Northern Ireland Assembly

Research and Information Service
Review of Bill Costs

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Public Finance Scrutiny Unit

The Human Transplantation Bill

On 13 October 2015 the Human Transplantation Bill (the Bill) was introduced in the Assembly. This Review of Bill Costs provides a framework to facilitate the Assembly's financial scrutiny of the Bill. It should be read in conjunction with RaISe Bill Paper NIAR 650-15 (dated 3 December 2015) which addresses policy implications arising from the Bill.

Introduction

On 13 October 2015 the Human Transplantation Bill (the Bill) was introduced in the Assembly by Mrs Joanne Dobson MLA (the Bill Sponsor). The Bill is accompanied by an Explanatory and Financial Memorandum (EFM). At paragraphs 15-28, the EFM sets out the Bill Sponsor's estimated introductory and on-going costs to implement a a soft opt-out regime for organ donation. It relies on unpublished research and information previously compiled by the Research and Information Service in 2013 regarding initial proposals relating to this Bill.

This Review of Bill Costs is intended to supplement information provided in RaISe Bill Paper NIAR 650-15 (dated 3 December 2015), which addresses policy issues. It provides a framework to orientate the Assembly's financial scrutiny of the Bill:

- **Section 1** thematically reviews the key clauses in the Bill and accompanying Schedule as well as relevant paragraphs within the EFM;
- **Section 2** briefly discusses the absence of an enabling power to issue a code of practice; and,
- **Section 3** provides concluding remarks, highlighting key observations relating to the financial implications of the Bill.

Scrutiny points are provided throughout.

Members should note at the outset that, in a number of places, the Review of Bill Costs provides estimates compiled by the Public Finance Scrutiny Unit (PFSU) within RaISe. These may suggest a fairly specific prediction – either in terms of the cost of implementation, or savings by avoiding costs. **These 'estimated costs' however, should <u>not</u> be taken as actual predictions. To do so would be inappropriate as it would suggest a spurious level of forecasting accuracy.**

In addition, Members should note that **references to "the Bill" refer to the Bill <u>as introduced</u>**.

1. Bill Clauses

This section reviews the estimated costs assigned by the Bill Sponsor to implement the Bill. It examines the Sponsor's estimate, as specified in the EFM; while looking at the costs drivers and underlying assumptions. Each sub-section groups the clauses thematically, in line with the following duties proposed in the Bill:

- To promote transplantation
    - Clause 1: Duty to promote transplantation.
- To provide information, in particular about consent to transplantation
    - Clause 1: Duty to promote transplantation;
    - Clause 2: Authorisation of transplantation activities;
    - Clauses 3-10: Express and deemed consent; and,
    - Clause 11-13: Offences.
- To report on transplantation activities and review the effectiveness of the Bill
    - Clause 14: Annual report on transplantation.

It should be noted that an 'opportunity cost' is likely to arise from the implementation of the Bill, if enacted as introduced. In other words, **resources to implement the Bill would have to be diverted from other expenditure needs.**

1.1. Duty to promote transplantation

Clause 1(1)(a) provides that the Department of Health, Social Services and Public Safety (DHSSPS) must "*promote transplantation.*"[1] In the second stage debate on 16 November 2015, the Bill Sponsor argued this clause is "*central to increasing public awareness*."[2]

Relying on the work previously undertaken by RaISe on the bill proposals, the EFM states *"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.*"[3] That indicative estimate drew from a range of data sources and comprised a number of elements, including both one-off costs and costs that may recur over a number of years.

In producing the indicative figure, RaISe took more than one approach to estimating the communications element of implementation costs. These were:

1. To adjust figures produced by the Welsh Government during the legislative stages of the *Human Transplantation (Wales) Act 2013*[4] on a population

[1] Human Transplantation Bill, as introduced (see page 1)
[2] Official Report, 16 November 2015 (see page 10)
[3] Explanatory and Financial Memorandum (see page 9)
[4] Relevant documents are available at:

basis, and uplift to account for inflation using Gross Domestic Product (GDP) deflators.[5][6]

2. To assume that the communications strategy associated with the bill proposals would be broadly comparable with a recent smoking campaign, which ran over a number of years, involved a range of media, and was tailored to the Northern Ireland population and media, again uplifted for inflation.

The results are shown in Table 1 below. The following caveats should be noted:

1. The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

2. The estimate produced by RaISe following the Welsh Government's approach put a lower recurring cost on communications than in the initial four years.

Table 1: communications costs, indicative estimate, 2013-14 prices

£000s (2013-14 prices)	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21	2021-2022	2022-2023
Welsh Government estimate	173	383	808	1453	90	50	50	50	50	50	
RaISe estimate 1.		108	239	503	905	56	31	31	31	31	31
RaISe estimate 2.		446	457	203							

RaISe had adopted a **prudent**[7] approach when producing indicative cost estimates on the bill proposals: it had chosen and applied the **higher figure** where there was a choice between two or more apparently robust figures for the same procedure or element of cost.

In relation to communications costs, this meant , the first RaISe estimate was included in the £2,081,000 to £5,149,000 cost range over a ten-year period.

