Bill summary
Human Transplantation (Wales) Bill

January 2013
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Bill summary
Human Transplantation (Wales) Bill

January 2013

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Human Transplantation (Wales) Bill

1. Introduction

**Introduction date:** 3 December 2012

**Member in charge:** Lesley Griffiths AM, the Minister for Health and Social Services

**Assembly Committee undertaking Stage 1 scrutiny of the Bill:** Health and Social Care Committee

**Stage 1 reporting deadline:** 22 March 2013

The *Human Transplantation (Wales) Bill*1 (‘the Bill’) and the communications associated with it aims to increase the number of organs donated in Wales in order to save and improve lives. In particular, the intention of the Welsh Government through the Bill is to address the UK’s comparatively low consent rate by clarifying the wishes of more people in relation to consent for organ donation and by effecting changes to public attitudes and awareness about the issue in Wales.

The Bill’s introduction is a culmination of a number of inquiries and consultations held in Wales by successive Assemblies and Welsh Governments since 2008.

This paper includes some historical background information about the current legal framework that regulates organ donation in Wales and consultations held on the Welsh Government’s proposals to date. It also provides an overview of the Bill’s main objectives and provisions, and summarises some initial reactions.

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1 *Human Transplantation (Wales) Bill* [accessed 3 January 2013]
2. Timeline


The issue of presumed consent for organ donation was widely debated during the third Assembly. The third Assembly’s Health, Well-being and Local Government Committee conducted an inquiry into presumed consent for organ donation between February and July 2008 and published a report on its findings and recommendations on 30 July 2008.

In the report’s summary, the Committee stated that the most urgent and productive steps for improving donation rates rested with the early implementation in Wales of the UK Organ Donation Task Force recommendations. The Committee did not rule out introducing presumed consent in Wales at some point in the future. However, it did not believe that it was at that time the most urgent priority and believed that it could be a distraction from other more productive actions.

In a written response to the Committee’s recommendation, the then Minister for Health and Social Services, Edwina Hart AM, stated that:

> The Assembly Government considers that the Committee’s report does not reflect adequately the evidence it received on the strength of opinion in relation to presumed consent nor does the report acknowledge some of the actions already announced in relation to organ donation and transplantation by the Welsh Assembly Government.

Between October 2008 and January 2009 the then Minister initiated a public debate to capture opinion on whether Wales should become the first UK country to introduce an opt-out system. The Welsh Government then launched a public consultation on the issue, entitled Options for Changes to the Organ Donation System in Wales, in May 2009 and published a consultation report based on submissions received in September 2009. The report stated that ‘the majority of responses supported a change to the organ donation consent system in Wales to a soft opt-out system’. On 18 December 2009, the then Minister made a Written Cabinet Statement on Organ Donation in Wales stating that she intended to explore the possibility of

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2 Further information about organ and tissue donation in Wales is contained in National Assembly for Wales, Research Paper: Organ and Tissue Donation, November 2011 [accessed 3 January 2013]


4 In December 2006, the UK Government set up the Organ Donation Taskforce to identify barriers to organ donation and recommend actions needed to increase organ donation and procurement within the current legal framework.


6 Welsh Government, Consultation Paper - Options for changes to the organ donation system in Wales, May 2009 [accessed 19 December 2012]

7 Ibid

8 Ibid
introducing a soft opt-out system for organ donation in Wales and that a bid for a Legislative Competence Order had been submitted as part of the annual trawl for legislative items. In a subsequent statement on the Welsh Government’s 2010-2011 Legislative Programme on 13 July 2010, the First Minister confirmed his intention to seek the necessary legislative powers in relation to organ donation through a Legislative Competence Order.

The proposed The National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011 (the proposed Order), which sought to transfer legislative powers in relation to organ donation from Westminster to the National Assembly, was introduced by the Welsh Government on 10 January 2011.

