause makes it lawful to keep the body of a deceased person (and preserve organs) whilst the issues of consent are being resolved. Once it is clear that there is no consent, it is no longer lawful to preserve the body. Preservation activity must be minimal and as un-invasive as possible.

Clause 16: Coroners

Coroners carrying out their jobs are exempt from the rules set out in this Bill. If a body is required by a coroner, the coroner must give consent before the body can be used for transplantation activities.

Clause 17: Relevant material

This clause sets out the definition of material removed from the body for the purposes of transplantation.

Clause 18: Interpretation

This clause defines various terms referred to in the Bill.

Clause 19: Orders and regulations

This clause sets out the procedure for making subordinate legislation under the Bill. The subordinate legislation is subject to the draft affirmative procedure.

Clause 20: Consequential amendments to the Human Tissue Act 2004

As a consequence of this Bill, there needs to be some amendments to the Human Tissue Act 2004. This clause and the Schedule make those amendments.

Clause 21: Commencement

The duty to promote transplantation and the structural parts of this Bill come into operation 3 months after the Bill becomes an Act. The rest of the Bill comes into operation on 31 May 2018.

Schedule – Consequential amendments to the Human Tissue Act 2004

The Schedule makes amendments to the Human Tissue Act 2004 which are consequent upon the making of this Bill. These include amendments to the Codes of Practice that the Human Tissue Authority must prepare.

FINANCIAL EFFECTS OF THE BILL

15. There will be a limited cost associated with the new duty to run a promotional campaign in support of transplantation but the main financial effect of the Bill will be to increase the number of organ transplantations conducted by the Health Service. This will result in a net gain, not only due to a reduction in the number and cost of people undergoing expensive renal dialysis in Northern Ireland, but because it will also give those individuals waiting for transplants (including heart, pancreas, liver, bowel and lung) a greater chance to return to a relatively normal life, all of which will have a knock-on benefit to the wider economy.

16. A research paper entitled ‘Organ Donation Bill: estimated financial costs and benefits’ was compiled for the Sponsor by the Northern Ireland Assembly Research and Information Service (RaISe) in November 2013.

17. The paper concluded that the ‘indicative estimate of implementation costs of introducing the proposed legislation is between £2,081,000 and £5,149,000 over a ten-year period.’

18. The paper looked at a number of scenarios in relation to the financial impact of the introduction of the legislation. The paper assumed that implementation will be two years after the passage of the Bill. The paper came to the following financial conclusions:

The net discounted financial benefits from achieving one additional transplant per year over a ten-year period, by organ type, are as follows:

- Kidney = £4.6m;
- Liver = £6.3m;
- Heart = £2.3m; and
- Lung = £1.4m;

19. Using these figures, and assuming one additional donor per year for a range of scenarios, the potential net financial impact of the proposed legislation over ten years could be as much as £+7.4m to the Northern Ireland economy.

20. The National Health Service Blood and Transplant Service describe kidney transplantation as “highly cost-effective, particularly in relation to NHS spend, and is the treatment of choice for many patients with end-stage renal failure”.

21. Based on a Fact Sheet released by NHS Blood and Transplant in October 2009 in relation to kidney dialysis alone, the indicative cost of maintaining a patient with end-stage renal failure on renal dialysis, is £17,500 per patient per year for a patient on peritoneal dialysis and £35,000 per patient per year for a patient on hospital haemodialysis.

22. The NHS estimates that 76% of dialysis patients are on haemodialysis and 24% of patients are on peritoneal dialysis and that the average cost of dialysis is £30,800 per patient per year.

23. According to an answer to an Assembly Written Question asked of the Health Minister by the Sponsor in 2013, Health Trusts in Northern Ireland estimate that 932 patients underwent renal dialysis. This works out at roughly 739 haemodialysis and 193 peritoneal costing over £29M to the health budget based on NHS cost estimates.

24. The indicative cost of a kidney transplant (including induction therapy but excluding NHSBT costs) is £17,000 per patient per transplant.

25. Post-transplant, the average cost of immuno-suppression medication is £5,000 per patient per year which is considerably less than the cost of dialysis.

26. Therefore the NHS estimates that kidney transplantation leads to a cost benefit in the second and subsequent years of £25,800 p.a.

27. Therefore the cost-benefit of kidney transplantation compared to dialysis over a period of ten years (the median transplant survival time) is £241,000 or £24,100 per year for each year that the patient has a functioning transplanted kidney.

28. These figures do not take into account the life-saving and life-enhancing impact, beyond the financial benefits of organ transplantation, whatever the organ being transplanted. Neither do these figures take into account the contribution that individuals in receipt of a successful transplant are able to make to wider society and the economy.

Source: AQW 42402/11-15 and AQW 26889/11-15

NHSBT:http://www.organdonation.nhs.uk/newsroom/fact_sheets/cost_effectiveness_of_transplantation.asp.

HUMAN RIGHTS & EQUALITY ISSUES

29. The Bill is considered to be compatible with the European Convention on Human Rights.

30. It is further considered that the Bill will not have an adverse impact on any of the groups listed in section 75 of the Northern Ireland Act 1998.

LEGISLATIVE COMPETENCE

31. At Introduction, the Member in charge of the Bill, Mrs Jo-Anne Dobson, had made the following statement under Standing Order 30:

“In my view the Human Transplantation Bill would be within the legislative competence of the Northern Ireland Assembly.”