



Northern Ireland
Assembly

Committee for Health, Social Services and Public Safety

Report on the Human Transplantation Bill

Together with the Minutes of Proceedings of the Committee Relating to the Report,
Minutes of Evidence, Written Submissions and Other Papers

Ordered by the Committee for Health, Social Services and Public Safety
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Powers and Membership

The Committee for Health, Social Services and Public Safety is a Statutory Departmental Committee established in accordance with paragraphs 8 and 9 of the Belfast Agreement, section 29 of the Northern Ireland Act 1988 and under Standing Order 48.

The Committee has the power to:

- Consider and advise on Departmental budgets and annual plans in the context of the overall budget allocation;
- Consider relevant secondary legislation and take the Committee stage of primary legislation;
- Call for person and papers;
- Initiate inquiries and make reports; and
- Consider and advise on any matters brought to the Committee by the Minister for Health, Social Services and Public Safety.

The Committee has 11 members including a Chairperson and Deputy Chairperson and a quorum of 5.

The current membership of the Committee is as follows:

Ms Maeve McLaughlin (Chairperson)

Mr Alex Easton (Deputy Chairperson)

Mrs Pam Cameron

Mrs Jo-Anne Dobson

Mr Thomas Buchanan

Mr Kieran McCarthy

Ms Rosaleen McCorley

Mr Michael McGimpsey

Mr Daithí McKay

Mr Fearghal McKinney

Mr Gary Middleton

¹With effect from 23 January 2012 Ms Sue Ramsey replaced Ms Michaela Boyle

² With effect from 06 February 2012 Ms Sue Ramsey replaced Ms Michelle Gildernew as Chairperson

³ With effect from 23 April 2012 Mr Conall McDevitt replaced Mr Mark Durkan

⁴ With effect from 02 July 2012 Ms Michelle Gildernew is no longer a Member

⁵ With effect from 10 September 2012 Ms Maeve McLaughlin was appointed as a Member

⁶ With effect from 15 October 2012 Mr Roy Beggs replaced Mr John McCallister

⁷ With effect from 04 September 2013 Mr Conall McDevitt resigned as a Member

⁸ With effect from 16 September 2013 Mr David McIlveen replaced Ms Paula Bradley

⁹ With effect from 16 September 2013 Ms Maeve McLaughlin replaced Ms Sue Ramsey as Chairperson

¹⁰ With effect from 30 September 2013 Mr Fearghal McKinney was appointed as a Member

¹¹ With effect from 04 July 2014 Mrs Jo-Anne Dobson replaced Mr Samuel Gardiner

¹² With effect from 23 September 2014 Ms Paula Bradley replaced Mr Jim Wells as Deputy Chairperson

¹³ With effect from 06 October 2014 Ms Rosaleen McCorley was appointed to the Committee

¹⁴ With effect from 06 October 2014 Mr George Robinson replaced Mr David McIlveen

¹⁵ With effect from 06 October 2014 Mr Michael McGimpsey replaced Mr Roy Beggs

¹⁶ With effect from 01 December 2014 Mr Paul Givan replaced Mr Gordon Dunne

¹⁷ With effect from 11 May 2015 Mr Alex Easton replaced Ms Paula Bradley as Deputy Chairperson

¹⁸ With effect from 03 June 2015 Mr Mickey Brady resigned as a Member

¹⁸With effect from 14 September 2015 Mr Daithí McKay was appointed as a Member

²⁰With effect from 5 October 2015 Mr Thomas Buchanan replaced Mr Paul Givan

²¹With effect from 9 November 2015 Mr Gary Middleton replaced Mr George Robinson

Executive Summary

1. The stated purpose of the Human Transplantation 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. 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.
2. The majority of evidence from stakeholders on the Bill focused on Clause 4 which introduces the concept of deemed consent. Some stakeholders supported the principle of deemed consent, while others opposed it. Following consideration of the written and oral evidence, Committee Members also came to opposing conclusions on Clause 4 and the issue of deemed consent. Fundamentally, some believed that introducing deemed consent would result in an increase in organ donations in Northern Ireland, while others believed that it could result in a reduction in the number of organ donations. A view was also expressed that a robust evidence base did not exist to demonstrate a positive or negative impact of deemed consent.
3. Members who supported Clause 4 proposed amendments to it that would require that deemed consent can only be effective if contact has been made with a family member who confirms that they have no objection to donation. These Members were of the view that the amendments would serve as a 'double lock' in that the retrieval of organs could not take place unless the family or a person in a qualifying relationship had confirmed that they had no objections. However, other Members felt that these amendments did not address the fundamental concerns around deemed consent, as expressed by local clinicians and others.
4. The Committee divided on the proposed amendments to Clause 4, with the majority opposing the amendments. The Committee then considered Clause 4 as drafted, and again divided, with the majority position being opposition to Clause 4 forming part of the Bill.
5. While the key purpose of the Bill is to change the law governing consent for organ donation, Members who opposed to the introduction of deemed

consent, nevertheless believed that there was merit in keeping the other aspects of the Bill which do not touch on the issue of consent.

6. Clause 1 places a duty on the Department of Health, Social Services and Public Safety to promote and raise public awareness on organ donation. Members who were opposed to Clause 4 supported the retention of these duties, and therefore supported an amended form of Clause 1, which left out the reference to an annual promotional campaign on deemed consent. Members who supported Clause 4 were content with Clause 1 as drafted. The majority Committee position was to agree Clause 1 as amended.
7. Members who were opposed to Clause 4 also supported the retention of Clause 14 which places obligations on the Department to both report the statistics on transplantation activities and to undertake a wider review on the law once every five years. These Members voted in favour of an amendment to Clause 14 to broaden the scope of the wider report so that it would also cover the Human Tissue Act 2004. This was because if deemed consent is not introduced, then the Human Tissue Act 2004 will continue to be the key piece of legislation in terms of consent. Members who supported Clause 4 were content with Clause 14 as drafted. The majority Committee position was to agree Clause 14 as amended.