Following the Yes vote in the 3 March 2011 referendum on further powers to the National Assembly for Wales, the proposed Order was withdrawn by the Welsh Government. In Plenary on 9 March 2011 in a statement on the proposed Order the then Minister stated that:

In light of the successful referendum result on 3 March [...] I have written to the Secretary of State for Wales and to the Chair of the Welsh Affairs Committee to inform them of my intention to withdraw the Proposed National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011. [...] The referendum result has paved the way for a future Welsh Assembly Government to introduce a Bill, with appropriate legislative scrutiny to take place here in the Assembly. In that event, Presiding Officer, it will be for you to decide whether a Government proposed Bill is within the Assembly’s legislative competence. The Assembly Government’s clear view is that, given the wording of Schedule 7 to the Government of Wales Act 2006, the Assembly would have the power to pass an Act about organ donation.

2.2. Developments in the fourth Assembly to date

A commitment to introduce an Assembly Bill relating to organ donation was contained in Welsh Labour’s manifesto for the May 2011 Assembly elections. Their manifesto stated that:

We will introduce an Assembly Bill in order to move to an ‘opt out’ system of donation, backed up by a comprehensive communication programme. The key benefit would be an increase in the number of organ donors in Wales and the result that a number of lives will be saved and the quality of lives of many more improved.

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9 Welsh Government, Edwina Hart (Minister for Health and Social Services), Organ donation system in Wales, Cabinet Written Statement, 18 December 2009 [accessed 19 December 2012]
10 National Assembly for Wales, Plenary, RoP [page 51], 13 July 2010 [accessed 3 January 2013]
11 The National Assembly for Wales (Legislative Competence) (Health and Health Services) Order 2011) [accessed 19 December 2012]
12 National Assembly for Wales, Plenary, RoP –[page 43], 9 March 2011 [accessed 20 November 2012]
Similar proposals were also included in the Welsh Liberal Democrat\textsuperscript{14} and Plaid Cymru\textsuperscript{15} 2011 election manifestos.

The First Minister announced shortly after the election that an organ donation Bill would be included in the Welsh Government’s five year legislative programme, announced on 12 July 2011.\textsuperscript{16} He subsequently announced on 17 July 2012 that such a Bill would be formally introduced in the Assembly during the 2012-2013 session.\textsuperscript{17}

On 8 November 2011 the Welsh Government published a White Paper\textsuperscript{18} on proposals for legislation on organ and tissue donation. The White Paper proposed that a ‘soft opt-out system’ be introduced which would allow the removal and use of organs and tissues unless the deceased objected during their lifetime. Under the proposals, the family of the deceased would still be involved in the donation decision making process. The ‘soft opt-out system’ would apply to people aged 18 or over, who lived and died in Wales. The White Paper also proposed that the NHS Organ Donor Register would continue to be available to those in Wales in conjunction with the ‘soft opt-out system’ and a number of record keeping options were proposed. The consultation ran until 31 January 2012. In March and April 2012 the Welsh Government published the 1,234 responses received and a summary of these which analysed the themes raised.\textsuperscript{19}

On 18 June 2012 the Welsh Government published the draft Human Transplantation (Wales) Bill and draft Explanatory Memorandum and Consultation Document.\textsuperscript{20} This consultation sought views on the draft Bill and Explanatory Memorandum and ran until 10 September 2012. In October 2012 the Welsh Government published a summary of the responses (which was subsequently updated on 3 December 2012).\textsuperscript{21} The consultation received 2,977 responses, although a vast majority (2,688) were either identical letters or based upon a standard briefing circulated by the Society for the Protection of the Unborn Child.

In October 2012 the Welsh Government also published the Public Attitudes to Organ Donation: Baseline Survey 2012\textsuperscript{22} report. As part of the Wales Omnibus