In the second stage debate on 16 November 2015, the Bill Sponsor stated:

[5] GDP deflators are produced for a number of years in advance of the current year on the basis of Office of Budget Responsibility projections.
[6] The Treasury's GDP deflators are available online.
[7] Accountingexplained.com defines 'prudence' as: a key accounting principle which makes sure that assets and income are not overstated and liabilities and expenses are not understated. See http://accountingexplained.com/financial/principles/prudence

> *I am also looking forward to a close working relationship with the Department of Health, and the Minister will be aware that, two weeks ago, I had a preliminary meeting with one of his directors.*[8]

It seems possible that the "*close working relationship*" might include work on the estimated costs of implementing the Bill.

Scrutiny point:

1. The Assembly may wish to ask the DHSSPS to provide: an outline approach to the communications that would be required under Clause 1; and, an estimated cost.

1.2. Duty to provide information, in particular about consent to transplantation

Clause 1(1)(b) and 1(c) provide that the DHSSPS must:

> *(b) provide information and increase awareness about transplantation, and*
>
> *(c) inform the public about the circumstances where consent to transplantation is deemed to be given, and the role of relatives and friends in affirming that deemed consent.*[9]

Clause 1(2) further provides that:

> *(2) The duty under subsection (1)(c) includes in particular a duty to promote a campaign informing the public at least once a year.*[9]

The EFM states:

> *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.*[10]

The Clause 1 duties - to provide information and increase awareness **and** to inform – appear to be more specific than the general duty to promote transplantation. It seems reasonable to infer that these two duties and the duty to promote transplantation could be exercised in a complementary and coordinated manner.

This should go some way to reduce the amount of costs incurred by each duty. For example, it is conceivable that a single communications campaign could achieve both aims. And then costs unique to each duty also may incur costs. For example, the duty

[8] Official Report, 16 November 2015 (see page 7)
[9] Human Transplantation Bill, as introduced (see page 1)
[10] Explanatory and Financial Memorandum (see page 3)

under Clause 1(1)(c) has a specific requirement to explained the role of friends and family in deemed consent, whereas the duty under 1(1)(b) appears aimed at more general awareness raising. It is reasonable to assume therefore that the duty under Clause 1(1)(c) would require more complex messaging, and as a result could be more costly.

Additional Welsh Duty

As noted in RaISe Bill Paper NIAR 650-15 (dated 3 December 2015), the *Human Transplantation (Wales) Act 2013* has an additional duty to those mentioned above, i.e. to "*ensure that the resources available to Local Health Boards include the specialist skills and competencies required for the purposes of this Act.*"[11] The Bill here is silent on any such duty for the DHSSPS.

Having said this, the Bill Sponsor stated the legislative intent as follows:

> *The plain truth about organ donation is that the number of available organs does not meet the demand; and that, in a nutshell, is the reason why a change in legislation is required.*[12]

So, although the need for resources is not plainly stated on the face of the Bill, the intention of the Bill is to increase the number of organs for transplantation. It therefore is reasonable to infer that the Bill Sponsor would expect the DHSSPS to make necessary resources available. In this context, it is worth noting that in the second stage debate on 16 November 2015, the Minister of Health and Social Services and Public Safety stated that there would be:

> *…important operational matters that will require careful consideration. Those include an assessment of the impact on critical-care capacity in our hospitals of an increase in the number of donors.*[13]

For this reason, this Review of Bill Costs explores the implementation and recurring variable costs associated with the proposed change to the consent regime in the following subsections (1.2.1. – 1.2.3). Thereafter, the Review focuses on costs and savings in relation additional transplant activity that might result if additional organs did become available.

RaISe Bill Paper NIAR 650-15 (3 December 2015) discusses the policy issues relating to consent to transplantation. The cost-related implications for the Health Social Care system include the following:

- To produce and present the necessary information to secure informed express consent from potential donors or their representatives;
- To produce and present the necessary information to explain deemed consent;

[11] http://www.legislation.gov.uk/anaw/2013/5/section/2/enacted
[12] Official Report, 16 November 2015 (see page 6)
[13] Official Report, 16 November 2015 (see page 73)

- To train specialist staff about express/deemed consent;
- To provide the necessary IT equipment, and staff to record consent information, provide reports and data to the DHSSPS and other bodies - such as NHS Blood and Transplant; and,
- To ensure compliance with the requirement for consent, enforcement and legal costs in relation to offences under Clauses 11-13.

Information and communication were discussed above in section 1.1. The remaining elements are discussed below.

1.2.1. Training

As noted above, relying on the work undertaken by RaISe on the bill proposals, the EFM states *"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."*[14] That indicative estimate included a figure for training clinical staff. RaISe's methodology to estimate training costs in relation to the bill proposals is explained in the following paragraphs.