Introduction

1. The Human Transplantation Bill (NIA 64/11-16) was introduced to the Assembly on 13 October 2015. At Introduction, the Bill sponsor Mrs Jo-Anne Dobson MLA 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.”

2. The Bill passed its Second Stage on 16 November 2015 and was referred to the Committee for Health, Social Services and Public Safety on 17 November 2015.
3. The stated purpose of the Bill is to make provision concerning the consent required for the removal, storage and use of human organs and tissue for the purpose of transplantation; and for connected purposes. The Bill has 22 clauses and 1 Schedule.
4. During the period covered by this Report, the Committee considered the Bill and related issues at 11 meetings. Details of the meetings can be found at Appendix 1.
5. At its meeting on 18 November 2015, the Committee agreed a motion to extend the Committee Stage of the Bill to 5 February 2016. The motion to extend was supported by the Assembly on 7 December 2015.
6. The Committee had before it the Human Transplantation Bill and the accompanying Explanatory and Financial Memorandum. On 20 November 2015, the Committee wrote to key stakeholders and inserted public notices in the Belfast Telegraph, Irish News, and News Letter seeking written evidence on the Bill by 4 December 2015.
7. A total of 19 individuals and organisations responded to the request for written evidence and details of the submissions received by the Committee are included at Appendix 3.
8. Prior to the introduction of the Bill, the Committee took evidence from the Bill sponsor on 4 November 2015. During committee stage of the Bill, the Committee took evidence from the following:
 - a. Departmental officials and the Public Health Agency on 2 December 2015;

- b. Transplant surgeons, nephrologists and Dr James Douglas on 2 December 2015;
 - c. The Welsh Government, Eurotransplant International Foundation and NHS Blood and Transplant on 2 December 2015; and
 - d. Dr John Darling, Dr George Gardiner, Dr TJ Trinder, Belfast Health and Social Care Trust, Human Tissue Authority, NI Kidney Research Fund, British Heart Foundation in Northern Ireland, British Medical Association, Opt for Life, Royal College of Physicians in Edinburgh, Christian Action and Research in Education in Northern Ireland, Presbyterian Church in Ireland and the Society for the Protection of the Unborn Child on 6 January 2016.
9. The Committee deliberated on the Bill at its meetings on 13 and 20 January 2016. On 27 January 2016, the Committee carried out its clause-by-clause scrutiny of the Bill. At its meeting on 3 February 2016, the Committee agreed its report on the Bill and that it should be published.

Consideration of the Bill

Introduction

10. In response to its call for evidence, the Committee for Health, Social Services and Public Safety received 19 written submissions from organisations and individuals. While there was general support for human transplantation legislation the evidence raised a number of issues and concerns, particularly in relation to Clause 4 (Deemed consent: deceased adults).
11. This section of the report provides a summary of the key issues considered by the Committee during its consideration of the Bill. The evidence received on every single clause and the Schedule is not rehearsed in this section of the report; a complete picture of the written and oral evidence received can be found in Appendices 2 and 3.

Clause 4: Deemed consent: deceased adults

12. Clause 4 provides that if an adult has died and has not 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' which is defined in Clause 10 as a close relative or friend of long standing.
13. A wide range of views were expressed in written and oral evidence in relation to the issue of deemed consent and how the change in law would operate in practice. Some of those who responded to the Committee's request for evidence made arguments against deemed consent, either in its entirety or in part, while others made arguments in support of it in its current state of drafting or in an amended format.
14. The key evidence presented and the main issues raised are set out below.
15. The Welsh Government provided information on its new system introduced on 1 December 2015, whereby people living in Wales are regarded as having no objection to organ donation after death, unless they have indicated otherwise. Officials pointed out that the law contains a safeguard for relatives and friends of long standing to object to deemed consent on the basis that they know the deceased would not have consented.

16. The Welsh Government was of the view that a change in the law to an opt-out system is likely to deliver the revolution in attitudes and behaviour around consent called for in the “Taking Organ Donation and Transplantation to 2020 Strategy”.

17. During its oral evidence session on 9 December 2016, the Welsh Government referred to its review of international evidence on organ donation:

“... our review of international evidence suggests that there is an association between the countries with assumed consent-type systems and an increased donation rate. I could not go as far as to say that that is the cause of the increase in the donation rate, but, taking all other things into account, it certainly appears to be a contributory factor.”

18. The Welsh Government also outlined how the proposed soft opt-out system was initially viewed by clinicians in Wales:

“The BMA in Wales has always supported a move to the opt-out system. Perhaps, to begin with, some of our clinical colleagues were a bit more sceptical about whether it would work, and perhaps some of them remain so. There are a couple of things to say. We did some research with NHS staff in Wales. There was considerable support for the law change, but it depended on the staff group. It varied amongst the different staff groups. As we have gone on with the work, we have worked very closely with colleagues in NHSBT and the organ donation committees in Wales, and we have seen people become more and more comfortable with the idea, and thinking, “Yes, it probably can work”... I take the message from the clinical teams now that they are approaching this with some confidence. They feel equipped to deal with it. At first, perhaps, concerns were expressed, but that has diminished as we have gone along and more information has been made available.”