\textsuperscript{14} Welsh Liberal Democrats, \textit{Welsh Liberal Democrat Manifesto: Wales CAN do better}, page 37 [accessed 19 December 2012]
\textsuperscript{15} Plaid Cymru, \textit{Ambition is Critical: A Manifesto for a Better Wales}, page 30 [accessed 19 December 2012]
\textsuperscript{16} National Assembly for Wales, Plenary, \textit{RoP [page 59]}, 12 July 2011 [accessed 3 January 2013]
\textsuperscript{17} National Assembly for Wales, Plenary, \textit{RoP [page 56]}, 17 July 2012 [accessed 3 January 2013]
\textsuperscript{20} Welsh Government, draft Human Transplantation (Wales) Bill and draft Explanatory Memorandum and Consultation Document, June 2012 [accessed 19 December 2012]
Survey the Welsh Government commissioned the collection of data from questions within the survey between June 2012 and June 2016. During the June 2012 survey, questions about organ donation were asked of the 1,006 respondents aged 16 years and over. The Welsh Government is committed to undertaking a communications campaign to ensure the population of Wales are aware of the new law and know how to register their objection if desired. The Welsh Government will use the information collected to assess the on-going effectiveness of the communications campaign.

2.3. **Existing legislative provisions**

The current legal framework relating to organ and tissue donation in England, Wales and Northern Ireland is set out in the *Human Tissue Act 2004*. The Act sets out a requirement to obtain ‘appropriate consent’ from specified persons before certain activities are carried out. Such activities include the storage and use of whole bodies and the storage and use of human material (organs, tissues and cells) from the bodies of deceased persons. The Act also makes it unlawful to use bodies or human material, once donated, for purposes other than those set out in the Act. The Act does not apply to the removal (as opposed to the storage and use) of human material from living persons.

In relation to organ transplantation, the Act makes ‘appropriate consent’ a requirement before the activity of removing from the body of a deceased person for the purpose of transplantation of any relevant material which has come from a human body.

Those persons who currently wish to give their consent to become organ donors after their death, can do so by registering confidentially on the NHS Organ Donor Register. The Register is held and maintained by NHS Blood and Transplant, which is a Special Health Authority operating on an England and Wales basis.

Although people on the Register have given their consent to donate their organs, the person’s relatives will be asked to confirm the donation in the event of the death of the person in question to ensure action is being taken on the most recent wishes of the deceased. If the deceased have not expressed their opinion on whether they would be for or against donation, the relatives to the deceased can still give their consent for the donation.

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23 *Human Tissue Act 2004*, (Chapter 30) [accessed 19 December 2012]
3. The Bill

3.1. Policy aims and objectives

The Bill’s main overarching objectives are to increase the number of organ donors in Wales. It aims to achieve this by:

- introducing a ‘soft opt-out system’ (i.e. a system whereby organs and tissues are removed unless the deceased objected during their lifetime but where the family of the deceased would still be involved in the donation decision making process);
- making provisions for what constitutes consent;
- imposing a duty on Welsh Ministers to promote transplantation in order to improve the health of the people of Wales; and
- imposing a duty on Welsh Ministers to ensure people are aware of the arrangements for deemed consent.

The Bill will provide people with the opportunity to express a decision (referred to in the Bill as ‘expressed consent’ - i.e. a decision as to either ‘opt-in’ or ‘opt-out’ of organ donation) by placing their name on a register. The Bill states that by taking no action, despite having the opportunity to do so, people will be treated as having given their consent (referred to in the Bill as ‘deemed consent’). The ‘soft’ element of the system refers to the involvement of a person in a ‘qualifying relationship’ (which is set out in Section 17(2) of the Bill) to the deceased who will be consulted in the decision making process.

The Bill applies only to:

- people 18 years old and over, who have the mental capacity to understand that consent could be deemed;
- people who have been ordinarily resident in Wales for a period of at least six months before they died and who die in Wales.

The Bill does not affect the law relating to provisions of the Human Tissue Act 2004 which are not directly related to consent, as those provisions will continue to apply in Wales.

The Bill will also not alter the existing arrangements of the NHS Blood and Transplant service. Wales therefore will continue to share a transplant waiting list with the rest of the UK and organs will be allocated on the basis of clinical need and a suitable match.
3.2. Provisions

The Bill is relatively short, containing only 20 Sections and no Schedules. A summary of each Section is included below:

Section 1 provides an overview of the Bill.

Section 2 places a duty on Welsh Ministers to promote transplantation, including informing and educating the public about the circumstances in which consent to transplantation can be deemed.