The Welsh Government provided an estimate of £310,000 for training clinicians in relation to implementation of the Welsh Act. This was provided by the NHS Blood and Transplant (NHSBT). The NHSBT is a Special Health Authority in the NHS, with responsibility for "*optimising the supply of blood, organs, and tissues and raising the quality, effectiveness and efficiency of blood and transplant services.*" [15]

The NHSBT estimate was to train clinicians to respond to various possible scenarios. For example, if a Welsh resident were to die elsewhere in the UK after opting out, their wishes would still need to be respected. It is unclear as to whether further training for clinicians would be required, if the Bill is enacted as introduced.

The RaISe indicative estimate was based on three scenarios:

- The same amount of training associated with the Welsh Act would also be required in relation to the Bill;
- Some additional training would be required, but less than originally required by the Welsh Act; and,
- No additional training costs would flow from the Bill.

Because RaISe adopted a prudent approach to costing, the most costly of these estimations was included, as shown in Table 2 below.

The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An

[14] Explanatory and Financial Memorandum (see page 9)
[15] http://www.nhsbt.nhs.uk/about/

alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

Table 2: estimated training costs, 2013-14 prices

£000s (2013-14 prices)	2014-15	2015-16	2016-17
Welsh Government estimate	224	100	
RaISe estimate		233	104

RaISe Bill Paper NIAR 650-15 (dated 3 December 2015) discusses the differences between the Welsh Act and the Bill. It is uncertain whether these would give rise to significant additional training needs, though it is reasonably foreseeable that some degree of training would be required. This is especially the case because of the sensitivity surrounding transplantation and consent.

A further issue which could impact on training is potential interaction between the Bill, and the application of the Mental Capacity Bill, if both bills are enacted. The issue of capacity is discussed further in RaISe Bill Paper NIAR 650-15 (dated 3 December 2015)

Scrutiny points:

2. The Assembly may wish to ask the DHSSPS and/or the NHSBT to provide: an assessment of training needs that would arise under the Bill, if enacted as introduced; and, an estimated cost.

3. The Assembly may wish to ask the DHSSPS about any possible costs arising from both this Bill and the Mental Capacity Bill, if they are enacted as introduced.

1.2.2. Recording and reporting consent

As noted above, relying on the work undertaken by RaISe on the bill proposals, the EFM states *"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."*[16] That indicative estimate included figures that relate to recording and reporting consent under the Bill. These included: management of business change; IT changes; receiving and processing additional registrations; and, notifying 17 year olds prior to their attaining adult status, and therefore falling within the remit of the Bill.

Management of business change

The Welsh Government estimated a cost of £557,000 over four years for 'management of business change'. This figure was based on the NHSBT estimates of the required

[16] Explanatory and Financial Memorandum (see page 9)

changes to its working practices when implementing the Welsh Act – such as the development of call centres.

The degree to which the NHSBT might need to make *further* business changes in response to the Bill is unknown.

The RaISe indicative estimate was based on three scenarios:

- **No cost**: the business changes that the NHSBT undertook in response to the Welsh Act would be adequate to implement the bill proposals with no further change – and therefore there would be no cost for the management of business change;
- **Some cost**: the business changes that the NHSBT undertook in response to the Welsh Act would not be adequate to implement the bill proposals with no further change. But any further change would be less significant, on the basis that the Welsh Act has already made the significant alteration to the consent system – and therefore there would be some cost for the management of business change, but less than estimated in response to the Welsh Act; and/or,
- **Equal cost**: the business changes that NHSBT is undertaking in response to the Welsh Bill will not allow it to implement the bill proposals with no further change. Further change could be equally significant, leading to the same level of costs as provided by the Welsh Government.

Because RaISe adopted a prudent approach to costing, the most costly of these estimations was included, as shown in Table 3 below.

The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

Table 3: management of business change, 2013-14 prices

£000s (2013-14 prices)	2012-13	2013-14	2014-15	2015-16	2016-17
Welsh Government estimate	91	182	273	40	
RaISe estimate		94	189	283	42

RaISe Bill Paper NIAR 650-15 (dated 3 December 2015) discusses the differences between the Welsh Act and the Bill. It is uncertain whether these would have an impact upon the NHSBT's costs in in relation to business change.

Scrutiny point:

4. The Assembly may wish to ask the DHSSPS and/or the NHSBT to provide: an assessment of business change required under the Bill, if enacted as introduced; and, an estimated cost.

IT changes

The Welsh Government provided an estimated cost of £2.46 million for changes to IT systems over a period of eight years. This was to cover alterations to the organ donation register; as the register was to be capable of handling and recording the consent changes introduced by the Welsh Act.

The degree to which the NHSBT might need to make *further* IT changes in response to the Bill is not known. A number of scenarios are possible:

- The system changes introduced by the NHSBT in response to the Welsh Bill are sufficient to also accommodate any further impacts from the Bill; or,
- The system changes introduced by NHSBT in response to the Welsh Bill are **not** sufficient to also accommodate any further impacts arising from the Bill, and further redevelopment costs would be incurred.

Because RaISe adopted a prudent approach to costing, the most costly of these estimations was included, as shown in Table 4 below.