19. During its oral evidence session on 6 January 2016, the British Medical Association (BMA) expressed support for a move from an opt-in system to a soft opt-out system in Northern Ireland:

“In broad terms, the BMA welcomes this private Member’s Bill and the intentions to increase the numbers of organs available for transplantation, to increase the social acceptability of organ donation and to change societal culture in that regard. We have supported an opt-out system with safeguards

for organ donation since 1999, and we support continuing improvements in the infrastructure, resourcing and organisation of the organ donation and transplant system. In general, we welcome a move from the current opt-in system to a new soft opt-out system with safeguards.”

20. The BMA recognised the sensitivities around the issue of the role of relatives and consent at such a distressing time. However, it highlighted that the key issue should be what the deceased person wanted in relation to donation, and its view was that the family role is to provide information to contribute to that decision, rather than to provide a positive affirmation. The BMA provided further explanation of this point during oral evidence:

“First, while we support the intention that the family should always be consulted about an individual's wishes, except where a person has appointed a representative to make a transplant decision on their behalf, we would prefer that the way in which the family is involved did not require a positive formal affirmation that a person would not have objected; rather, we prefer that the family should be asked about any unregistered objection. I appreciate that that is a fine distinction, but I believe that avoiding a positive requirement to affirm would place less pressure on the bereaved family and achieve more donations.”

21. The BMA was confident that the introduction of an opt-out system with the appropriate publicity campaign would encourage more discussion within families so that the views of loved ones are known by family members prior to their death. The BMA therefore proposed that references to affirmation should be removed:

“In essence, if an individual has not registered an objection and those close to the person are not aware of any unregistered objection, the deceased individual's organs should be available for donation, unless, in a particular case, the clinical team believes that donation is not appropriate – for example, if it would cause significant distress to the family. That is a simple message that is easy to convey.”

22. Like the BMA, the Royal College of Physicians of Edinburgh (the College) supported a soft opt-out option. However, it expressed the view that it is vital that the proposed legislation has appropriate checks and balances to maintain the role of close family. It felt that public confidence would be quickly

undermined if family did not continue to play a key role in decision making. The College stated that the family should always be consulted about the request to harvest organs and asked about the expressed wishes of the deceased.

23. The College recognised the differing opinions within the medical profession and society at large regarding an opt-out system. It noted that some believe that opt-out legislation effectively means acquisition by the State of organs, and that removal of the altruistic aspect of donation is of real concern to some of its fellows, who feel that bereaved families take great solace from a positive act of giving. It was the College's view that these and other ethical issues have prevented the global adoption of presumed consent legislation.

24. During oral evidence on 6 January 2016, the British Heart Foundation (BHF) outlined why it supported a soft opt-out system for Northern Ireland:

“System change is urgently needed, as the current system is failing to meet the demand for donor hearts. The demand for a heart has increased across the UK by 143% since 2006. Currently, 262 people in the UK are waiting for a new heart, and, in the past year alone, 38 people died while waiting for a heart transplant and a further 47 were removed from the waiting list. In Northern Ireland, eight people are waiting for a life-saving heart. We know that, in the past two quarters, there have been two transplants in Northern Ireland. That is welcome news, but, in the previous 12 months, there had been no heart transplants in Northern Ireland. As I am sure you will all agree, statistics can be quoted, but, as a charity that works with people living with and, sadly, dying with severe heart failure, we know that, behind every statistic, there is a family and an individual waiting for this.”

25. The BHF was of the view that the aim of this legislation should be threefold: to increase the number of organs available for donation; maintain and respect the wishes of the deceased as paramount; and give families/qualifying person an important confirmation role at the point of donation. However, it expressed concern that Clause 4(2) did not deliver on these aims. In its view, the Bill in its current format would make donation more difficult in deemed consent circumstances. It explained that if families are expected to affirm that the deceased would not have objected, this could then place the wishes of the

family or qualifying person above those of the deceased or make families reluctant to provide affirmation when they have no absolute proof of this.

26. Whilst the BHF firmly believed that the family or qualifying person of the deceased should play a role at the point of donation, it supported the Welsh legislation approach on this issue which gives families/qualifying persons the opportunity to object to donation based on the views of their loved ones rather than asking them to 'affirm' in every case of donation that the deceased did not object. This view was echoed by the Northern Ireland Kidney Patients' Association in its written evidence and by the Northern Ireland Kidney Research Fund during oral evidence, the latter stating:

"We believe that simplifying clause 4 to read "unless an objection can be recorded" would facilitate the decision-making involved at such a sensitive time."

27. CARE in Northern Ireland (CARE) was clear that the notion of organ donation should remain as a gift. It outlined its views on this issue during oral evidence on 6 January 2016:

"Our major concern is the idea of organs being taken from an individual with no form of affirmative consent being provided by that individual, their relatives or a close friend. If an organ were removed in such circumstances, we do not believe that that constitutes a gift at all. We actually feel that it sees the state overreaching its rightful place by effectively taking ownership of a person's organs after death. If some form of familial consent or consent from a close friend is given, we believe that the notion of organ donation as a gift is maintained."

28. CARE noted that 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 highlighted that this does not provide the family with the opportunity to affirm consent strictly speaking; rather it proposes a right for the deceased's family to input what information is available on the deceased views. It pointed out that if the family has no explicit information about the views of the deceased regarding donation, perhaps because the matter was never discussed, then the Bill provides the family with no role.