Section 3 clearly specifies that consent is required in order to carry out lawful transplantation activities in Wales and introduces the concepts of 'deemed' and 'express' consent. Section 3(3) deals with the cases where organs and tissues have been imported into Wales from outside of Wales and therefore do not need consent.

Section 4 outlines ‘deemed consent’ as the default position in Wales, apart from in relation to certain excepted adults and children. It also highlights when possible exceptions could apply, such as:

- where an adult is alive (‘express consent’ would always be required in this instance apart from in cases where the person lacks capacity);
- the adult has died but their decision about consent for transplantation was in force immediately before death (in which case that decision prevails); and
- the adult has died with no decision in force, but the adult has appointed another person to take the decision.

An additional exception is where a person in a ‘qualifying relationship’ to the deceased provides information that the deceased would not have consented (a definition of ‘qualifying relationship’ is included in Section 17 of the Bill).

Section 5 makes it clear that for an excepted adult ‘express consent’ will always be required.

Section 6 makes provision for when the deceased is a child or young person (i.e. under the age of 18 years old). Although the provisions relating to deemed consent in the Bill does not apply to anyone under the age of 18, a child or young person will still be able to express and record their wish to be or not to be a donor on the new register and upon their death their wish will be discussed with a person in a qualifying relationship. If ‘express consent’ from the deceased prior to death has not been stated a person in a ‘qualifying relationship’ will be asked to make the decision on organ donation.

Section 7 specifies that an adult may appoint a representative (or representatives) to give express consent after their death, and may specify to which transplant activities they have consent power over. An appointment may be made orally or in
writing, as long as they abide by certain criteria. An appointment may be revoked or renounced at any time.

Section 8 applies where a living adult lacks capacity to consent to the donation of material and no decision is in force. In such instances, the living adult's consent to the donation is deemed if the activity is done by a person who is acting in the adult's best interests or is done in circumstances of a kind specified by regulations made by the Welsh Ministers.

Section 9 makes it a criminal offence for a person to undertake a transplantation activity in Wales without consent. However the Section states that a person does not commit an offence:

- if they believe they are doing the activity with consent;
- if they believe it is not a transplantation activity; or
- the organs in question relates to imported material (Section 3(3)), or the preservation of material for transplantation (Section 12(1)).

It also states that a person commits an offence if they knowingly falsely state that there is consent to perform a transplantation activity or that the activity is not a transplantation activity. This Section also specifies details of the punishment for a person guilty of an offence under this Section.

Section 10 relates to when offences under Section 9 is committed by a body corporate.

Section 11 relates to the prosecutions for offences committed under Section 9.

Section 12 makes it lawful for the body of the deceased to be retained and preserved for potential transplantation activity while the issue of consent to the use of organs is resolved. The Bill makes it clear that the preservation of the body must involve the minimum steps necessary and the least invasive procedures.

Section 13 maintains the current legal position that before any transplantation activity takes place and if it is likely the body or relevant material is, or may be, required by the coroner, then the coroner’s consent is required.

Section 14 provides details of the amendments made to the Human Tissue Act 2004 by the Bill to reflect Welsh legislation. Guidance relating to the provisions of the Bill will be set out in the codes of practice prepared by the Human Tissue Authority.

Section 15 provides details of consequential and incidental amendments to the Human Tissue Act 2004 made by the Bill and amendments to the general function of the Human Tissue Authority.
Section 16 defines relevant material as material, other than gametes, which consists of or includes human cells. The Bill does not cover material from embryos outside the human body or the hair and nail from the body of a living person.

Section 17 defines certain terminology associated with the Bill, such as ‘qualifying relationships’.

Section 18 provides that all subordinate legislation made under the Bill by Welsh Ministers is subject to the affirmative procedure in the Assembly.

Section 19 deals with the commencement of the Bill once it has received Royal Assent. In particular, the Section specifies that the duty on Welsh Ministers to promote and provide information on transplantation will commence on Royal Assent but the remaining provisions will be commenced no sooner than two years following Royal Assent. It is proposed the Bill will receive Royal Assent in 2013 and the Act will come into force in 2015.

Section 20 states that the short title of the Act once it has received Royal Assent will be the Human Transplantation (Wales) Act 2013.