The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

Table 4: estimated cost of IT changes, 2013-14 prices

£000s (2013-14 prices)	2012-13	2013-14	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20
Welsh Government estimate	202	1124	553	156	156	156	156	156
RaISe estimate		562	277	78	78	78	78	78

An additional consideration is that, during the passage of the Welsh Act, there was some indication that the DHSSPS would make a contribution to the cost of IT changes. In correspondence dated 9 October 2013, DHSSPS stated to RaISe that:

> *A group has been established to agree the requirements and funding contribution from each country – membership is made up of NHSBT and the four UK Health Administrations.*[17]

Scrutiny points:

5. The Assembly may wish to seek an up-to-date position from the DHSSPS on the funding contributions made to date.

6. The Assembly may wish to ask the DHSSPS and/or the NHSBT to provide: an assessment of further IT development needs under the Bill, if enacted as introduced; and, an estimated cost.

Receiving and processing additional registrations

Like the Welsh Act, the Bill intends legislative change that would increase the number of organs available for transplantation. The Welsh Government provided an estimated cost to the NHSBT for receiving and processing additional registrations over a six-year period as a consequence of the Welsh Act. The Welsh Government's Regulatory Impact Assessment (RIA) states:

> *Some of these ongoing [implementation] costs are shown as reducing to zero before year 10, because it is considered that the costs would be the same in later years if there was no change in legislation. For example, the costs of handling both opt-in and opt-out requests would in time be comparable to requests for opt-in only.*[18]

The RaISe indicative estimate provided in the EFM had applied a population adjustment to those costs over the same period of time, because it is reasonable to assume that the main cost driver in relation to additional registrations is the number of people to whom the new consent regime applies. Secondly, an inflationary uplift was applied, as shown in Table 5 below.

The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

[17] Correspondence from DHSSPS official, 9 October 2013

[18] Welsh Government (2012) 'Human Transplantation (Wales) Bill: Explanatory Memorandum' available online at: http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum (accessed 1 August 2013) (see page 38)

Table 5: estimated cost of receiving and processing additional registrations, 2013-14 prices

£000s (2013-14 prices)	2014-15	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21
Welsh Government estimate	419	328	81	81	81	81	
RalSe estimate		261	204	50	50	50	50

Scrutiny point:

7. The Assembly may wish to ask the DHSSPS and/or the NHSBT to provide: an assessment of registrations under the Bill (as introduced) in light of experience in relation to the Welsh Act; and, an estimated cost.

Notifying 17 year olds

In order to implement the Welsh Act, it was assumed that 17 year olds would be notified in advance of their eighteenth birthday to inform them of how the system of deemed consent works. This would give individuals the opportunity to opt-out as they become adults; the concept of deemed consent would require those who do **not** want to donate their organs to expressly record that wish.

The Welsh Government's RIA allowed an annual recurring cost for this. To provide the **indicative estimate** noted in the EFM, RaISe had applied a population adjustment to the Welsh Government's estimate since it was reasonable to assume that the main cost driver in this category would be the number of individuals aged 17 each year. Secondly, an inflationary uplift was applied, as shown in Table 6 below.

The research previously conducted by RaISe had applied a general inflationary uplift using the Treasury's Gross Domestic Product (GDP) deflators, as it was based on the Welsh Government's figures, which relied on a GDP approach. An alternative approach is to use a measure of health cost inflation, as it can vary from general price inflation.

Table 6: estimated cost of notifying 17 year olds, 2013-14 prices

£000s (2013-14 prices)	2015-16	2016-17	2017-18	2018-19	2019-20	2020-21
Welsh Government estimate	**25**	**50**	**50**	**50**	**50**	**50**
RalSe estimate		**18**	**35**	**35**	**35**	**35**

Scrutiny points:

8. The Assembly may wish to ask the Welsh Government for an up-to-date position on the cost of notifying 17 year olds.

9. The Assembly may wish to ask the DHSSPS to provide: an assessment of the notification of 17 year olds under the Bill, if enacted as introduced; and, an estimated cost.

1.2.3. Variable costs and savings

Looking beyond implementation costs, the EFM refers to the work previously undertaken by RaISe on the bill proposals, stating:

> *…looked at a number of scenarios in relation to the financial impact of the introduction of the legislation [and ...] 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;*
>
> *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.*

In the context of the Bill, the most obvious variable factor is the number of additional transplant procedures that would be conducted following implementation of the Bill. Clearly, this would vary depending upon the response of the public to change and the number of additional available organs, if any.

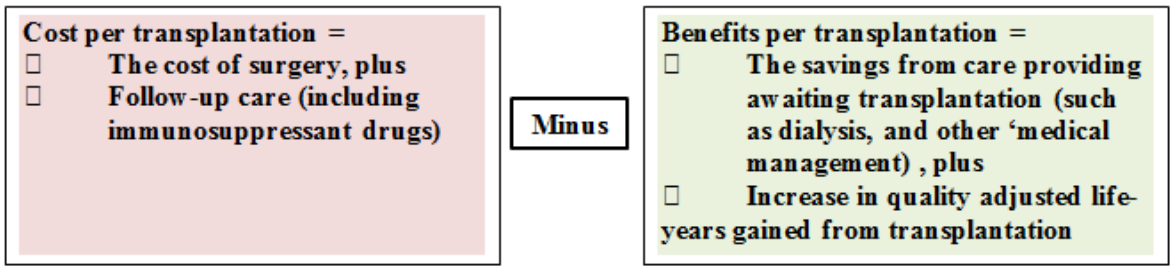
The Welsh Government identified a number of key elements in relation to variable costs. These are:

- Life expectancy on medical management compared to following a transplant;
- The value of additional healthy life years for a transplanted patient;
- The cost of surgical procedures;
- The costs of post-surgical follow-up; and,
- The annual cost of medical management avoided by transplantation.