29. During oral evidence on 6 January 2016, the Presbyterian Church in Ireland raised a number of issues in relation to Clause 4:

“Our council for church in society recognises that the Bill before us is different in that the Bill sponsor has expressed a wish to retain the role of the family in providing consent for organ donation to proceed in the event of the deceased’s wishes being unknown. If that is what the Bill provides for, it would certainly mitigate concerns about loss of consent and the loss of the concepts of a gift or donation. However, in saying that a qualifying person or persons must affirm that the person would not have objected, the Bill is unclear on what the role of the family is in those situations. That raises two ethical concerns. First, that it would create confusion for families at a time of already significant distress. Secondly, that the legislation could actually deprive us of organs that would be available under the current system, as what is currently in place allows families to take the decision; a point that I believe was made by one of the consultant surgeons back in December. We would simply ask and suggest that a simple change be made to give families the final say on whether to donate or to object when the deceased’s wishes are unknown. That would not only resolve the issues around consent and donation as a gift but make the Bill less restrictive.”

30. The Society for the Protection of Unborn Children (SPUC) highlighted that organ transplantation is potentially life-giving and has a very important societal contribution. However, it noted that it raises fundamental issues surrounding respect for the human body, the meaning of gift giving and diagnosis of death. SPUC was of the view that these were serious issues that needed to be faced by anyone wishing to promote ethical forms of donation while protecting donors and the common good. It recognised that in seeking to benefit patients whose need for organs may be urgent and compelling, the rights of potential donors and their families must always be respected.

31. NHS Blood and Transplant was of the view that it is difficult to predict whether the proposals under Clause 4(2)(b) will achieve their objective of providing more deceased donor organs for transplantation. It pointed out that although the legislation is very similar to that in Wales, it appears to give a more central role to families (or those in a qualifying relationship) and the test of the potential donor’s wish is more ambiguous than it is in Wales. It felt that it would

be helpful to be clearer about what is meant by 'would not have objected' and how this is tested.

32. During its oral evidence session on 6 January 2016, the Human Tissue Authority (HTA) firstly advised the Committee that it is a statutory regulator and has a role in providing advice and guidance, rather than to support or oppose proposals for legislation. In that context it raised issues in relation to the drafting of Clause 4:

“One of the main differences between the Welsh legislation and this Bill is that deemed consent is effective only if a person in a qualifying relationship affirms that the deceased would not have objected to transplantation. We are concerned about how "affirmed" may be interpreted. In England, if the deceased's wishes are unknown, a person in a qualifying relationship is asked to make a decision on behalf of the deceased person. We have yet to seek legal advice on that, but it appears to us that asking a qualifying person to affirm that a potential donor would not have objected to the transplant activity could be counterproductive to the aims of the Bill. Put more simply, if a person in a qualifying relationship has never discussed organ donation with the donor, they would not be in a position to either affirm or refute whether a person would have objected to donation. If that interpretation is correct, consent could not be deemed.”

33. The HTA pointed out that establishing whether consent is in place and seeking consent are complex matters and involve communication with people in a period of high emotion. It stressed that it is important that any move to a system of deemed consent does not add further complexity and that everyone involved in the process is informed fully of their role and responsibilities.
34. In its written evidence, Opt for Life stated that the Bill was confusing. It recommended that the phrase 'deemed consent' be deleted, adding that it was meaningless, since the retrieval of organs must be entirely dependent on express family consent. Likewise, it recommended that the phrase 'family affirmation' be deleted and replaced with family consent. Opt for Life also stated that it did not support deemed consent in any circumstances.
35. Opt for Life asserted that the Bill should be based on communicating a clear message that all organ retrieval requires express family consent and, that

those who do not wish to be considered for organ donation can opt-out using the online register. They stated during oral evidence:

“There will be wholesale confusion if this Bill is enacted. If you simply have an Act that says that organ donation can proceed only, if the person is alive, with the express consent of that person or, in all other circumstances, with the express consent of the family, as defined below. You then define the family widely, including gay partner, civil partner, partner, half-brother, stepmother and all the other gradations. Then you say that those who do not wish to be considered for organ donation for any reason after death can opt out in an online register. That deals with it; it is as simple as that. It is not threatening, everybody understands it, it is easy to publicise, and you guys will make an enormous difference.”

36. The Department of Health, Social Services and Public Safety expressed particular concern about Clause 4 because in its view, 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. It highlighted that 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. The Department noted that deemed consent as described in the Bill is at the heart of some of the most difficult conversations that any family might face, and as a consequence the Bill must provide appropriate safeguards in that sensitive area.

37. During an oral evidence session on 2 December 2015, the Department expanded on the difficulties that could be experienced in relation to the implementation of Clause 4 as drafted:

“Clause 4 is at the heart of the Bill in setting the direction of the other main clauses... Under the Bill, consent cannot be deemed unless there is an affirmation that the deceased would not have objected. We need to make sure that that will not cause complications when clinical staff are talking to relatives in the most tragic of situations to ensure that that is not complicated by going through the affirmation process. We want to explore this with clinicians, with

Mrs Dobson, and with the legislative draftsman to ensure that we have as much clarity as possible. At the moment, the way in which the consent procedure is carried out in the hospital is set out in the codes of practice issued by the Human Tissue Authority. There are proposed amendments to those, but we want to get absolute clarity on the qualified persons under Mrs Dobson's Bill and how they would relate to the notion of affirming that the deceased would not have objected so that we do not confuse the situation. We may need to look at our own code of practice, for example, in Northern Ireland to ensure that there is maximum clarity on it."