3.3. Differences between the draft Bill and the Bill as introduced

The Explanatory Memorandum states that the following changes have been made to the Bill as introduced following the Welsh Government’s consultation on the draft Bill which took place between June and September 2012:

Two consultations have assisted with the drafting of the legislation and a number of areas have been clarified as a result. In particular, the Bill has been refined to provide clearer provision relating to people who lack capacity and the role of qualifying relations and appointed representatives in the donation process. The Bill has been further refined in terms of different processes to be followed for deceased and living donation. There have also been a number of drafting changes in relation to the interplay with the 2004 Act.  

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4. Financial implications

The Explanatory Memorandum (‘the EM’) states that the Bill may give rise to a number of additional costs. The Welsh Government has identified two broad categories of costs in the EM which are outlined below:

The first category relates to setting up and maintaining the infrastructure required to operate a ‘soft opt-out system’ of organ donation. This will include costs to business and system changes, the processing of opt-out requests, public communications and evaluation. The EM estimates that this will cost approximately £8 million over a ten year period. These costs will be borne by the Welsh Government.

The second category relates to the costs incurred when organs are retrieved from the deceased and transplanted. According to the EM, these costs are variable and will differ by organ type (the EM considers the four most common organs transplanted). The total costs and benefits will depend on the number of additional donor numbers and operations.

The benefits of the Bill will also depend on how improvement to the quality of life is quantified. The Regulatory Impact Assessment contained in the EM makes an estimation of this value in terms of quality of life improvements (known as ‘Quality Adjusted Life Years’ or ‘QALYs’) for patients who will receive organ transplantation as a result of this Bill. The EM estimates this as a saving of £60,000 per additional year of perfect health. However, as this figure is subjective, the EM provides a range of figures from £20,000 to £60,000 per QALY. Also, as the number of additional donors per year is difficult to predict, a range of scenarios has been provided in the EM, from 1 to 25 additional donors a year.

Based on the assumptions included in the modelling in the Regulatory Impact Assessment even a very modest increase in the number of donors will result in net benefits. For example, one additional donor each year with associated increases in organ transplantations has an estimated net present value of £3 million, if this were increased to 15 donors this figure would rise to £148 million.

The EM states that benefits emanating from the Bill are calculated at a UK level, as it is recognised that a large proportion of any additional organs donated by residents of Wales could be transplanted into residents living in other parts of the UK.

The Welsh Government will commission a scoping project in 2012-13 to establish baselines which will be followed by an independent study beginning in 2013-14 to

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26 Welsh Government, Human Transplantation (Wales) Bill, Explanatory Memorandum, 3 December 2012, paragraph 111 and Appendix 1 [accessed 19 December 2012]
27 The UK Department of Health estimates that one QALY has a monetised value of £60,000.
monitor and evaluate the effect of the introduction of this legislation with a final report being published in March 2017. Interim reports will be published to an agreed timetable, with the Welsh Government carrying out a full review within five years of implementation.
5. Reactions

In her legislative statement on the Bill to Assembly Members in plenary on 4 December 2012, the Minister for Health and Social Services, Lesley Griffiths AM, stated that:

The UK has one of the lowest consent rates in the EU when it comes to families agreeing to donate the organs of a loved one. One of the biggest barriers influencing family behaviour is people not knowing what their loved one would have wanted. I believe that our legislation, together with all the communications that will surround it, will change this situation in Wales, will clarify the wishes of more people, and will effect a breakthrough in public attitudes and awareness about organ donation.28

In response, the Welsh Conservatives welcomed the opportunity to look at the issue of organ donation. Darren Millar AM stated that:

You mentioned that there has been a record response to the consultation on this piece of legislation, and that just goes to show the strength of feeling around the country about organ donation, on all sides of the argument. Because there is such a significant variation in views, it is really important that we take this issue forward sensitively. For that reason, and because there are differences of view even within our own Welsh Conservative group, we consider it appropriate to have a free vote in the Assembly on this issue. We will certainly be having a free vote on these benches.29

Darren Millar also pressed the Minister on issues relating to the legislative competence of the Bill:

Minister, could you provide a little more information on legal competence? I know that you have expressed thanks to the UK Government and the Wales Office in your statement today, and I welcome the fact that you have been having discussions. However, what assurances do you have that your assumed competence is absolutely watertight? We do not want to end up in the Supreme Court at the end of this if there is some sort of legal challenge. You have clearly set out a timetable by which you want to deal with this issue and get it on the statute book, but can you tell us a little bit more about the advice that you have had?30

The issue of whether the Bill was within the Assembly’s legislative competence was also raised by Labour Member Rebecca Evans AM.31

Speaking on behalf of Plaid Cymru, Elin Jones AM welcomed the principle behind the Bill:

This is a significant and groundbreaking Bill and its implications are far-reaching for us all as citizens of this country. The Plaid Cymru policy has been to support the principle behind such legislation, and this has been the case since the early days of the Assembly when Dai Lloyd was an Assembly Member who visibly championed an opt-out organ donation system. Only since the Assembly has had further powers to make legislation has the Government

28 National Assembly for Wales, Plenary, RoP [page 45], 4 December 2012 [accessed 3 January 2013]
29 Ibid, page 48
30 Ibid
31 Ibid, page 53
been in a position to bring forward such a Bill. Therefore, we acknowledge that today is an important day in the legislative story of Wales.\textsuperscript{32}

The leader of the Welsh Liberal Democrats, Kirsty Williams AM, also stated that her party would support the Bill in principle, adding that:

We have long supported the system of a soft opt-out, with appropriate safeguards in place. The Minister referred to the fact that this was contained in our manifesto at the last Assembly election. However, that does not mean that we do not have a role to play in scrutinising this legislation, and making sure that it is as robust as it possibly could be.\textsuperscript{33}

A number of views were expressed by external organisations and stakeholders about the Welsh Government’s proposals during the consultations held in relation to the White Paper and draft Bill.

On the whole, the proposals contained in those documents were generally welcomed by health charities in Wales, including the Kidney Wales Foundation, Diabetes UK Cymru and British Lung Foundation Cymru.\textsuperscript{34} Support for the Welsh Government’s proposals was also expressed by the British Medical Association.\textsuperscript{35}

A number of religious groups and bodies however expressed concerns regarding the Welsh Government’s draft proposals. These included representatives from the Welsh Muslim and Jewish Communities\textsuperscript{36} along with the Church in Wales, the Roman Catholic Church in Wales and the Wales Orthodox Mission.\textsuperscript{37}

A full summary of the responses received in relation to the consultations held to date on the White Paper\textsuperscript{38} and the draft Bill\textsuperscript{39} is available on the Welsh Government’s website.

The Assembly’s Health and Social Care Committee is currently conducting a consultation on the Bill as introduced as part of its scrutiny of the general principles of the Bill at Stage 1 of the legislative process. The consultation will close on 18 January 2013 and the Committee is required to produce a report on the Bill’s general principles by 22 March 2013.

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\textsuperscript{32} National Assembly for Wales, Plenary, \textit{RoP [pages 55-56]}, 4 December 2012 [accessed 3 January 2013]
\textsuperscript{33} Ibid, page 58
\textsuperscript{34} Kidney Wales Foundation, \textit{Opt out needed as a solution for the UK}, 30 January 2012 [accessed 20 December 2012]
\textsuperscript{35} BMA, \textit{Doctors welcome ‘ground-breaking’ donor scheme in Wales}, 19 June 2012 [accessed 20 December 2012]
\textsuperscript{36} BBC News, \textit{Organ donation: Jewish and Muslim presumed consent worries}, 5 November 2012 [accessed 20 December 2012]
\textsuperscript{38} Welsh Government, \textit{Consultation – Summary of responses}, Proposals for Legislation on Organ and Tissue Donation, 8 March 2012 [accessed 20 December 2012]
\textsuperscript{39} Welsh Government, \textit{Consultation – Summary of responses}, Draft Human Transplantation (Wales) Bill and Explanatory Memorandum: Consent to organ and tissue donation in Wales, 3 December 2012 [accessed 20 December 2012]
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