RaISe's earlier work on the bill proposals was modelled on the Welsh Government's methodology. The various factors were examined, and then the indicative cost of a transplant procedure (and follow-up care) was calculated over a number of years. These costs were then discounted to determine their Net Present Value (NPV). For an explanation of NPVs, see Appendix 1.

The calculation of NPVs enabled examination of future financial benefits and costs in a variety of scenarios. The calculations inevitably relied upon a number of assumptions. As with implementation costs, RaISe adopted a prudent approach to estimate variable costs, and modelled scenarios designed to protect against over- or under-estimation.

The results are shown in Tables 7 to 9 below. These Tables show an assessment of the net impact, i.e. the estimated financial benefits, minus implementation costs. Implementation costs were discussed above. In this context financial benefits were calculated by RaISe in this previous work on the bill proposals as follows:



An explanation of Quality Adjusted Life Years (QALYs) is provided in Appendix 2.

Readers should note that QALYs are used as an attempt to value non-financial impacts in a way that can be compared with financial impacts. An implication is that the benefits captured by QALYs would not impact on the resource requirements of the Health and Social Care system (HSC) when implementing the Bill. In contrast, the implementation costs, for example, would lead to direct resource consumption. Therefore this costing should not be taken as a calculation of the actual resource cost to the HSC. Rather, it is an attempt to measure the net costs and benefits associated with the implementation of the Bill, if enacted as introduced.

Table 7: Costs and benefits analysis following 1 additional donor per year, by scenarios with no donated organs transplanted into non-Northern Ireland recipients

£000s	A Value of Change in Kidney Transplants	B Value of Change in Liver Transplants	C Value of Change in Heart Transplants	D Value of Change in Lung Transplants	E Implementation costs	Net Present Value of Change in Transplants (A+B+C+D-E)
Scenario 1: Costs as stated in Tables, QALY £60K	7,890	3,957	291	408	5,149	**7,397**
Scenario 2: Costs as stated in Tables, QALY 25% lower (£45K)	6,935	2,811	169	239	5,149	**5,003**
Scenario 3: Costs as stated in Tables, QALY 50% lower (£30K)	5,979	1,664	156	221	5,149	**2,871**
Scenario 4: implementation costs 50% higher, QALY £60K	7,890	3,957	291	408	7,724	**4,822**
Scenario 5: implementation costs 50% higher, QALY 50% lower	5,979	1,664	156	221	7,724	**296**
Scenario 6: implementation costs as stated in Tables, surgical costs 50% higher, QALY £60K	6,998	3,550	181	232	7,724	**3,237**
Scenario 7: Costs as stated in Tables, QALY £0	£4,069	-£629	-£198	-£270	£5,149	**-£2,176**

In all the main scenarios considered above, RaISe found in its previous work that the addition of one donor per year would lead to a net financial benefit over the appraisal period. **This would mean that even in the worst-case scenario considered (if**

implementation costs were to overrun by 50%, and where QALY benefits were to be reduced by 50%), there still would be an indicative estimated net financial gain of £296,000. When QALY benefits were removed altogether, there was an estimated net financial cost of £-2,176,000.

Table 8: Costs and benefits analysis following 1 additional donor per year, by scenarios, with 25% of donated organs transplanted into non-Northern Ireland recipients

If 25% of donated organs are transplanted into recipients from outside Northern Ireland.						
£000s	A Value of Change in Kidney Transplants	B Value of Change in Liver Transplants	C Value of Change in Heart Transplants	D Value of Change in Lung Transplants	E Implementation costs	Net Present Value of Change in Transplants (A+B+C+D-E)
Scenario 8: Costs as stated in Tables, QALY £60K	5,917	2,968	218	306	5,149	**4,260**
Scenario 9: Costs as stated in Tables, QALY 25% lower (£45K)	5,201	2,108	126	179	5,149	**2,465**
Scenario 10: Costs as stated in Tables, QALY 50% lower (£30K)	4,485	1,248	117	166	5,149	**866**
Scenario 11: implementation costs 50% higher, QALY £60K	5,917	2,968	218	306	7,646	**1,685**
Scenario 12: implementation costs 50% higher, QALY 50% lower	4,485	1,248	117	166	7,646	**-1,709**
Scenario 13: implementation costs as stated in Tables, surgical costs 50% higher, QALY £60K	5,249	2,663	136	174	7,646	**497**

Table 8 shows that RaISe found in its previous work that if one quarter of the organs donated in Northern Ireland were to go to non-Northern Ireland recipients, the addition

of one donor per year would lead to a net financial benefit over the appraisal period in all of the scenarios considered, **except** where implementation costs were to overrun by 50% and QALY benefits were to be reduced by 50%.