38. Mr Rafael Matesanz, a leading Spanish Nephrologist, submitted a paper by John Fabre and colleagues, of which he was co-author, in which he summarised his views on presumed consent. The paper outlined the legislative position in Spain and made comparisons with the UK in terms of organ donation rates. It highlighted a number of factors which might be shaping the high rates of donation in Spain compared to the UK including the number of potential donors; differences in end of life care; the absence of donation after withdrawal of cardiorespiratory support; the placement of transplant coordinators at each procurement hospital; and training.
39. Mr Matesanz's paper also referred to the conclusions of the UK Organ Donation Taskforce which conducted an extensive assessment of presumed consent. The Taskforce found that this approach was unlikely to improve organ donation rates in the UK. Moreover, it suggested that the costs of implementing presumed consent in the UK, which are approximately £45m in establishment costs and several million pounds per annum thereafter, might divert resources away from more effective initiatives.
40. The paper concluded by pointing out that advocates of presumed consent often cite the Spanish organ donation system as an example of the success of presumed consent legislation. However the authors argued that, in fact, what Spain has shown is that the highest levels of organ donation can be obtained while respecting the autonomy of the individual and family, and without presumed consent.
41. A number of consultant surgeons and intensive care consultants from the Belfast Health and Social Care Trust provided both oral and written evidence

in relation to Clause 4 of the Bill. The oral evidence sessions took place on 2 December 2015 and 6 January 2016.

42. Whilst recognising that there are people on organ donation waiting lists who might not get an organ transplant because one does not become available, the consultants pointed out that Northern Ireland has the highest rate of organ donation in the United Kingdom, and compares favourably to other countries. One of the key messages from the consultants was that international evidence does not show clearly that presumed or deemed consent improves organ donation rates.

43. During oral evidence, Dr Trinder expressed concern that presumed consent legislation could heighten any perceived conflict of interest between continuing life support, and stopping it to allow the retrieval of organs:

“It is vital that Committee members heed the concerns of those of us who are involved in decisions to terminate life support and who have, for many years, also been engaged in discussions with family members on organ donation. As I address the issues, I encourage you to imagine yourselves in the shoes of a soon-to-be-bereaved family. Often, there will have been a sudden catastrophic event, so think about what they will be going through and the powerful emotions they will have, particularly as cessation of life support is proposed and organ donation is discussed. I am particularly concerned about how intensive care staff can be perceived to have a conflict of interest, especially in the context of organ donation after circulatory death. In such circumstances, we withdraw life support from patients who, at that point, are still alive. If families were to find that their objections to organ donation were not heeded, facilitated by new legislation, it might generate feelings that the decision to withdraw life support was influenced by a desire to harvest organs.”

44. A number of the consultants pointed out that deemed or presumed consent by its very nature means that there is a possibility that patients’ organs could be retrieved against their wishes if they have not made their wishes known. Concerns were expressed that should this happen and the media were to become involved, this could have a detrimental impact on organ donation rates.

45. During oral evidence, Mr Brown provided an example of how public perception can impact on organ donation rates:

“ In 2001, when I was on call in the Edinburgh liver transplant unit, a 24-year-old woman arrived with fulminant liver failure. The clinical scenario was that she needed a liver transplant within 48 hours or she was going to die. Unfortunately, it happened just after the Alder Hey scandal, where children’s organs were retained by one of the pathologists there. That woman went to the very top of the super-urgent Europe-wide liver transplant list, waiting for the next available liver to save her life. She waited four days for that liver – she managed to survive for four days – but, by the stage she got her liver, she was irretrievably brain damaged. That was on the basis of the public attitude to the Alder Hey scandal, which meant that the organ donor rates took a massive dip. The public are very reactive to stories such as that.”

46. The clear message from the consultants was that if a family has the conversation about organ donation and an individual’s wishes are known, the family is more likely to give consent to organ donation. Dr Glover illustrated this point with some statistical information:

“ ... in the Public Health Agency survey, 86% of the population said that they supported organ donation, yet we still have only 60% of families consenting. There is a disparity between what people will say in a survey and the decision that they will take at this emotional and difficult time. I go back to the earlier phase of the conversation: all the issues or concerns about family veto and family override would be eliminated if the wishes of the deceased were known and the family were not being asked to make a decision.”

47. In relation to Clause 4, the consultants pointed out that there were potential negative impacts in relation to the family affirmation requirement. During oral evidence, Dr Darling made a comparison to the present system to clarify the point:

“In the case of a potential donor where relatives cannot affirm that the person would not have objected, deemed consent is not effective and, therefore, transplantation cannot go ahead in the way that it could under the present system. That might reduce the number of organs available for donation and transplantation, which is exactly the opposite of the reason for the Bill.”

48. In his oral evidence, Dr Gardiner referred to the new Welsh law on presumed consent and the lessons that could be learned before any change is introduced in Northern Ireland:

“All of us are supporters of organ donation. We all seek to achieve improvements at every stage of the process, but I have to inform you that there is significant concern among my colleagues. We cannot predict the effect that the change in legislation would have, and there is little evidence to guide us. We are essentially trialling a new intervention that may have a positive, negative or neutral effect. Meanwhile, in Wales – a similar nation – that experiment, if you like, is already in progress. We should at least await the results. If I had a great idea about changing practice in my intensive care unit and I went ahead, if it worked, you would hail me as an innovator; if it had no effect, the trust would wonder why I spent the money; if it had a negative effect, I would be censured. If I did that while a similar experiment was already ongoing, serious concerns would be raised. I suppose that is what we are embarking on. We do not have a great deal of evidence, and we are about to change legislation without really knowing what the effect will be, while, to a certain degree, the experiment is already under way.”

49. Mr Brown echoed Dr Gardiner’s views:

“Strength of feeling is very difficult to measure. No one is standing in front of Belfast City Hospital with a placard saying, “Soft opt-out down”, but everyone would really like to see what happens to the Welsh system and whether the curve goes one way and then another, or whether it goes down or stays on the same path. If it stays on the same path, you will invest a lot of money in changing a law that is not making any difference to what we are achieving at the moment with our organ donor improvement as it stands.”

