

Finance Committee

Financial Scrutiny of Human Transplantation (Wales) Bill

Paper to note: Financial Memorandum

Date of paper

16 January 2013

Related Information

[The Human Transplantation \(Wales\) Bill](#) (as introduced)

[Explanatory Memorandum to the Human Transplantation \(Wales\) Bill](#)

Welsh Government, [Consultation on the Draft Human Transplantation \(Wales\) Bill](#), closed September 2012

This briefing has been produced by the Research Service for use by Finance Committee.

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1. Introduction

The *Human Transplantation (Wales) Bill (hereafter the Bill)* was introduced before the Assembly on Monday 3 December 2012. The Health and Social Care Committee will consider and report on the Bill's **general principles** by 22 March 2013.

2. Aims and content

The Bill's main overarching objectives are:

- To increase the number of organ donors through the introduction of a soft opt-out system;
- Make provisions for what constitutes as consent;
- Impose a duty on the Welsh Ministers to promote transplantation in order to improve the health of the people of Wales;
- Impose a duty on the Welsh Ministers to ensure people are aware of the arrangements for deemed consent;
- Make amendments to the *Human Tissue Act 2004*.

The Bill applies to people 18 year old and over, who have the mental capacity to understand that consent could be deemed, who have been ordinarily resident in Wales for a period of at least six months before they died¹ and who die in Wales².

The Bill will provide people with the opportunity to express a decision (**express consent**), i.e. opt-in or opt-out of organ donation by placing their name on a register, or by taking no action, despite having the opportunity to do so, be treated as giving their **deemed consent**. As it is the introduction of a soft opt-out system a person in a qualifying relationship³ to the deceased will be involved in the decision making process. The wishes of the deceased, whether through deemed or express consent, will be made known to a person in a qualifying relationship as part of discussions.

The Bill introduces the concept of deemed consent and it therefore restates, for Wales, certain sections of the *Human Tissue Act 2004* which directly relate to consent for the purposes of transplantation. The Bill does not affect the law relating to provisions of the 2004 Act which are not directly related to consent and have therefore not been restated as they will continue to apply in Wales.

The Bill will not alter the existing arrangements with the NHS Blood and Transplant (NHSBT) service, therefore Wales will still share a transplant waiting list with the rest of the UK and organs will be allocated on the basis of clinical need and suitable match.

The NHS Organ Donor Register (ODR) will be redeveloped so that it can provide both its existing functions for people outside Wales, and provide the opportunity for people in Wales to express their wish for or against donation (including partial donation of some but not all of their organs).

3. Financial implications of the Bill

The Explanatory Memorandum (EM) considers **one policy option** - to introduce a soft opt-out system of deceased organ and tissue donation in Wales.

¹ Where the deceased does not live in Wales the NHS Organ Donor Register (ODR) would be checked and procedures followed accordingly. If they haven't lived in Wales for at least six months the new register and ODR will be checked to ascertain if the deceased had expressed a wish.

² If people living in Wales die in England, Scotland or Northern Ireland then the new register will be checked by the NHS staff and procedures followed accordingly. Deemed consent would not apply outside of Wales.

³ What constitutes a qualifying relationship is set out in section 17(2) of the Bill.

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Costs

The costings in the Regulatory Impact Assessment (RIA) are separated into two broad categories:

- **Fixed setup costs** – the RIA states that these are infrastructure costs (business and system changes; the process of processing opt-out requests; public communications and evaluation) required to operate a soft opt-out system of organ donation. The RIA estimates the costs (discounted over 10 years at 3.5 per cent) to be approximately **£8 million** and will be **borne by the Welsh Government**. Of this, almost 40 per cent (£2.9 million) relates to communications and just over 30 per cent (£2.5 million) to IT changes.
- **Variable costs** – the RIA states that there are costs which will be incurred when organs are retrieved from deceased people and transplanted, these costs will differ by organ type. The regulatory impact assessment only considers kidneys, livers, hearts and lungs as they are the most common organs transplanted. Costs will be borne in part by the NHS in Wales within existing Local Health Board resources and in part within the Welsh Government Grant to NHS Blood and Transplant.
- **Costs not included in the Bill** – the RIA states that some costs have not been included in the analysis as they are likely to be relatively minor and would be met within the Welsh Government grant to NHS Blood and Transplant. These costs are associated with the retrieving, storing and transporting of any additional organs that may be retrieved as a result of a soft opt-out system being adopted.

Annual benefits

The financial benefits in the RIA are separated into two categories:

- **Quality of life improvements (QALYs)** – the RIA states that patients who receive transplants on average benefit from extended life and an improvement in quality of life valued at £60,000 per additional year of perfect health⁴. The QALY approach weights life years (saved or lost) by the quality of life experienced in those years.⁵In the Net Present Value (NPV) calculation these weighted QALYs reflect that years of good health are more desirable than years of poor health e.g. in the case of a person receiving a kidney transplant the annual benefit equates to four QALYs as compared to a patient treated with dialysis i.e. £240,000 benefit per annum.⁶
- **Savings from not having their conditions managed medically** which differ by organ – from £22,000 per annum for savings against medical management of a heart to £306,000 for savings against kidney dialysis.⁷

Net Present Value

Appendix 2a-2d reflects the NPV over a 10 year appraisal period of 1 additional transplant by main organ taking into account the annual net benefits discounted at 3.5 per cent (1.5 per cent for QALYs)⁸

Appendix 2e of the RIA produces a summary NPV table of a given number of changes in transplantations. **The table shows that even with one additional donor the NPV is an additional £3 million.**⁹

⁴ National Assembly for Wales, Human Transplantation (Wales) Bill, [Explanatory Memorandum](#) paragraph 127 [accessed 10 December 2012]

⁵ Ibid Appendix 3

⁶ Ibid Appendix 2a

⁷ National Assembly for Wales, Human Transplantation (Wales) Bill, [Explanatory Memorandum](#) Appendix 2a – 2d [accessed 12 December 2012]

⁸ National Assembly for Wales, Human Transplantation (Wales) Bill, [Explanatory Memorandum](#) para. 110 states that the HM Treasury discount rate of 3.5% was used except when estimating the QALY benefits where 1.5% was used as recommended by the UK Department of Health. [accessed 12 December 2012]

⁹ Ibid Appendix 2e

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Key Issues

The overall net financial impact of the Bill cannot be specifically determined due to the difficulty in predicting changes in organ donation numbers. The EM assumes that the Bill will lead to additional donors so no consideration is included in the event that the Bill reduces the levels of donors (although the financial consequences have been modelled in the Appendices).

- The RIA states that of the £8 million fixed costs, **the greatest uncertainty is in the £2.5 million of system development costs.**¹⁰
- Predicted savings are dependent on the value attached to each additional year of perfect health following transplant surgery. The EM includes analysis reflecting a range from £20,000 to £60,000 per QALY. Even if a QALY is valued at £20,000 the RIA shows that **breakeven would be achieved after only two additional donors a year.**
- The RIA recognises that it is likely that a large proportion (up to 70 per cent) of any additional organs donated by residents of Wales as a result of introducing a soft opt-out system could be transplanted into residents living in other parts of the UK. The RIA states that if benefits were calculated on a **Wales only basis** (i.e. claiming 30 per cent) it **would have no material impact on the number of donors** needed for an opt-out system to break-even i.e. breakeven would still be achieved after 2 additional donors.¹¹

¹⁰ Ibid paragraph 131

¹¹ Ibid paragraph 130