This would mean that in the worst-case scenario considered, there would be an indicative estimated net financial loss of £-1,709,000.

Table 9: Impact of 20% re-transplant rate for kidneys

£000s	20% re-transplantation adjustment (all organs transplanted into Northern Ireland recipients)	20% re-transplantation adjustment (25% of organs transplanted into non-Northern Ireland recipients)
Scenario 1: Costs as stated in Tables, QALY £60K	5,819	3,077
Scenario 2: Costs as stated in Tables, QALY 25% lower (£45K)	3,616	1,425
Scenario 3: Costs as stated in Tables, QALY 50% lower (£30K)	1,675	-31
Scenario 4: implementation costs 50% higher, QALY £60K	3,244	502
Scenario 5: implementation costs 50% higher, QALY 50% lower (£30K)	-900	-2,606
Scenario 6: implementation costs as stated in Tables, surgical costs 50% higher, QALY £60K	1,837	-553

Table 9 shows that RaISe found in its previous work that the 20% re-transplantation rate would have a relatively significant impact on the scenarios considered in Tables 7 and 8. In total, after allowing for one-in-five kidney transplants failing, four of the twelve scenarios would show a net financial loss (increasing from one when re-transplantation rates for kidneys werenot considered).

1.3. To report on transplantation activities and review the effectiveness of the Bill

Clause 14 of the Bill provides a two-part duty on the DHSSPS to report on the operation of the proposed promotion of transplantation and the consent mechanisms. The EFM states:

> *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.*[19]

The cost of providing an annual report would be likely to be driven by the time required from the relevant person or persons to research, compile, draft and finalise the report. Impacting on this would be the accessibility, complexity and breadth of information to be reviewed and included, meaning whether the information would be readily accessible to the person making the report, i.e. both available and easily retrievable, in a usable format.

1.3.1. Review

The second part of the duty would require a more comprehensive review of the impact of the Bill. In effect, this implies a policy evaluation which would give rise to costs in relation to research, analysis, writing, etc.

As noted in sub-section 1.2, relying on the work previously undertaken by RaISe on the bill proposals, the EFM states *"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."*[20] That indicative estimate drew from a range of data sources and comprised a number of elements, including both one-off costs and costs that may recur over a number of years.

One element of those implementation costs included in the RaISe estimate concerned evaluation. The Welsh Government's RIA allowed £240,000 over five years for evaluation of the policy.[21]

RaISe had applied more than one approach to provide an indicative estimate for evaluation costs. The first had been to replicate the Welsh Government's estimated cost, with an uplift to account for inflation. The second had been to take 10 per cent of

[19] Explanatory and Financial Memorandum (see page 7-8)
[20] Explanatory and Financial Memorandum (see page 9)
[21] Relevant documents are available at: http://www.assembly.wales/Pages/Error.aspx?aspxerrorpath=/laid%20documents/pri-ld9121-em-r%20-%20revised%20explanatory%20memorandum%20human%20transplantation%20(wales)%20bill-25062013-247379/pri-ld9121-em-r-e-english.pdf

the total implementation costs. The ten per cent figure was based upon a 'general rule' adopted by RaISe, i.e.:

> *One general rule for estimating an evaluation budget is 5 to 10 per cent of the total program budget. This includes the value of the time that staff will spend on the evaluation, as well as out-of-pocket costs.*[22]

The first approach had applied an inflationary uplift to 2013-14 prices, which yielded an indicative estimate of £249,000 for Northern Ireland. It should be noted however, that this estimate for the bill proposals had been for a **one-off evaluation;** whereas the Bill would require review once **every five years**.

The second approach had yielded a lower estimate of £189,000 and an upper estimate of £468,000. The width of this range had been due to the uncertainty around elements of the implementation costs, such as communications, for example, as discussed in sub-section 1.1. above. Because the calculation of indicative estimates had resulted in a range, the 10 per cent 'general rule' approach had also resulted in a range.

In this context, the Assembly may wish to further note that in May 2013 the DHSSPS officials indicated a figure of £100-150,000 might be more usual for a policy evaluation.

Scrutiny point:

10. The Assembly may wish to ask the DHSSPS to provide an estimated cost to implement the duties in Clause 14, as introduced.

[22] https://dps.mn.gov/divisions/ojp/forms-documents/Documents/Wilder_Program_Evaluation_3.pdf

2. Code of practice

As noted in RaISe Bill Paper NIAR 650-15 (dated 3 December 2015), the Bill does not provide for the DHSSPS to introduce any codes of practice. The EFM however, states that 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.*[23] [emphasis added]

Paragraph 7(d) of the Schedule to the Bill introduces a requirement on the Human Tissue Authority (HTA) "*to give practical guidance*"[24] in relation to deemed consent. This requirement would inevitably incur costs for the HTA to produce a code, possibly including consultation costs, publication and training.