50. The consultants expressed the view that there are three strands to increasing donor rates and achieving a societal shift in relation to organ donation: improving infrastructure; education; and passing legislation that is palatable to the rest of society.

51. Following consideration of the written and oral evidence, Committee Members came to opposing conclusions on Clause 4 and the principle of deemed consent. Fundamentally, some believed that introducing deemed consent would result in an increase in organ donations in Northern Ireland, while others believed that it could result in a reduction in the number of organ donations.

52. At its meeting on 27 January 2016, the Committee considered amendments to Clause 4 that would require that deemed consent can only be effective if

contact has been made with a person in a qualifying relationship and a response has been received; and remove reference to affirmation and instead replace it with objection.

53. These amendments were supported by those Members who were in favour of deemed consent but who wanted to amend Clause 4 to allay the fears expressed by witnesses that organs could possibly be removed without family consent. The amendments would mean that in scenarios where a person in a qualifying relationship cannot be contacted, or where a person in a qualifying relationship has been contacted but does not reply, then deemed consent would not apply and transplantation activity cannot take place. The amendments would also mean that a person in a qualifying relationship would no longer have to affirm that the person immediately before death would not have objected to the transplantation activity; rather they would be asked if they had any objections.
54. In effect, the amendments would serve as a 'double lock' in that the retrieval of organs could not take place if an objection had been expressed by a person in a qualifying relationship or, no one in a qualifying relationship had responded when contacted to either object or give consent to organ donation.
55. However, those Committee Members who did not support deemed consent were logically opposed to these amendments, because the amendments are based on the premise that deemed consent would remain at the heart of the Bill. The Members opposed to the concept of deemed consent shared the concerns expressed by many respondents, including the local consultants, that deemed consent could have a negative impact on the number of organs donated.
56. The Committee divided on the amendment, with the majority of Members voting against the amendments. The proposed Committee amendments were therefore not agreed.
57. Given that the amendments were not agreed, the Committee then had to come to a decision on whether to support Clause 4 as drafted. Again, the Committee divided, with those Members in favour of the concept of deemed consent supporting Clause 4, and those against the concept opposing Clause 4. The majority position was therefore opposition to Clause 4 being part of the Bill.

Clause 1: Duty to promote transplantation

58. Clause 1 places three broad duties on the Department for Health, Social Services and Public Safety (the Department). The first is to promote transplantation. The second is to provide information and increase awareness about transplantation. The third is to inform the public about the new concept of deemed consent which the Bill proposes to introduce.
59. There was overwhelming support for the duty on the Department to promote organ donation by way of a public awareness campaign, the general view being that this would result in increased donation rates.
60. It was highlighted by many in their evidence that any public awareness campaign will need to motivate every family to discuss organ donation and understand what their responsibilities would be, should a member of their family be in a position to save a life through organ donation.
61. During oral evidence, Dr Paul Glover, Regional Clinical Lead for Organ Donation, BHSCT, provided statistical information on recent levels of family consent to organ donation in Northern Ireland and outlined the main obstacle to increasing donor numbers:

“The biggest obstacle to increasing donor numbers remains consent. While being on the organ donor register (ODR) is highly predictive of a family giving consent, the majority of our donors are, in fact, not on the ODR. Consent and the factors that influence whether families give consent are complex issues, ranging from something as simple as the environment where the consent discussions take place to something much more complex, such as an understanding of the concept of brain death.

Of the 30 families approached in Northern Ireland from April to September past, 20% did not give consent because their relative had already expressed a wish not to become a donor; seven families were not sure whether their relative would have agreed to donation; and a further three were divided over the decision. Those three scenarios accounted for over half of the refusals. Families will give a range of other reasons, such as not wanting the person to suffer any further, the length of the donation process and not wanting surgery to the body.”

62. Similarly, during its oral evidence session, the BHF highlighted the importance of families discussing organ donation and the need for a public awareness campaign to focus on encouraging the wider public to have that conversation:

“We know that familial consent rates in the UK are among the lowest in Europe, and that presents a serious barrier to increasing the number of organs available for donation. It is therefore paramount that any public awareness raising accompanying the campaign should aim at encouraging the public to have a conversation with their loved ones about their wishes for organ donation. Any campaign should focus on upstreaming the conversation that they are having with the living much sooner. As we know and as statistics have revealed, about 40% of families in Northern Ireland do not consent. We understand that: they are being asked to make probably one of the most difficult decisions of their lives on one of the most horrendous days of their life. Much more needs to be done to have that conversation earlier. That is why it is so important.”

63. NHS Blood and Transplant illustrated this point further during its oral evidence session:

“About 100 people in the UK every year are on the organ donor register, and their families on the day feel unable to support their decision. It is usually because they have not told their family that they have joined the register. You already have the shock of coping with the loss of your relative. Then you find out that they were on the organ donor register, and you knew nothing about it. What people often say to us is, “Well, they cannot have been that serious if they did not tell me”. When we ask people why they do not tell their families that they have joined the organ donor register, they say, “Well, I did not tell them because I did not want to upset them”. It is a real challenge. We want everybody to talk about this just in case, so that people do know what they want and it does not come as an awful surprise.”

64. The Human Tissue Authority highlighted the importance of good communication and welcomed the commitment in the Bill to inform the public about the new concept of deemed consent at least once a year:

“In our view, communication will be vital to ensure the legitimacy of deemed consent. Without it, Northern Irish residents may not know what action to pursue or whether they wish their consent to be deemed or not to be deemed.

The current law requires valid and appropriate consent. The giving of valid consent is a positive act. Valid consent is freely given by someone who is appropriately informed and has a mental capacity to give that consent. Appropriate consent relates to who is able to give the consent, and it places primacy on the wishes of the individual during their life.