RaISe contacted the HTA for information on relevant costs that would be incurred by the Bill. In its response, the HTA stated that the Welsh Government paid the HTA:

> *…to draft the Code of Practice and run the public consultation on the Code of Practice. The amount paid was in the region of £37,000 and included legal advice, administrative costs, and expenses of the member of staff responsible for drafting the Code. However, **it is important to bear in mind that these costs are not necessarily reflective of the costs that would be charged to the Northern Ireland Assembly**. Clearly any potential costs would need to carefully reflect the specific work that the HTA may be asked to undertake. What has been proposed in the Bill may have significant resource implications for the HTA and further discussions with officials will be required.*[25] *[emphasis added]*

The HTA also noted that is has been contacted by officials from the DHSSPS

A further issue is that, during the second stage debate on 16 November 2015, the Minister of Health, Social Services and Public Safety stated:

> *My Department believes that it will be essential for it also to produce a code of practice to ensure that guidance on the new transplantation policy proposed by the Bill is available for healthcare professionals, patients and their families — guidance that they can easily understand and apply at hospital level.*[26]

It is therefore reasonably foreseeable that, if the Bill was enacted as introduced **and** the DHSSPS consequently needed to produce a code of practice, there would be associated costs to the DHSSPS. In the absence of further information at present, it is difficult to assess what costs would be incurred by the DHSSPS and the wider public

[23] Explanatory and Financial Memorandum (see page 7)
[24] Human Transplantation Bill, as introduced (see page 12)
[25] E-mail from HTA to RaISe, dated 8 December 2015
[26] Official Report, 16 November 2015 (see page 73)

sector when writing a code of practice.. If additional information is sought and secured, it would be necessary to revisit the Review of Bill Costs in this regard.

Scrutiny points:

11. The Assembly may wish to explore why the DHSSPS believes a code of practice is necessary if the Human Tissue Authority already produces one.

12. The Assembly may wish to seek further information from the DHSSPS on what a code of practice would need to include. In particular, such information should include an assessment of the resources required to produce and implement the code.

13. The Assembly may also wish to explore potential costs relating to the HTA further.

3. Concluding remarks

This Review of Bill Costs has explored a number of implementation costs that could be incurred by the Bill, if enacted as introduced.

Members should note at the outset that, in a number of places, the Review of Bill Costs provides estimates previously compiled by RaISe. These may suggest a fairly specific prediction – either in terms of the cost of implementation, or savings for avoided costs. **These 'estimated costs' however, should not be taken as actual predictions. To do so would be inappropriate, as it would suggest a spurious level of forecasting accuracy.**

This Review raises a number of issues about which the Assembly could seek further, updated information. Doing so would increase its understanding of the Bill's financial implications.

However, readers are also reminded that QALYs were used in RaISe's previous work on the bill proposals as an attempt to value non-financial impacts in a way that could be compared with financial impacts. An important implication to note in this regard is that the benefits captured by QALYs would not impact on the resource requirements of the HSC in delivering this policy. In contrast, the implementation costs, for example, would lead to direct resource consumption. Therefore the figures discussed in the Review of Bill Costs should not be taken as a calculation of the actual resource cost to the HSC. Rather, they are an attempt to measure the net costs and benefits associated with the implementation of the Bill.

Appendix 1: Net Present Value.

The following extract from the Treasury's *Green Book* explains the concept of discounting and the use of Net Present Values (NPVs). [27]

DISCOUNTING

5.48 Discounting is a technique used to compare costs and benefits that occur in different time periods. It is a separate concept from inflation, and is based on the principle that, generally, people prefer to receive goods and services now rather than later. This is known as 'time preference'.

5.49 For individuals, time preference can be measured by the real interest rate on money lent or borrowed. Amongst other investments, people invest at fixed, low risk rates, hoping to receive more in the future (net of tax) to compensate for the deferral of consumption now. These real rates of return give some indication of their individual pure time preference rate. Society as a whole, also prefers to receive goods and services sooner rather than later, and to defer costs to future generations. This is known as '*social* time preference'; the 'social time preference rate' (STPR) is the rate at which society values the present compared to the future.

The discount rate is used to convert all costs and benefits to 'present values', so that they can be compared. The recommended discount rate is 3.5%. Calculating the present value of the differences between the streams of costs and benefits provides the net present value (NPV) of an option. The NPV is the primary criterion for deciding whether government action can be justified.

5.50 The mathematical expressions used to calculate discounted present values are set out in the footnote below.[9]

[9] Year 0 is the present. Accordingly, the present value, at the middle of year 0, of a payment of £1 made at the middle of year n is given by:

$$D_n = \frac{1}{(1+r)^n}$$

where r is the discount rate and Dn is the discount factor. For example, a payment of £150 at the middle of year 5 has a present value at the middle of year 0 of:

$$£150 \times \frac{1}{(1.035)^n} = £150 \times 0.8420 = £126.30$$

5.51 For projects with very long-term impacts, over thirty years, a declining schedule of discount rates should be used rather than the standard discount rate. The schedule of long term discount rates is shown in Annex 6.

5.52 Annex 6 also explains the derivation of the social time preference rate, why the rate declines over time, and the circumstances when exceptions to the standard discount rates are allowed.

5.53 Table 1 shows how the present value of £1,000 declines in future years with a discount rate of 3.5 per cent. More detailed discount rate tables are provided in Annex 6.

TABLE 1: PRESENT VALUES AND DISCOUNT RATE

Time (mid year)	0	1	2	3	4	5	6	7	8	9	10
PV of payment (mid year)	£1,000	£966	£934	£902	£871	£842	£814	£786	£759	£734	£709

[27] Available online at: https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/220541/green_book_complete.pdf (see pages 26-7)

Appendix 2: QALYs

QALYs are used to assess the financial benefits to patients from extended life and improved quality of life following transplantation. Economists generally rely on cost-benefit analysis in which all outcomes are reduced to the common metric of money. This is helpful in some ways since anything can be compared with anything else. On the other hand, a shortcoming is the necessity of valuing everything – including a life in good health – in monetary terms.[28]

The National Institute for Clinical Excellence (NICE) defines a QALY as:

> *1. A measure of the state of health of a person or group in which the benefits, in terms of length of life, are adjusted to reflect the quality of life. One QALY is equal to 1 year of life in perfect health.*
>
> *2. QALYS are calculated by estimating the years of life remaining for a patient following a particular treatment or intervention and weighting each year with a quality of life score (on a zero to one scale). It is often measured in terms of the person's ability to perform the activities of daily life, freedom from pain and mental disturbance.*[29]

The Welsh Government's EM states that the UK Department of Health attaches a monetary value of £60,000 to a QALY, although this value is subject to debate in the academic and medical fields.[30] The monetary value attached to a QALY is significant to the indicative cost-benefit estimate; if QALY value is too high, then the assessment of the benefits accruing from an increased rate of donation and transplantation following passage of the NI Bill will also be too high. Conversely, if the QALY value is too low, the assessment will underestimate those same benefits.

The Welsh Government mitigated the risk of overstating the financial benefits by undertaking sensitivity analysis with different QALY values. The EM states:

> *3. Our sensitivity analysis shows that even if the value of a QALY reduced by a quarter to £45,000 it would still be the case that one additional donor a year would generate sufficient benefits for an opt-out system to 'break-even'.*[31]

[28] Beard, T, Kaserman, D, Ostercamp, R (2013) 'The Global Organ Shortage: Economic Causes, Human Consequences, Policy Responses' Stanford University Press, California (see page 75)
[29] http://www.nice.org.uk/website/glossary/glossary.jsp?alpha=Q (accessed 2 August 2013)
[30] Welsh Government (2012) 'Human Transplantation (Wales) Bill: Explanatory Memorandum' available online at: http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum (accessed 1 August 2013) (see page 41)
[31] Welsh Government (2012) 'Human Transplantation (Wales) Bill: Explanatory Memorandum' available online at: http://www.assemblywales.org/bus-home/bus-business-fourth-assembly-laid-docs/pri-ld9121-em-e.pdf?langoption=3&ttl=PRI-LD9121-EM%20-%20Human%20Transplantation%20%28Wales%29%20Bill%20-%20Explanatory%20Memorandum (accessed 1 August 2013) (see page 41)

RaISe asked the Department of Health, Social Services and Public Safety (DHSSPS) and the NHSBT for views on the appropriateness of the £60,000 value for Northern Ireland. Neither provided a view.[32]

On that basis, RaISe undertook a review of literature in relation to QALY value. One American source suggests a value of US$100,000 per QALY.[33] At a rate of US$1 = £0.6592,[34] this would equate to nearly £66,000 – 10% higher than the value cited by the Welsh Government for the UK.

Another comprehensive piece of research based on European data suggests a QALY value for the UK in the range €33,562-102,373 depending on the methodology applied, whether discounting is used, and whether a quality-of-life weighting is applied.[35] At a rate of €1 = £0.8736,[36] this would give a range of £29,320-89,436. The mid-point of this range is £59,378. This is very close to the value cited by the Welsh Government.

These findings give a measure of confidence that the £60,000 value used by the Welsh Government is reasonable. In addition, a scenario analysis has also been conducted to demonstrate, for illustrative purposes, the impact of different levels of QALY value on the cost-benefit assessment by:

- Reducing the QALY value by 25% to £45,000
- Reducing the QALY value by 50% to £30,000; and,
- Reducing the QALY value by 100% to £0.

[32] Correspondence from NHSBT, 30 May 2013 and meeting between RaISe and DHSSPS officials, 16 May 2013
[33] Beard, T, Kaserman, D, Ostercamp, R (2013) 'The Global Organ Shortage: Economic Causes, Human Consequences, Policy Responses' Stanford University Press, California (see page 83)
[34] Rate obtained from http://www.oanda.com/currency/converter/ , 2 August 2013
[35] EuroVaQ (2010) 'European Value of a Quality Adjusted Life Year' available online at: http://research.ncl.ac.uk/eurovaq/EuroVaQ_Final_Publishable_Report_and_Appendices.pdf (accessed 2 August 2013)
[36] Rate obtained from http://www.oanda.com/currency/converter/ , 2 August 2013