Deemed consent will no longer necessarily require a positive act. Therefore, if the primacy of the individual's choice is to be maintained, each Northern Irish citizen needs not just to understand what it means to opt in or opt out but to have the information to understand what it means to take no action. That is also broadly the view taken by the Nuffield Council on Bioethics and one that was made to us during the consultation on the Welsh code of practice.”

65. It was clear from the written and oral evidence received that consent was the main obstacle to transplantation, and that one of the ways to overcome this obstacle was to encourage families to have the conversation around organ donation. Having the conversation would mean that in those circumstances where a family is asked to make the extremely difficult decision around whether they were willing to donate their loved one's organs, they would know the wishes of their loved one and this would likely influence their decision on whether or not to consent to donation.
66. It was also clear that, in relation to informing the public about deemed consent, the yearly information campaign would be vital to inform the public about what it means to take no action and the role of relatives and friends in affirming that the deceased person would not have objected to the transplantation activity.
67. Having considered the written and oral evidence on Clause 1, the Committee was firmly of the view that a duty should be placed on the Department to promote and provide information on transplantation with the aim of enhancing awareness and understanding of organ donation, to encourage everyone to tell their loved ones their wishes. However, given the diverging views on deemed consent there was no consensus in relation to the duty placed on the Department in Clause 1(c) to inform the public through a yearly promotion campaign about the meaning of deemed consent.
68. At its meeting on 27 January 2016, the Committee considered an amendment to Clause 1 that would leave out reference to the annual promotional

campaign on deemed consent, but would keep the duty to promote transplantation and provide information and increase awareness.

69. This amendment was supported by those Committee Members who were opposed to the concept of deemed support (Clause 4). Those Members were of the view that the primary benefit that legislation on organ donation could bring at this point in time was in relation to promotion and public awareness. Therefore, they believed it was important that Clause 1 was retained in an amended form. While the Department has already carried out valuable work in terms of public awareness campaigns on the issue of organ donation, Clause 1 will make this an ongoing statutory duty. Members felt this was a significant step forward, given that departmental priorities can change over time.
70. However, those Committee Members who supported deemed consent (Clause 4) were logically opposed to this amendment, because the amendment removed the need for the Department to operate an annual campaign informing the public about deemed consent. Those Members were in favour of retaining the clause as drafted.
71. The Committee divided on the amendment, with the majority of Members voting in favour of the amendment. The proposed Committee amendment was therefore agreed.

Clause 14: Annual report on transplantation

72. Clause 14 sets up a mechanism to require annual reporting by the Department on transplantation activities, including the number and nature of such activities. It also requires that once every five years, the Department must report on whether the Human Transplantation Act has been effective in promoting transplantation activities, and on any potential ways in which the law could be amended to increase transplantations.
73. A number of organisations referred to the reporting requirements contained in Clause 14 in their written evidence. The HTA suggested that any report produced should seek to highlight both successes and challenges and, if there is a change in the number of organs being donated, steps should be taken rapidly to understand the root causes. The Presbyterian Church in Ireland urged that, in the interests of full and proper understanding of the whole

picture relating to human transplantation, the periodic report should include quantitative data on the numbers of potential donors, the provision and availability of intensive care facilities in relation to demand for transplantation, resources available for end of life care, and the workload and use of transplant coordinators.

74. The Committee was of the view that Clause 14 was important in terms of the obligations it places on the Department to both report the statistics on transplantation activities and to undertake a wider review on the law once every five years. However, given the diverging views on deemed consent there was a difference in approach between Members in terms of the scope of Clause 14.
75. At its meeting on 27 January 2016, the Committee considered an amendment to Clause 14 that would broaden the scope of the report that is required every five years. Rather than the review being limited to reviewing the effectiveness of the new Act, it would also cover the Human Tissue Act 2004.
76. This amendment was supported by those Members who opposed the concept of deemed consent (Clause 4). This was because if deemed consent was removed from the Bill, the Human Tissue Act 2004 would continue to be the legislative framework in terms of organ donation and the issue of consent. Members who wished to retain the consent arrangements set out in the Human Tissue Act 2004, nevertheless believed that there was value in reviewing that piece of legislation in five years time. In particular, Members expressed the expectation that such a review would include comparative studies of the effectiveness of approaches and legislation in other jurisdictions. In particular, Members referred to the introduction of the soft opt-out system for organ and tissue donation that was introduced in Wales on 1 December 2015.
77. However, those Committee Members who supported deemed consent (Clause 4) were logically opposed to this amendment, because the amendment is based on the premise that the Human Tissue Act 2004 will continue to be the key piece of legislation in terms of consent, rather than the new Act as drafted which creates the concept of deemed consent.
78. The Committee divided on the amendment, with the majority of Members voting in favour of the amendment. The proposed Committee amendment was therefore agreed.

Clauses 2 to 13, 15 to 22, Schedule and Long Title

79. The Committee's approach to the remaining clauses of the Bill was informed by Members' views on Clause 4 and the concept of deemed consent.
80. Those Members who supported Clause 4 and the introduction of deemed consent were content with all the other clauses of the Bill and the Schedule.
81. However, those Members who were in favour of the Bill being structured around duties to promote, report and undertake a future review of the law through amendments to Clause 1 and Clause 14, did not support the majority of the remaining clauses of the Bill. This was because the majority of other clauses hinged on the introduction of the concept of deemed consent.
82. However, there were a small number of clauses, with minor amendments, that these Members supported, as they were required for the technical operation of the Bill (e.g. Clauses 2, 17, 18, 21 and 22).

Other issue - Specially Trained Personnel

83. During the evidence session with the Belfast Health and Social Care Trust consultant surgeons on 2 December 2015, some consultants referred specifically to the increase in consent rates when specialist nurses are involved with clinicians at the time when families are approached in relation to consent to organ donation. The Committee recognised the increase in consent rates where specialist nurses are involved and recommended that this involvement be included in the Human Tissue Authority's Code of Practice as the preferred approach.

Clause by Clause Scrutiny of the Bill

84. The Committee conducted its clause-by-clause consideration of the Bill on 27 January 2016. Information on the Committee's deliberations on the clauses in the Bill, which sets out the context to the decisions reached by the Committee, can be found in the previous section of this report.

85. Clause 1: Duty to promote transplantation

Agreed: the Committee is content with Clause 1 subject to the Committee's proposed amendment to leave out reference to the annual promotional campaign that is connected to deemed consent, as follows:

Clause 1, page 1

Leave out lines 7 to 11

86. Clause 2: Authorisation of transplantation duties

Agreed: the Committee is content with Clause 2 subject to the Committee's proposed amendments to leave out those subsections that do not define transplantation activities, as follows:

Clause 2, page 1

Leave out subsection (1)

Clause 2, page 2

Leave out subsection (3)

87. Clause 3: Express consent: adults

Agreed: the Committee is not content with Clause 3 as drafted.

The Committee agreed to formally register opposition to Clause 3 with the Bill Office.

88. Clause 4: Deemed consent: deceased adults

Agreed: the Committee is not content with Clause 4 as drafted.

The Committee agreed to formally register opposition to Clause 4 with the Bill Office.

89. Clause 5: Express consent: excepted adults

Agreed: the Committee is not content with Clause 5 as drafted.

The Committee agreed to formally register opposition to Clause 5 with the Bill Office.

90. Clause 6: Express consent: children

Agreed: the Committee is not content with Clause 6 as drafted.

The Committee agreed to formally register opposition to Clause 6 with the Bill Office.

91. Clause 7: Express consent: transplantation activities involving excluded material

Agreed: the Committee is not content with Clause 7 as drafted.

The Committee agreed to formally register opposition to Clause 7 with the Bill Office.

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

Agreed: the Committee is not content with Clause 8 as drafted.

The Committee agreed to formally register opposition to Clause 8 with the Bill Office.

93. Clause 9: Appointed representatives

Agreed: the Committee is not content with Clause 9 as drafted.

The Committee agreed to formally register opposition to Clause 9 with the Bill Office.

94. Clause 10: Qualifying relationships

Agreed: the Committee is not content with Clause 10 as drafted.

The Committee agreed to formally register opposition to Clause 10 with the Bill Office.

95. Clause 11: Offences

Agreed: the Committee is not content with Clause 11 as drafted.

The Committee agreed to formally register opposition to Clause 11 with the Bill Office.

96. Clause 12: Offences by bodies corporate

Agreed: the Committee is not content with Clause 12 as drafted.

The Committee agreed to formally register opposition to Clause 12 with the Bill Office.

97. Clause 13: Prosecutions

Agreed: the Committee is not content with Clause 13 as drafted.

The Committee agreed to formally register opposition to Clause 13 with the Bill Office.

98. Clause 14: Annual report on transplantation

Agreed: the Committee is content with Clause 14 subject to the Committee's proposed amendment to insert a reference to the current legislation, the Human Tissue Act 2014, to ensure that it is subject to review at least once every five years, as follows:

Clause 14, page 9, line 13

Leave out 'has' and insert 'and the Human Tissue Act 2004 have'

99. Clause 15: Preservation for transplantation

Agreed: the Committee is not content with Clause 15 as drafted.

The Committee agreed to formally register opposition to Clause 15 with the Bill Office.

100. Clause 16: Coroners

Agreed: the Committee is not content with Clause 16 as drafted.

The Committee agreed to formally register opposition to Clause 16 with the Bill Office.

101. Clause 17: Relevant material

Agreed: the Committee is content with Clause 17 as drafted.

102. Clause 18: Interpretation

Agreed: the Committee is content with Clause 18 subject to the proposed Committee amendments to leave out the definitions of adult, child, qualifying relationships and excluded material, and to leave out subsections relevant to deemed consent, as follows:

Clause 18, page 10

Leave out lines 23 and 24

Clause 18, page 10

Leave out line 27

Clause 18, page 10, line 28

Leave out from 'and "excluded' to the end of line 29

Clause 18, page 10, line 31

Leave out subsections (2), (3) and (4)

103. Clause 19: Orders and regulations

Agreed: the Committee is not content with Clause 19 as drafted.

The Committee agreed to formally register opposition to Clause 19 with the Bill Office.

104. Clause 20: Consequential amendments to the Human Tissue Act 2004

Agreed: the Committee is not content with Clause 20 as drafted.

The Committee agreed to formally register opposition to Clause 20 with the Bill Office.

105. Clause 21: Commencement

Agreed: the Committee is content with Clause 21 as drafted.

106. Clause 22: Short title

Agreed: the Committee is content with Clause 22 as drafted.

107. Schedule - Consequential amendments to the Human Tissue Act 2004

Agreed: the Committee is not content with the Schedule as drafted.

The Committee agreed to formally register opposition to the Schedule with the Bill Office.

108. Long Title

Agreed: the Committee is not content with the Long Title as drafted.

The Committee agreed to formally register opposition to the Long Title with the Bill Office.

Links to Appendices

Minutes of Proceedings can be viewed [here](#)

Minutes of Evidence can be viewed [here](#)

Written submissions can be viewed [here](#)

Correspondence from the Department of Health, Social Services and Public Safety and Other Papers can be viewed [here](#)

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